

# MEMORANDUM

## Texas Department of Aging and Disability Services

**TO:** Regulatory Services Division  
Regional Directors and State Office Managers

**FROM:** Michelle Dionne-Vahalik, Manager  
Policy Development and Support Unit  
State Office MC E-370

**SUBJECT:** Regional Survey and Certification (RS&C) Letter No. 05-06

**DATE:** June 20, 2005

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The attached Centers for Medicare and Medicaid Services (CMS), Regional Survey and Certification (RS&C) Letter was issued on June 10, 2005. This letter, which was distributed by e-mail on June 14<sup>th</sup>, is being provided to you for information purposes and should be shared with all professional staff.

- **RS&C Letter No. 05-06 – Multiple Patient Use of Fingertick and Glucose Monitoring Devices in Health Care Facilities**

If you have any questions, please contact Bevo Morris, Program Specialist, Policy Development and Support, at (512) 438-2363.

[signature on file]

Michelle Dionne-Vahalik

MDV:bbm

Attachment



**Division of Survey and Certification, Region VI**

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June 10, 2005

**REGIONAL SURVEY AND CERTIFICATION LETTER NO. 05-06**

**TO:** All State Survey Agencies (Information)  
All Title XIX Single State Agencies (Information)

**SUBJECT: Multiple Patient Use of Fingertick and Glucose Monitoring Devices in Health Care Facilities**

The Centers for Disease Control (CDC) Morbidity and Mortality Weekly Report (MMWR) dated March 11, 2005 includes an article on the outbreak of Hepatitis B transmissions among diabetic residents in two nursing homes and one assisted living center. The CDC article reports a high incidence of Hepatitis B among these residents which is associated with deficient infection control practices. In these facilities, staff used the same fingertick and glucose monitoring devices for multiple patients. The staff failed to clean the glucose monitoring devices between residents and failed to use universal precautions, including handwashing and change of gloves between residents. One nursing home failed to contact the state health department or initiate an internal investigation when laboratory tests determined one resident had an acute Hepatitis B infection. The article reports that two nursing home residents died from acute Hepatitis B infections. The article includes recommendations for preventing patient-to-patient transmission of the hepatitis virus from diabetes-care devices and procedures. Please refer to the attached copy of the MMWR or you may go to the CDC website at <http://www.cdc.gov/mmwr/>.

Although noncompliance with infection control regulations is not automatically immediate jeopardy, the deaths of the two nursing home residents meet the definition of immediate jeopardy at 42 CFR 488.3. When citing the facility, the surveyor may utilize the above article as a reference. When citing noncompliance above Level 2 in nursing homes or at the Condition Level for non-long term care providers, the surveyor should include evidence regarding the level of harm or the potential for harm to a resident/patient, the number of residents/patients harmed or at risk, their medical conditions, and evidence that their immune systems are compromised.

If you have any questions please contact Susana Cruz at 214-767-4415 or [scruc@cms.hhs.gov](mailto:scruc@cms.hhs.gov).

Sincerely,

Calvin G. Cline  
Associate Regional Administrator,  
Division of Survey and Certification

MMWR March 11, 2005

## **Transmission of Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term– Care Facilities — Mississippi, North Carolina, and Los Angeles County, California, 2003–2004**

Regular monitoring of blood glucose levels is an important component of routine diabetes care (1). Capillary blood is typically sampled with the use of a fingerstick device and tested with a portable glucometer. Because of outbreaks of hepatitis B virus (HBV) infections associated with glucose monitoring, CDC and the Food and Drug Administration (FDA) have recommended since 1990 that fingerstick devices be restricted to individual use (2,3). This report describes three recent outbreaks of HBV infection among residents in long-term–care (LTC) facilities that were attributed to shared devices and other breaks in infection-control practices related to blood glucose monitoring. Findings from these investigations and previous reports suggest that recommendations concerning standard precautions and the reuse of fingerstick devices have not been adhered to or enforced consistently in LTC settings (2–5). The findings underscore the need for education, training, adherence to standard precautions, and specific infection control recommendations targeting diabetes-care procedures in LTC settings (4–6) (Box 1).

The three outbreaks described in this report were all reported by state or local health departments to CDC, which provided epidemiologic and laboratory assistance. In each of the three LTC settings, residents were tested for serologic markers for HBV infection. Under the case definitions used in these investigations, residents who tested positive for IgM antibody to hepatitis B core antigen (anti-HBc) were defined as having acute HBV infection. Residents who tested positive for hepatitis B surface antigen (HBsAg) and total anti-HBc, but who tested negative for IgM anti-HBc, were considered to have chronic HBV infection. Residents who tested positive for total anti-HBc, but who tested negative for HBsAg, or those who had antibody to HBsAg (anti-HBs) >10 milli-International Units (mIU) per milliliter were considered immune to HBV infection. Residents were considered susceptible to HBV if they had no HBV markers. A retrospective cohort study was performed as part of each investigation; the study was restricted to acutely infected and susceptible residents to identify risk factors. In all three investigations, staff members were evaluated; none were identified as sources of infection. Medical records were reviewed and infection-control procedures were assessed through direct observation and by interviews with nursing staff members.

### **Nursing Home A, Mississippi**

During November–December 2003, the Mississippi Department of Health received reports of two fatal cases of acute HBV infection among residents of nursing home A. The first patient with recognized symptoms of HBV infection had received serologic testing for viral hepatitis infection in June 2003 as part of a hospital emergency department evaluation for abdominal pain. Although this patient was found to have a positive test for IgM anti-HBc, indicating acute HBV infection, and the finding was noted in the patient's chart in September 2003, nursing home A did not contact the state health department or initiate an internal investigation. Subsequently, the patient died.

In December 2003, after a second patient with acute HBV infection had died, and after a third with acute HBV infection was reported, serologic testing was performed on specimens from all 158 residents. Test results were available for 160 residents, including the two decedents; 15 (9%) had acute HBV infection, one was chronically infected, 15 (9%) were immune, and 129 (81%) were susceptible. Percutaneous and other possible exposures among residents were evaluated. Among 38 residents who routinely received fingersticks for glucose monitoring, 14 had acute

HBV infection, compared with one of 106 residents who did not receive fingersticks (relative risk [RR] = 39.0; 95% confidence interval [CI] = 5.3–290.0).

Glucose monitoring of 14 residents with acute HBV infection and the resident with chronic HBV infection was performed by staff members based at the same nursing station. Reviews of infection-control practices and site inspections indicated that each of the four nursing stations in nursing home A was equipped with one glucometer and one springloaded, pen-like fingerstick device. Staff members reported that a new end cap and lancet assembly was used for each fingerstick procedure; however, the spring-loaded barrel and glucometer were not routinely cleaned between patients. Investigators also observed that insulin and other multidose medication vials were not labeled with patient names or the dates the vials were opened. In an anonymous survey, several staff members reported observing other workers reuse a needle or lancet or fail to change gloves between patients. No other percutaneous exposures were associated with illness.

### **Assisted Living Center B, Los Angeles County, California**

During January–February 2004, the Los Angeles County Department of Health Services received reports of four residents with diabetes in assisted living center B who had acute HBV infection during November 2003–January 2004. Because these initial reports were among residents with diabetes, serologic testing was performed in January 2004 on residents who had received fingersticks for blood glucose monitoring during May–December 2003. Of 22 residents tested (three declined), eight (36%) had acute HBV infection, including the four residents previously identified; six (27%) were immune (and excluded from the analysis), and none had chronic infection. Reviews of patient records indicated that one of the acutely infected residents had been repeatedly tested at a separate hemodialysis center and had seroconverted to HBsAg-positive in July 2003. Of the nine patients who had daily exposure to fingerstick procedures performed by nursing staff, eight had acute HBV infection, compared with none among the seven residents who performed their own fingersticks (RR = undefined; CI = 2.8–undefined). Although receipt of insulin was also significantly associated with infection, two residents with acute HBV infection had not received insulin. Other percutaneous exposures (e.g., podiatric or dental care) were not associated with HBV infection.

Fingerstick procedures were often performed by nursing staff members in a central living area, with diabetes patients seated at a common table. Although residents had their own fingerstick devices, nurses reported occasionally using a pen-like fingerstick device barrel from their own kits to collect consecutive blood samples; a single glucometer was typically used for all residents. Nurses reported that they were discouraged from wearing gloves to decrease the sense of a clinical environment, and hand hygiene was not performed between procedures.

### **Nursing Home C, North Carolina**

In May 2003, a case of HBV infection in a resident of nursing home C was reported to the North Carolina Department of Health. During June–July 2003, serologic testing was performed on specimens from all 192 residents; 11 (6%) had acute HBV infection, 16 (8%) were immune, and 165 (86%) were susceptible. No resident had chronic HBV infection. Of 45 residents who received fingersticks for glucose monitoring, eight (18%) had acute HBV infection, compared with three (3%) of 117 residents without this exposure (RR = 6.9; CI = 1.9–25.0). After data were controlled for fingerstick exposures, acute HBV infection was not associated with other percutaneous exposures (e.g., insulin injections, podiatry procedures, or phlebotomy). Two diabetes patients at nursing home C who were potential sources of the outbreak were identified retrospectively; one had clinical symptoms of hepatitis B and serologic markers of acute infection during 2002, whereas the other had chronic HBV infection and died in February 2002.

Interviews with staff and direct observation of glucose monitoring practices revealed that only single-use lancets were used, and insulin vials were not shared among patients. However, on each wing of the facility, a single glucometer was used for all patients receiving fingersticks; glucometers were not routinely cleaned between patients. On some days, a single health-care worker performed approximately 20 fingerstick procedures during a single work shift. In an anonymous survey, nursing staff members indicated that some health-care workers did not always change gloves between patients when performing fingerstick procedures.

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### **Editorial Note:**

Lack of adherence to standard precautions and failure to implement long-standing recommendations against sharing fingerstick devices place LTC residents at risk for acquiring infections from bloodborne pathogens such as HBV (2,3,7). In nursing home A, the spring-loaded barrel of a fingerstick device was used for multiple patients. Previous outbreaks have been linked to such devices when the platform or barrel supporting the disposable lancet was reused for multiple patients, when used lancets were stored with unused lancets, or when lancet caps were reused (2,3; CDC, unpublished data, 1999). In assisted living center B, nursing staff members routinely administered fingersticks without wearing gloves or performing hand hygiene between patients, and spring-loaded fingerstick devices were also occasionally shared.

In nursing home C, as with other recent outbreaks (8; CDC, unpublished data, 2002), transmission of HBV among residents with diabetes occurred despite use of single-use fingerstick devices or insulin medication vials that were dedicated for individual patient use. In these settings, glucose monitors, insulin vials, or other surfaces contaminated with blood from an HBV-infected person might have resulted in transfer of infectious virus to a health-care worker's gloves and to the fingerstick wound or subcutaneous injection site of a susceptible resident. Similar indirect transmission of HBV in health-care settings through contaminated environmental surfaces or inadequately disinfected equipment has been reported with other health-care procedures, such as dialysis (6,9). HBV is stable at ambient temperatures; infected patients, who often lack clinical symptoms of hepatitis, can have high concentrations of HBV in their blood or body fluids (6). To prevent patient-to-patient transmission of infections through cross-contamination, health-care providers should avoid carrying supplies from resident to resident and avoid sharing devices, including glucometers, among residents.

The risk for patient-to-patient transmission of HBV infection can be reduced by implementing specific prevention measures (Boxes 1 and 2). LTC staff often perform numerous percutaneous procedures; frequent blood glucose monitoring increases opportunities for bloodborne pathogen transmission. The outbreak investigations reported here identified residents with diabetes who received fingersticks from nursing staff members as often as four times per day, according to their physician's routine orders, despite having consistently normal glucose levels. Expert panels have concluded that approximately 8 years are needed before the benefits of glycemic control result in reductions in microvascular complications (1,10). In LTC settings, schedules for fingerstick blood sampling of individual patients should be reviewed regularly to reduce the number of percutaneous procedures to the minimum necessary for their appropriate medical management. In

each of the investigations described in this report, implementation of infection-control measures (Boxes 1 and 2) was recommended, along with follow-up serologic testing for markers of HBV.

An estimated 70,000–80,000 HBV infections occur each year in the United States. Most of these infections occur among young adults with behavioral risk factors (i.e., sexual contact and injection-drug use); these adults should receive hepatitis B vaccine. Preventing transmission of HBV among patients in long-term-care settings requires adherence to recommended infection-control practices and prompt response to identified instances of transmission. Routine hepatitis B vaccination or screening of LTC residents is not recommended. In the outbreaks described in this report, initial cases were not identified or investigated in a timely fashion, resulting in missed opportunities to correct deficient practices and interrupt transmission. Evidence of acute viral hepatitis in any LTC resident should prompt a thorough investigation. For a case involving a resident with diabetes, fingerstick blood sampling procedures and insulin administration should receive particular scrutiny. Health departments should encourage reporting of such cases and offer assistance in identifying the source of infection. CDC continues to support investigations in LTC and other health-care settings and is working toward improved implementation of the infection-control recommendations described in this report.

**BOX 1. Recommended practices for preventing patient-to-patient transmission of hepatitis viruses from diabetes-care procedures in long-term-care Settings**

**Diabetes-care procedures and techniques**

- Prepare medications such as insulin in a centralized medication area; multidose insulin vials should be assigned to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.
- Restrict use of fingerstick capillary blood sampling devices to individual patients.
- Consider using single-use lancets that permanently retract upon puncture.
- Dispose of used fingerstick devices and lancets at the point of use in approved sharps containers.
- Assign separate glucometers to individual patients. If a glucometer used for one patient must be reused for another patient, the device must be cleaned and disinfected. Glucometers and other environmental surfaces should be cleaned regularly and whenever contamination with blood or body fluids occurs or is suspected.
- Store individual patient supplies and equipment, such as fingerstick devices and glucometers, within patient rooms when possible.
- Keep trays or carts used to deliver medications or supplies to individual patients outside patient rooms. Do not carry supplies and medications in pockets.
- Because of possible inadvertent contamination, unused supplies and medications taken to a patient's bedside during fingerstick monitoring or insulin administration should not be used for another patient.

**Hand hygiene and gloves**

- Wear gloves during fingerstick blood glucose monitoring, administration of insulin, and any other procedure involving potential exposure to blood or body fluids.
- Change gloves between patient contacts and after every procedure that involves potential exposure to blood or body fluids, including fingerstick blood sampling. Discard gloves in appropriate receptacles.
- Perform hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) immediately after removal of gloves and before touching other medical supplies intended for use on other patients.

**BOX 2. Recommended medical management, training, and oversight measures to prevent patient-to-patient transmission of hepatitis viruses from diabetes-care procedures in longterm-care settings**

- Regularly review patient schedules for fingerstick blood glucose sampling and insulin administration and reduce the number of percutaneous procedures to the minimum necessary for appropriate medical management of diabetes and its complications.
- Ensure that adequate staffing levels are maintained to perform all scheduled diabetes-care procedures, including fingerstick blood glucose monitoring.
- Consider diagnosis of acute viral hepatitis infection in patients with illness that includes hepatic dysfunction or elevated liver transaminases (serum alanine aminotransferase and aspartate aminotransferase).
- Provide a full hepatitis B vaccination series to all previously unvaccinated staff members with exposure to blood or body fluids. Check and document postvaccination titers 1–2 months after completion of the vaccination series.
- Establish responsibility for oversight of infection control activities. Investigate and report any suspected case of newly acquired bloodborne infection.
- Require staff members to know standard precautions and demonstrate proficiency in taking these precautions with procedures involving potential blood or body fluid exposures.
- Provide staff members who perform percutaneous procedures with infection-control training that includes practical demonstration of aseptic techniques and instruction regarding reporting exposures or breaches. Conduct annual retraining of all staff members who perform procedures with exposure to blood or body fluids.
- Assess compliance with infection-control recommendations (e.g., hand hygiene or glove changes) by periodic observation of staff and tracking use of supplies.

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