HEALTH REPORT

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HEPARIN INVESTIGATION CONTINUES AT CDC FOLLOWING ALLERGIC REACTION REPORTS

The U.S. Centers for Disease Control and Prevention (CDC) is currently investigating an outbreak of acute allergic-type reactions among patients who have undergone hemodialysis (dialysis* of the blood) since November 27, 2007. The total number of reported cases is now near 60 as the CDC takes its search nationwide. The thrust of the investigation has lead CDC to believe that the cause of the reaction is the drug heparin produced by Baxter Healthcare Corporation of Deerfield, Illinois.

CDC received the first reports of a potential problem with heparin from the Missouri Department of Health and Senior Services on Jan. 7, 2008. The reported symptoms that occurred within minutes of starting dialysis included facial swelling, excessively rapid heart beat, a drop in blood pressure, skin rash and nausea. A total of 8 episodes occurred at a pediatric hospital in the state from Nov. 19, 2007 to Jan. 17, 2008.

Upon learning of this initial cluster, CDC solicited reports of similar allergic-type reactions among hemodialysis patients nationally. On Jan. 9, 2008, CDC was contacted by a dialysis supply company that had received reports during the previous 2-week period of some 50 similar reactions among adult hemodialysis patients at dialysis facilities in 6 states. A second supply company reported learning of similar reactions from dialysis facilities as early as Dec. 10.

Of the episodes reported as of Jan. 30, CDC has identified 65 confirmed or probable cases among 53 hemodialysis patients that occurred from Nov. 19, 2007 to Jan. 21, 2008, at 19 dialysis facilities in 12 states. CDC currently is investigating an additional 36 possible cases. Other than the 8 episodes reported in Missouri, all cases have occurred among adults.

After learning of these adverse events among patients who received heparin during dialysis, Baxter voluntarily recalled nine lots of heparin multi-dose vials on Jan. 17, 2008. All nine lots were produced at a single plant; eight of the nine lots were produced during September to November 2007. Despite the Jan. 17th recall, an additional reaction occurred on Jan. 21, 2008, after a hemodialysis patient was administered Baxter heparin from one of the recalled lots. CDC has found indications of delays in removing the recalled lots of heparin from distribution, which might result in continued exposures.

In addition, these reactions might not be limited to hemodialysis settings. One cardiac-care facility has reported 7 allergic-type reactions among cardiac patients who received heparin from lots that were later recalled. CDC alerted the U. S. Food and Drug Administration (FDA) to these nationwide reports of allergic-type reactions on Jan. 9, 2008, and is collaborating with FDA on the investigation.

* Def. Dialysis: (Med.) Purification of the blood in substitute of the kidneys.

Source: The U.S. Centers for Disease Control and Prevention, "Acute Allergic-type Reactions Among Patients Undergoing Hemodialysis, Multiple States, 2007-2008." January 2008. http://www.cdc.gov/mmwR/preview/mmwrhtml/mm57e201a1.htm