



The Florida ESRD Network

ALERT – FOLLOW UP!

Anaphylactoid Reactions Among Hemodialysis Patients

FMQAI: The Florida ESRD Network has been notified that several states in the country have reported cases of acute anaphylactic reactions characterized by angioedema (swelling of eyelids and lips), respiratory distress; some patients have nausea, vomiting and cardiac arrhythmias. The Centers for Disease Control and Prevention is doing an epi-investigation.

UPDATE: Most cases occurred between November 19, 2007 and January 16, 2008. To date, CDC is aware of approximately 114 cases from 14 states and has continued to receive additional reports of potential cases. Many of the case-patients had received 1000 U/ml heparin from 30 ml or 10 ml vials manufactured by Baxter just prior to their reaction. However, case-patients also shared several other healthcare exposures in common and these exposures have not been ruled out as the possible cause of the reactions. On January 18, CDC became alerted to 4 cardiac surgery patients in Florida who developed severe allergic-type reactions following administration of Baxter heparin.

Recall of Baxter heparin following reports of allergic-type reactions among dialysis and other patients in multiple states

On January 17, in response to increased reports of adverse patient reactions following heparin administration, Baxter announced a voluntary recall of 9 lots of heparin vials. The recalled lot numbers are listed below. Although the cause of the allergic-type reactions remains under investigation, healthcare providers should immediately discontinue use of and segregate the recalled lots of heparin. The FDA Safety Alert can be found at this link: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj>.

Please contact Drs. David Blossom (404-639-4514, dblossom@cdc.gov) or Priti Patel (404-639-4273, ppatel@cdc.gov) to report additional cases with similar symptoms occurring during between November 1, 2007 and the present.

Baxter:

Heparin sodium Injection 1000 units/mL 10 mL vial lot #s 107054 and 117085

Heparin sodium Injection 1000 units/mL 30 mL vial lot#s 047056, 097081, 107024, 107064, 107066, 107074, and 107111

The Florida ESRD Network (Network 7) is providing this fax blast as a
Technical assistance activity for the Florida renal community.

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