



June 10, 2013

Important change with heparin labels



In the November 29 and December 13 (2012) *ISMP Medication Safety Alert!* newsletters we reported that the US Pharmacopeial Convention (USP) recently updated its labeling standards for **Heparin Sodium Injection, USP** and **Heparin Lock Flush Solution, USP** (including prefilled heparin flush syringes). Presentation of the total amount of drug per vial is now required, rather than a per mL amount with the container volume appearing elsewhere on the label. With the older labeling, practitioners have sometimes overlooked the container volume and misunderstood the per mL amount as the total amount in the vial (**Figure 1**). This has led to dangerous heparin overdoses.

Earlier this month we learned of a fatal heparin overdose for this very reason. A nurse and medical resident planned to administer an IV bolus dose of 3,000 units of heparin to a patient. Both mistakenly thought each 10 mL vial of heparin held a total of 1,000 units when, in fact, each vial contained 10,000 units (1,000 units/mL). Instead of 3,000 units, they gave the patient 30,000 units (3 vials). The patient died after developing an intracranial hemorrhage and brain stem herniation.

The updated USP label standard became effective on May 1, 2013.

New heparin vial labels (**Figure 2**) must express the amount per the entire container (e.g., 10,000 units per 10 mL) followed by the amount per mL in parentheses.

In a May 28, 2013 letter, USP again stressed the need to inform pharmacists, nurses, physicians, clinical leaders, buyers, risk managers, informatics staff, and others about the label changes. We urge hospitals to



Figure 1. 10,000 unit vials misread as 1,000 units.

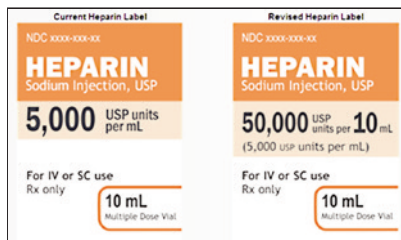


Figure 2. Old and new versions of heparin injection label. Both vials would hold the same exact amount.

follow this advice. There will be a transition period during which vials with the old labels and the revised labels will be available. As clinicians become accustomed to the new labels with the total container amount clearly displayed, there's an even greater risk of confusing the

per mL amount on older labels as the total amount in the container.

To minimize risk, hospitals should consider transitioning fully to the newly labeled heparin, even if it means discarding some older vials. (Don't forget vials stored in less obvious places.) Otherwise, separate heparin vials with the old and new labeling, and use all vials with the old labeling first before dispensing vials with the new labeling. As space permits, computer databases should express drug amounts the same way as the vial label (i.e., 10,000 units/10 mL [1,000 units/mL]).

The hospital where the error happened also displays warnings on automated dispensing cabinet screens when removing the older 10 mL vials, asking: "Are you aware you are removing 10,000 units of heparin?" They also affix auxiliary labels on vials with the total amount of drug in the total volume until they use the newly labeled vials. The hospital is reviewing heparin storage in an effort to restrict access to multidose vials when feasible. Hospitals should also keep vial sizes of all high-alert drugs, including heparin, as small as possible to limit the potential for overdoses. Vials may not be necessary in unit stock if heparin bolus doses are dispensed from pharmacy or can be safely administered via a bolus feature with a smart infusion pump.

The National Alert Network (NAN) is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.