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Important Changes to Heparin Container Labels

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Perspective on the labeling change

Labeling standards are located in different places in USP-NF

Integrate all labeling standards in the Proposed General Chapter <7> *Labeling*

Conform with standards regarding Strength and Total Volume for Single- and Multiple-Dose Injectable Drug Products

Why are the labels of **Heparin Sodium Injection**, USP, and **Heparin Lock Flush Solution**, USP, changing?

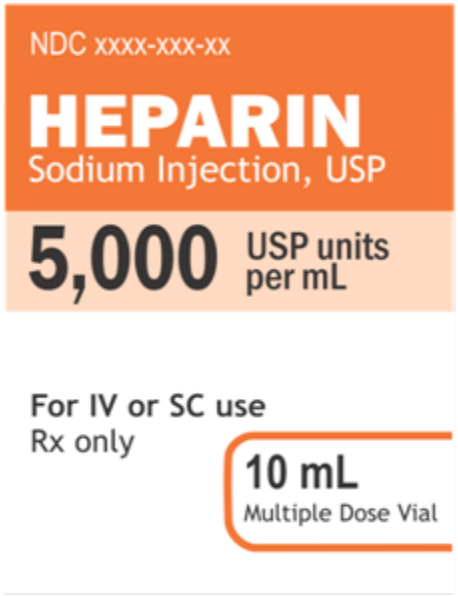
This change from the existing USP requirements is intended to prevent medication errors. It will align required labeling for heparin products with USP's general requirements for all small-volume injectable products, which currently display the total strength per content and unit strength/mL.

How are the labels for **Heparin Sodium Injection**, USP, and **Heparin Lock Flush Solution**, USP, being changed?

The label change will require manufacturers of Heparin Sodium Injection, USP, and Heparin Lock Flush Solution, USP, to clearly state the strength of the entire container of the medication followed by how much of the medication is in each milliliter (mL).

What will the labels look like?

Current Depiction:
Shows only the unit strength per volume (5,000 units per mL).



Revised Depiction:
The total strength per volume (50,000 units per 10 mL) and the unit strength per volume (5,000 units per mL), are clearly stated on the label.

When will the change occur?

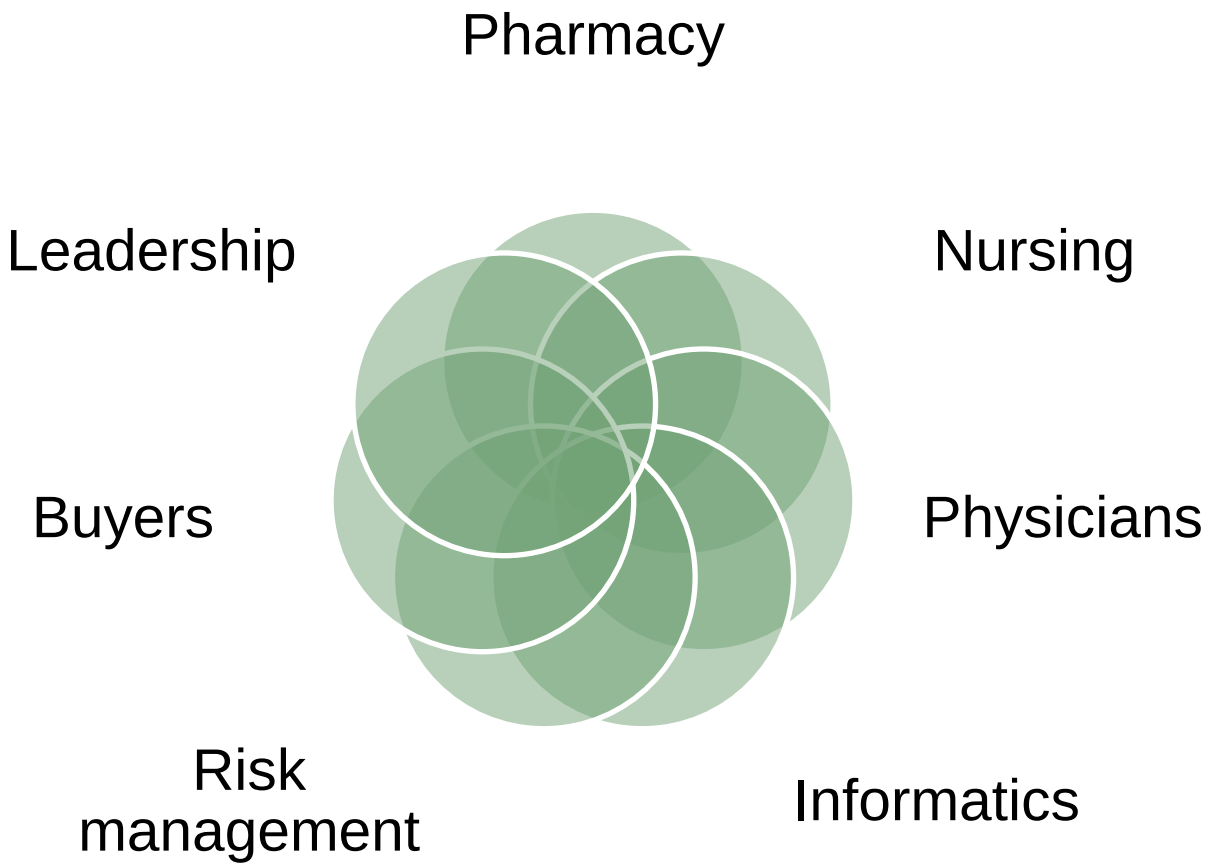
This labeling transition has already begun prior to the date on which the revised standards become official (May 1, 2013). USP, FDA, and professional organizations are attempting to get the word out since both the current and the revised heparin container labels may appear simultaneously in the marketplace during the transition.

What are some general strategies to protect patients during the transition?

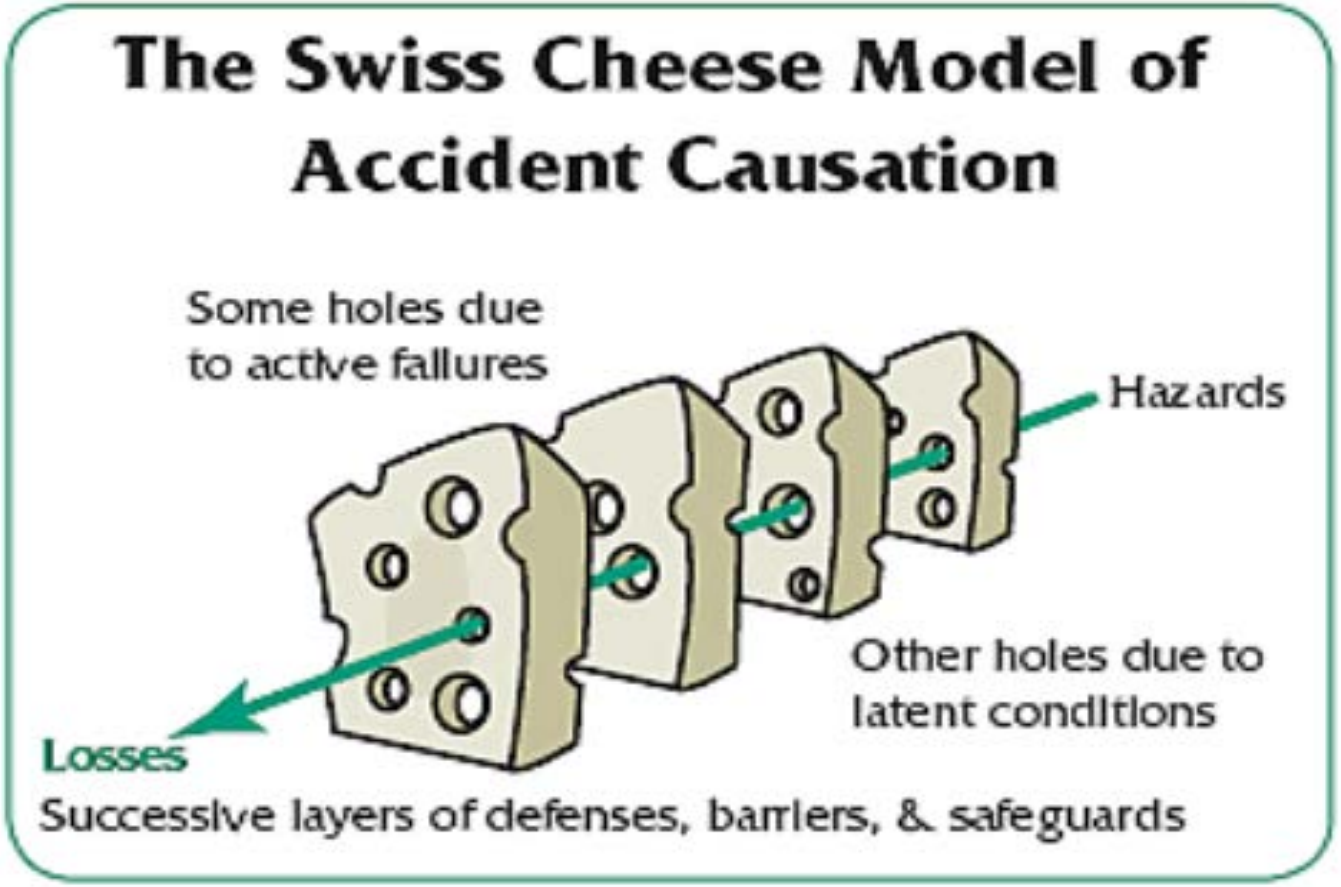
- To minimize the potential for medication errors, hospitals and pharmacies may wish to consider separating the supplies of “current” and “revised” labeled heparin and exhausting the supplies of the “current” heparin before transitioning to products with the “revised” label.
- Practitioners should always look at the label on the heparin vial being dispensed.
- It is strongly recommended for general heparin safety that facilities put in place heparin protocols, policies and procedures that highlight this label transition. An independent double-check process that is robust will help practitioners identify the new labeling and apply correct dosing.

Integrated Implementation

An Interdisciplinary team essential in developing and communicating the changes to staff



Accident Causation



James Reason, 1990

Strategies – a deeper dive

Risk points in the medication use process that should be addressed prior to transition

First Line of Defense

Last Line of Defense

Procurement & Storage	• Segregation • Sequestration • Informatics
Ordering	• Education • Informatics
Dispensing	• Education • Independent double check • Informatics
Administration	• Education • Informatics • Independent double check

Does the labeling change affect all types of heparin products?

The labeling change only affects:

Heparin Sodium Injection, **USP**, and

Heparin Lock Flush Solution, USP

How will USP communicate to practitioners?

- Practitioners will be notified regarding these changes through letters, webinars and organizational communications.
- An article will be available for your organization's e- newsletter.
- Publication in USP's free-access, online journal, Pharmacopeial Forum.
- USP-NF – publication of the revised standard.
- USP.org at:

  http://www.usp.org/usp-healthcare-professionals/medication-safety-labeling

USP & Healthcare Professionals

Compounding

Medication Safety & Labeling

Medicare Model Guidelines

Related Topics & Resources

Medication Safety & Labeling

To assist healthcare professionals in the delivery of optimal patient care, USP establishes standards in the USP–NF for labeling and physical environments that promote safe medication use (e.g., procurement, prescribing, transcribing, order entry, preparation, dispensing, administration, and monitoring of medications). USP serves as the secretariat and is a member of the National Coordinating Council for Medication Error Reporting and Prevention (NCC–MERP).

Click on the links below to learn about USP's current medication and safety initiatives.

General Chapters

- <1> Injections, Labeling on Ferrules and Cap Overseals
- <17> Prescription Container Labeling
- <1066> Physical Environments that Promote Safe Medication Use

Labeling

- Heparin Labeling Changes for Healthcare Practitioners

Monographs

- Vincristine

CONTACT INFORMATION

- USP Healthcare Quality & Safety Staff
- Scientific & Technical Support
- Customer Service
- All USP Contacts

- Log in to USP–NF Online
- Log in to Pharmacopeial Forum
- Log in to USP on Compounding

FEATURED KEY ISSUES

- Compounding
- Prescription Container Labeling
- Monograph Modernization

RELATED RESOURCES

- Education on Dietary Supplement Verification
- Nomenclature Information
- Compendial Notices
- Sign Up for Newsletters & Updates
- Products & Services

FAQs during the USP Heparin Webinars

The Heparin Labeling Change is effective on **May 1, 2013**; the USP webinars ran from February 18 – February 28, 2013.

Q: Are the pharmacies that deliver to patients for home care also being educated?
The USP has reached out to our member organizations which include various pharmacist associations to disseminate information about the webinars and also to provide articles for e-newsletters to their constituents about the changes to the heparin labels.

Q: Is notification required from the FDA on this change? If yes what type / when?
Manufacturers may have already been notified of the change by the FDA. USP sets the standard which will be official May, 2013. The FDA has a webpage on the change to Heparin container labels: http://www.fda.gov/Drugs/DrugSafety/ucm330695.htm. Any questions regarding FDA enforcement should be directed to the FDA.

Q. After May 1, 2013 are we completely discarding already produced drugs, what is the lead time to scrap already produced drug products?
This is a question of enforcement and would need to be determined by the FDA.

Q. Can you please repeat the address for the USP Medication Safety and Labeling website?
http://www.usp.org/usp-healthcare-professionals/medication-safety-labeling/heparin-labeling-changes

FAQs during the USP Heparin Webinars (cont.)

Q. Will the labeling change apply to pre-filled heparin flush syringes?

Yes. The change applies to Heparin Lock Flush Solution, USP.

Q. Just to clarify, can we exhaust our current supply before transitioning to the new labeled vials?

The best safety strategy would be to identify and locate affected stock and begin to exhaust all supplies before introducing new (revised) stock into the facility.

Q. Will the labeling change affect prefilled bags of heparin used for infusions?

The change affects small volume injectables. Heparin prefilled bags already provide unit and total strength on the label.

Q. Does this policy mean that manufacturers cannot put an old-style label on a heparin product as of May 1, 2013?

The standard will be official May 1, 2013 and adherence to the standard is expected by the official date. USP is a standard setting body and does not enforce the standard. Enforcement will be determined by FDA.

For more information

USP: http://www.usp.org/

USP: Medication Safety & Labeling: http://www.usp.org/usp-healthcare-professionals/medication-safety-labeling

FDA: http://www.fda.gov/Drugs/DrugSafety/ucm330695.htm

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Thank You