

## Contents

**Improving the Safety  
of Anticoagulation  
Therapy in the VA**  
Pages 1 and 4

**Case Study: Biomedical  
Engineering**  
Page 2

**News From the Patient  
Safety Reporting  
System**  
Page 3

## VA National Center for Patient Safety

P.O. Box 486  
Ann Arbor, MI 48106-0486

Phone:..... (734) 930-5890

Fax: ..... (734) 930-5877

E-mail: ..... NCPS@va.gov

### Web sites:

Internet..... [www.patientsafety.gov](http://www.patientsafety.gov)

Intranet... [vawww.ncps.med.va.gov](http://vawww.ncps.med.va.gov)

VHA Chief Patient Safety Officer  
James P. Bagian, MD, PE

### Editor

Joe Murphy, APR

### Graphics

Deb Royal

### Copy Editing

Amy Carmack

Deb Royal

TIPS is published bimonthly by the VA National Center for Patient Safety. As the official patient safety newsletter of the Department of Veterans Affairs, it is meant to be a source of patient safety information for all VA employees. Opinions of contributors are not necessarily those of the VA. Suggestions and articles are always welcome.

Thanks to all contributors and those NCPS program managers and analysts who offered their time and effort to review and comment on these TIPS articles prior to publication.

## Improving the Safety of Anticoagulation Therapy

By Keith W. Trettin R.Ph., NCPS program manager

### Background

The Institute for Healthcare Improvement (IHI) in December 2006 announced an expansion of their “100,000 Lives Campaign.” The new campaign, “Protecting 5 Million Lives from harm,” expanded the list of safety interventions from the original six to twelve, and includes “Prevent harm from High-Alert Medications ... starting with a focus on anticoagulation, sedatives, narcotics and insulin.”<sup>1</sup>

In 2007, the Joint Commission (JC) expanded National Patient Safety Goal 3 (NPSG 3), “Improve the Safety of Using Medications,” to include NPSG 3E, “Reduce the likelihood of patient harm associated with the use of anticoagulation therapy.”<sup>2</sup> NPSG 3E is to be phased in this year and fully implemented by Jan. 1, 2009.

The rationale for both these actions includes:

- Anticoagulation is a high-risk treatment, which commonly leads to adverse drug events.
- Dosing of these medications is complex.
- Monitoring is required.
- Patient compliance directly affects outcomes.
- The use of standardized practices (that include patient involvement) can reduce the risk of adverse drug events associated with the use of heparin, low-molecular heparin, warfarin, and other anticoagulants.

These actions were supported by national anticoagulation therapy adverse event data. For instance:

- U.S. Pharmacopeia reported in 2006 that 4.7 percent of all incidents reported through its MEDMARX system involved anticoagulation therapy; that 7.8 percent of incidents causing patient harm were

related to anticoagulation.

- Bates reported that anticoagulants accounted for 4 percent of preventable adverse drug events (ADEs) and 10 percent of potential ADEs.<sup>3</sup>
- Butnitz also identified in 2007 that one-in-seven ADEs treated in emergency rooms and more than 25 percent of all hospitalizations were caused by anticoagulants.<sup>4</sup>

### The VA Response

The VA established a multidisciplinary anticoagulation work group to address safety issues identified by the IHI and JC, as well as those found within the VA. The work group first met in January 2007.

The multidisciplinary background of the group’s members and consultants has provided a firm foundation to analyze VA anticoagulation safety issues and develop recommendations for improvement.

In addition to safety concerns noted by the IHI and JC, we at VA NCPS also reviewed root cause analyses of medication incidents, available in our National Patient Safety Information System, to identify anticoagulation vulnerabilities.<sup>5</sup>

The work group has completed its recommendations and prepared a paper, “Consensus Guidance on the Elements Required to Insure the Safe Use of Anticoagulants,” to address them.<sup>6</sup>

Major work group recommendations include the following:

- All VA sites should establish outpatient programs where anticoagulation for all patients is managed by providers who are specially trained and skilled in managing anticoagulant therapy.

*Please Note:* In a recent VA study, it was found that 70.6 percent of patients seen in high-volume anticoagulation

# Case Study: Biomedical Engineering

By Joe Murphy, NCPS public affairs officer

## Background

A pathologist noted abnormally high test results when working with certain specialized test tubes.

Heparin, and a thixotropic substance used to separate cells from plasma in a patient's blood sample, are placed in these specialized test tubes during the manufacturing process.

Thixotropic substances are thick – like a solid – but can flow like a liquid when disturbed.

A recall of contaminated heparin produced in China was concurrent with the abnormal results.

NCPS Biomedical Engineer Bryanne Patail notes in the story below that though the “China” connection couldn't be discounted, it had nothing to do with the actual problem.

Patail said that many issues encountered by biomedical engineers require a significant amount of detective work. It's often about finding “the difference between what people tell us and what actually happened.”

## Abnormal Results

When a pathologist at a VA facility began finding abnormally high test results, he suspected a problem with the test tubes involved.

The tubes contained a thixotropic substance layer that, when spun on a centrifuge, prevents red blood cells from being aspirated by the automated chemistry analyzer – only the plasma is aspirated. Along with this substance, the tubes contained a lithium-heparin compound to keep the blood from coagulating.

“He was getting abnormal results and it happened at the same time as a big heparin recall,” said Patail. “We were getting contaminated heparin from China. And these test tubes contained a lithium-heparin compound, along with the thixotropic substance.”

Patail's first call was to the FDA. “We have a Memorandum of Understanding to do certain work together,

like sharing information on recalls or possible recalls,” he said.

He was given the name of the company that had supplied the tainted heparin. The firm claimed not to have sold heparin to any test tube company for the past seven years.

“I also called the lab analyzer company, because one of their service persons had been at the VA facility for a week, trouble-shooting and running controls and standards on the equipment,” said Patail. “The service person found no irregularities with the equipment.”

Patail learned from the test tube manufacturer that the thixotropic substance was very sensitive to variations in specific gravity: “You have to spin it on a particular kind of centrifuge at a particular g-force.”

The thixotropic substance floats above a patient's red blood cells. “The specific gravity is a little bit below that of red cells' specific gravity, but not as low as plasma,” said Patail. “So it separates the two.”

He started comparing all the information he had gotten from the various sources, along with conducting his own research. “I went through many different iterations before I learned what was wrong,” Patail said.

## What Went Wrong

It turned out that the mixture was being spun for too short a time and at too little a g-force.

The VA laboratory in question had been spinning this mixture on its centrifuge “for ages,” as the pathologist put it, with no erroneous results.

“When you spin test tubes, most don't require such specific rpms and g-forces,” said Patail. “Of the 17 different types of test tubes sold by this company, eight have different specifications for use on a centrifuge.”

He believes that the laboratory, through sheer luck, hadn't experienced problems with tests in the past. “I think he had been right on the cusp of being within tolerance for a

long time,” Patail said. “He had been doing this for so long that he didn't suspect that spinning was causing the problem.”

The complex instructions, placed within the packaging of the test tubes, hadn't been noticed by staff.

Part of the instructions indicated the time and g-force required, as well as that the test tubes would remain stable for no longer than 48 hours. (The pathologist had also been comparing results with test tubes that had been in storage for five days.)

## A Human Factors Problem

Patail had first thought the problem was due to tainted heparin. “I thought I had stumbled across something that was wide spread and based on the Chinese-supplied heparin,” he said. “But it's important not to jump to conclusions.”

Patail went to the company's web site, downloaded the specifications, and realized that the problem was associated with human factors engineering. “The system just didn't support the individual,” he noted.

“It seems to me that if there are only a few test tubes manufactured like this, the information about use should be in big block letters: ‘Important! Do this differently!’ ” Patail said.

“Human factors engineering problems are often involved in system failures,” he continued, “like providing information that is easy to overlook, as well as being printed in a very small font. It's important to improve weak or faulty systems, not blame the individuals who have had to work within them.”

Even though only three hospitals in the VHA use these kinds of test tubes, it is still important that all users have a clear understanding of what is required of them.

# News From the Patient Safety Reporting System (PSRS)

By Linda Connell, NASA PSRS director

## Background

The Patient Safety Reporting System (PSRS) is an external, confidential, voluntary, non-punitive reporting system that has been in use since 2001.

It provides VA employees with a “safety valve” to confidentially report adverse events and close calls that, for whatever reason, would not be reported elsewhere.

PSRS is operated and managed by NASA’s Ames Research Center, Moffett Field, Calif., through an interagency agreement with NCPS.

The program is modeled on the NASA Aviation Safety Reporting System (ASRS), a confidential reporting system that serves the FAA.

ASRS has been a collection point for important safety information used to support aviation system improvements since 1976.

## What’s New

The PSRS team has visited 117 VA facilities during the past few years to provide information about the PSRS program to VA staff.

We have a new web site: <http://psrs.arc.nasa.gov>.

The site includes issues of our “FEEDBACK” publication. This short, two-page newsletter is available in .html and .pdf formats for electronic distribution in your facility.

We have issued Patient Safety Bulletins on topics such as:

- Communication of abnormal test results.
- Partial tablet dosing.
- The use of benzocaine.

We have received feedback from VA Patient Safety Managers that there have been important changes to

policies and procedures owing in part to reports made by VA staff via the PSRS program!

Some of the changes have included:

- VA formulary modifications.
- Removal of disinfectant products used for dental services.
- Changes to facility policies related to oxygen use in the operating room.

## We’re Here to Help

To learn more about PSRS, you can visit our web site or send an email to a PSRS medical safety analyst, using the email addresses provided below.

We always appreciate learning how we can improve and how the program has helped in your facility – as well as receiving your safety reports.

We want to thank all VA staff members that have contributed reports to PSRS.

## Points of Contact

Linda Connell, PSRS Director:  
[Linda.J.Connell@nasa.gov](mailto:Linda.J.Connell@nasa.gov)

VISN 2, 4, 11, 16  
Sue Andrew, R.N.  
[suzanne.b.andrew@nasa.gov](mailto:suzanne.b.andrew@nasa.gov)

VISN 5, 7, 9, 22  
Paul Boehm, M.S., R.Ph.:  
[paul.e.boehm@nasa.gov](mailto:paul.e.boehm@nasa.gov)

VISN 1, 6, 15, 17, 20  
E. Charli Freeman, R.N.:  
[eileen.c.freeman@nasa.gov](mailto:eileen.c.freeman@nasa.gov)

VISN 10, 12, 18, 21  
Sho Kahatsu, M.D.:  
[shoichi.kohatsu-1@nasa.gov](mailto:shoichi.kohatsu-1@nasa.gov)

VISN 3, 8, 19, 23  
Steve Pakula, M.D.:  
[stephen.b.pakula@nasa.gov](mailto:stephen.b.pakula@nasa.gov)

## PSRS Products & Publications



**New PSRS Posters Will Arrive at Your Facility Fall 2008!**

# Improving the Safety of Anticoagulation Therapy

Continued from page 1

clinics had an International Normalization Ratio (INR) calculated; of these, 58 percent were within the therapeutic range. Of veterans not seen in a clinic, 42 percent had an INR calculated; 52 percent of these were in the therapeutic range. It was also identified that the most effective clinics were those that were adequately staffed – and had laboratory staff included as support personnel.

- Require pertinent lab tests be drawn and that lab values from tests conducted outside the VA be entered into the Computerized Patient Record System (CPRS)

*Please Note:* The work group identified a wide variation in how non-VA lab results are reported to VA providers, and/or entered into the electronic medical record. In most cases, the results had been entered into a progress note only. Unfortunately, this approach makes tracking difficult, and does not link to prescription dispensing. Some sites have developed ways to enter non-VA lab results into the VISTA lab package.

- Have each VA medical center adopt and place into CPRS a weight-based heparin protocol. A standardized protocol<sup>7</sup> reduces variation in practice. It is also a requirement of NPSG 3 implementation standards and a “Five Million Lives” recommendation.
- Offer educational opportunities to medical providers, nurses, pharmacists, laboratory staff, and others associated with anticoagulation therapy. Medical staff must remain up-to-date on prescribing, dispensing, and monitoring anticoagulants – a requirement of the NPSG 3

implementation standard.

- Reduce turnaround time for INR results at community-based outpatient clinics or other remote sites. Unlike patients who are seen at a main facility, those seen at remote sites often do not have access to immediate INR results. If the provider suspects a patient’s INR may be elevated, a delay in results can have significant consequences.

Guidance on implementing these recommendations is being developed by a VHA Central Office work group and will appear in a VA directive out due early fall 2008. The group includes representatives from pharmacy, primary care, surgery, operations, laboratory service, cardiology, nursing, care coordination, NCPS, and nutrition and food services.

## What Can Be Done Now?

Interested professionals can complete a safety “high-risk assessment” for their organizations, such as are available on the Institute for Safe Medication Practices (ISMP)<sup>8</sup> or ECRI web sites.<sup>9</sup>

VA employees can complete a VA medical center anticoagulation Healthcare Failure Mode Effect Analysis and/or a specific anticoagulation risk assessment. Samples are available on the NCPS web site.<sup>10</sup> Related information is available on the ISMP web site.<sup>11</sup>

VAMC pharmacy and therapeutics committees should evaluate the concentrations of heparin available in their institutions: The goal being to minimize use of high concentrations (such as 10,000 units/ml) – that have been associated with look-alike/sound-alike issues – through the use of less concentrated versions (such as 10 units/ml). Such look-alike/sound-alike problems have been well documented nationally.

VISN 15 recently reviewed heparin concentrations: As of July 31, 2008, heparin with a concentration of 10,000 units/ml was no longer to be stocked within their medical centers. This is an excellent example of taking the appropriate action.

## Notes

1. Click to: [www.ihl.org](http://www.ihl.org)
2. Click to: <http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals>
3. Bates DW, “Incidence of adverse drug events and potential adverse drug events: Implications for prevention,” ADE Prevention Study Group. JAMA 1995;274:22-34.
4. Budnitz DS, “Medication use leading to emergency department visits for adverse drug events in older adults,” Ann Internal Med 2007;147(11):755-765.
5. VA employees can read a summary of these vulnerabilities at: <http://vamw.ncps.med.va.gov/Initiatives/Hazards/anticoag.html>. A recent anticoagulation RCA topic summary is also available: <http://vamw.ncps.med.va.gov/Initiatives/RCATopics/index.asp>
6. The paper is available to VA employees on the VA-IHI High Risk Medication SharePoint: <http://vamw.national.cmop.va.gov/PBM/Clinical%20Guidance/Forms/AllItems.aspx?RootFolder=%2fPBM%2fClinical%20Guidance%2fClinical%20Recommendations&View=%7b786029AE%2d74D9%2d40BC%2dBC7%2dBECEf18B1B7FD%7d>
7. VA employees can find links to sample protocols and policies on the NCPS web site: <http://vamw.ncps.med.va.gov/Guidelines/NPSG/index.html>
8. The ISMP site: <http://www.ismp.org/selfassessments/Hospital/2004Hospism.pdf>
9. The ECRI site: [http://www.ecri.org/Documents/Sample\\_CCRM\\_Medication\\_Safety\\_SAQ.pdf](http://www.ecri.org/Documents/Sample_CCRM_Medication_Safety_SAQ.pdf)
10. The VA NCPS site: <http://vamw.ncps.med.va.gov/Initiatives/HFMEATopics/list.asp>
11. The ISMP site: <http://www.ismp.org/Tools/anticoagulantTherapy.asp>