Vioxx withdrawal teaches pharmacy important lessons on recalls

Have policy in place to satisfy JCAHO

The Merck & Co., Inc., market withdrawal of Vioxx in September underscored the need for hospital pharmacies to have a documented policy and procedure to handle drug recalls.

Most hospitals currently have drug-recall policies in place, something the JCAHO requires under medication standard MM.4.70. But the widespread reach of the Merck withdrawal—1.3 million Americans took the anti-inflammatory arthritis painkiller—caught many hospitals by surprise and emphasized the need for continuous readiness.

“While this is a very unfortunate incident, it will help us raise the bar on policies and procedures for this type of event,” says Frank McCree, RPh, director of outpatient pharmacy services at The Merck & Co., Inc.

Between September 1998 and August 2003, the U.S. Pharmacopeia (USP) MEDMARX error-reporting database collected 4,437 error reports involving preprinted order forms, says John Santell, MS, RPh, director of educational program initiatives at the USP Center for the Advancement of Patient Safety in Rockville, MD. Of those reports, 110 (2.5%) resulted in patient harm.

Check out three common problems with preprinted order forms below and some tips to improve JCAHO compliance.

1. Watch your abbreviations
Using abbreviations for drug product names, route of administration and others is rampant in healthcare, but a major source of error. A recent study showed that 10% of patients received the wrong dosage of insulin.

Review preprinted order forms to avoid three common pitfalls and remain compliant with JCAHO standard MM.3.20—one of the more cited in 2004.

Preprinted forms allow providers to prescribe medications—usually high-risk ones such as insulin, opioid analgesics, and anticoagulants—in a standardized way that minimizes misinterpretation of handwriting.

For example, a hospital would outline parameters for dosing, preparation, scheduling, administration, and monitoring in a standardized format for a preprinted heparin order form.

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Carolinias HealthCare System in Charlotte, NC. “This involves more patients than other recalls or market withdrawals.”

**Other alternatives available**

Merck withdrew the COX-2 inhibitor Vioxx from the market September 30 after data from a three-year clinical trial to determine the drug’s effectiveness in treating polyps revealed that study participants were twice as likely to suffer heart complications after taking the drug for more than 18 months.

Five patients taking Vioxx died during the study, and five patients died taking a placebo.

Vioxx was one of Merck’s leading brands. Its worldwide sales reached $2.5 billion in 2003, according to the company.

Pfizer’s Celebrex and Bextra are also COX-2 inhibitors, but the FDA says there are no data showing any dangers related to those drugs. Generic pain relievers such as aspirin or ibuprofen are other alternatives to Vioxx.

Celebrex netted $2.6 billion in U.S. sales alone in 2003, The Associated Press reported. Pfizer officials failed to respond to requests for comment about the Vioxx recall and its effect on Celebrex.

**Three steps to follow**

Hospitals routinely receive recall notices, sometimes on a weekly basis, says Saifi Vohra, PharmD, MBA, FASHP, FASCP, a consultant with the Westmont, IL–based Providers Solutions Inc. Many recalls occur because of problems with certain a certain batch of medications—each of which is assigned a lot number—such as subpotency, which the manufacturer’s quality-control scientists can detect through routine testing, he says.

Pharmacy purchasing coordinators or pharmacy buyers are often responsible for initiating the recall procedure at the hospital, Vohra says. Here are three steps to take when responding to a recall notice (see a sample policy on p. 4 for more information):

✔ Drug manufacturers assign a lot number to each batch of medications as they are manufactured and shipped. Therefore, when a recall notice is sent to individual pharmacy with specific information, pharmacy buyers should look for a specified lot number when the recall notice arrives.

✔ Check your pharmacy’s stock or any record for the recalled lot number. Depending on your hospital’s system, you may be able to record it in an electronic database or automated cabinets such as Omnicell or Pyxis. If not, you should keep it in a written log.

✔ Follow the manufacturer’s instructions provided with the recall notice. They may give you an address to which you should ship the medications.

Tracking lot numbers back to patients could be
difficult because hospital pharmacies dispense thousands of doses each day, says Douglas Scheckelhoff, MS, RPh, director of pharmacy practice sections for the American Society of Health-System Pharmacists in Bethesda, MD. “The resource requirements it would take to record the lot number manually would be astronomical,” he says. “It’s just not possible.”

A recall that requires hospital officials to contact patients is rare, Scheckelhoff says. Healthcare providers may need to contact patients about recalls involving blood derivatives or biologicals, but hospitals usually record the lot numbers for those products, Scheckelhoff says.

In the Vioxx case, patients and hospitals were able to receive information from local media, Merck, and the FDA, Scheckelhoff says.

**Tip:** Sign up for the FDA’s MedWatch, an e-mail service that alerts hospitals about the latest recalls and market withdrawals. Go to www.fda.gov/medwatch/elist.htm to learn more.

**Identify and educate patients**

McCree’s pharmacy staff at Carolinas HealthCare spent the first few hours after the Merck announcement identifying patients who take Vioxx. After identifying patients who use the medication, pharmacy staff spoke with physicians to help them identify alternative therapies.

Pharmacy staff may also educate patients about the recall and any effects it may have on their health, McCree says.

“We’re trying to reassure our patients that if they’ve been on this drug, the chances of serious complications are quite remote,” McCree says.

**Tip:** Use local media to help notify patients about the recall and any effects it may have on them.

**Document your actions**

Make sure you document every step you take during the recall process, Vohra says. This will help you show the JCAHO what you did after receiving a recall notice if surveyors ask during your survey.

**Tip:** Place recalls on the pharmacy and therapeutics (P&T) committee meeting agenda. Discuss how the pharmacy responded to the recall order and document it in the P&T minutes.

Whether the JCAHO looks at how you handled the Vioxx market withdrawal or another, smaller recall, hospitals should be ready to deal with these events in the future.

“This is going to be a new high-water mark,” McCree says. “We will be more prepared in the future.”
Sample drug recall policy

Policy
If a drug or drug product is subject to recall, the pharmacy department is responsible for locating, removing, sequestering, and disposing of the recalled drug.

Procedure
I. Definition
A drug recall is notification from a manufacturer or regulator such as the FDA requiring that a drug or drug product be removed from circulation and stock.

II. Responsibility
The pharmacy director is responsible for the overall management of the drug recall procedure.

All drug recall notifications will be given immediate attention by the director at the time the drug recall is received. Drug recall notifications may be received by telephone, letter, regulatory bulletin, wholesaler notification, facsimile, or electronic mail.

III. Recall process
A. Actions taken will be in accordance with the instructions received from the manufacturer or regulatory agency. If the hospital does not have and has not purchased the drug subject to recall, the purchaser will report this to the director.

B. Upon notification of a drug recall, the pharmacy technician will be directed to those areas that may have the recalled drug in stock. If recalled drugs are found in stock supplies outside the pharmacy, the technician will remove the recalled stock and return the stock to the pharmacy. The technician will also review all stock locations within the main pharmacy and all satellites and will remove the recalled stock.

C. Once all recalled drug stock is located, the technician will make a final count of the number of recalled tablets, capsules, vials, etc., and will note the final volume. The note of final volume and the recalled stock will be delivered to the pharmacy purchaser. The pharmacy purchaser will sequester the recalled stock until further notice or return the stock to the manufacturer as outlined in the recall notification.

D. The pharmacy purchaser will complete a written report with the details of the recall process to the director of pharmacy. The report will contain, at a minimum, the following details:

- The actual drug recall notification
- The date and time that all hospital inventory was reviewed (or a note that the hospital has not purchased the drug in question)
- The date and time that any recalled drug was located and removed from stock

administration, or dose designation is one of the common error-prone problems that occur with preprinted order forms, Santell says.

Some possible misinterpretations include

- reading MSO₄ (morphine sulfate) as MgSO₄ (magnesium sulfate)
- reading U as “zero” instead of “units”

“Even when it’s printed, the eye can still play tricks,” Santell says.

**Tip:** Avoid abbreviations on preprinted order forms. See the JCAHO’s National Patient Safety Goals Web page at [www.jcaho.org](http://www.jcaho.org) for more information on unapproved abbreviations.

2. **Don’t alter a preprinted order form**

Sometimes providers cross out the medication listed on a preprinted order form and write in a new medication. In some cases, however, they forget to adjust the preprinted dosage, resulting in a mismatch between the drug and the dose, Santell says.

For example, one error occurred when a physician crossed out the painkiller meperidine on a form and wrote in hydromorphone. He failed to change the basal rate, loading dose, and locking dose, resulting in an overdose of hydromorphone. The patient required an antidote to recover, according to Santell.

**Tip:** Prohibit providers from altering preprinted order forms. If providers want to deviate from parameters on the form, they should write out or electronically enter the medication order.

3. **Look out for typos**

Make sure forms are complete and accurate. Sometimes a minor typographical error can result in patient harm because of a misinterpreted dose, for example, says Melinda Joyce, FAPhA, CHE, pharmacy director at The Medical Center in Bowling Green, KY.

“There is always the potential for an adverse drug reaction, so you need to make sure that someone is always monitoring,” Joyce says.

Most organizations establish a schedule for reviewing preprinted order forms on a regular basis. One approach is to schedule certain types of forms, such as patient-controlled analgesia or total parenteral nutrition, for evaluation each month so every form gets reviewed over a one-year period, Santell says.

**Tip:** Give each form a unique identification number and list the revision date on the form to make sure it is updated.

New drug information may become available during the year that will require an organization to immediately review a particular order form, Santell says.
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salaries during the study, but the authors estimated savings of almost $39,000 by preventing errors and potential harm when pharmacists interviewed patients.

**Tap into your resources**
Pharmacists may also suggest an alternative therapy if the medication a patient took before admission is not on the hospital’s formulary, Porto says. The pharmacist can explain the substitute medication to both the physician and the patient and highlight any dosing differences between the normal drug and the substitute, she says.

Hospitals should utilize the pharmacist’s medication knowledge to their advantage in meeting the JCAHO goal, Gleason says.

“Pharmacists are more likely to recognize inaccurate or inappropriate dosages, contraindications, and omissions in drug therapy,” Gleason says.

**How do you document it?**
Once you collect this information, where do you keep it? You could create one form for reconciling medications. (See p. 8 for a sample medication reconciliation form.)

The form should include

- the dosage and frequency of each medication
- the date and time of the last dose
- information about the patient’s compliance with prescribed dosages and frequency
- information about allergies
- a space for the verifier’s initials
- a signature line for the physician

“People [in the group] agonized over how to get that gold-standard, perfect list,” says Griswold. “But don’t let the quest for the ‘perfect’ list be the enemy of the ‘good’ list. Just get the best information you can about the home medications that patients are taking.”

**Tip:** Place the form in a visible location in the patient’s chart. The history and physical or nursing assessment are also good forms to document a patient’s medications, Porto says, as reconciling medications using these forms can help reduce the workload on a resource-strapped hospital.

Enter the reconciled medication list into the electronic medication administration record (eMAR) if your hospital uses electronic medical records. Northwestern Memorial Hospital is currently transitioning to an eMAR and computerized physician order entry (CPOE), Gleason says.

**Tip:** Design your eMAR and CPOE system to alert caregivers to reconcile patients’ medications upon admission or each time they transfer to a new unit.

**Create a team approach**
Some hospitals may not have enough resources to have pharmacists interview patients upon admission. Remember physicians, nurses, and pharmacists all play an integral role in the medication reconciliation process. Gleason knows of one hospital that has a nurses reconcile medications upon admission, physicians reconcile them upon transfers, and pharmacists reconcile them upon discharge.

“It needs to be a multidisciplinary effort, and hospitals should develop a process for collaboration between clinicians to maximize resources and minimize rework,” Gleason says.

Patients should also be educated about the importance of maintaining an updated medication list and reconciling their medications at every healthcare encounter.

**Tip:** Have pharmacists work with patients upon discharge to develop an updated medication list and explain any new medications they may be taking, any differences in doses, and how drugs may interact with each other.
### Sample reconciling medications assessment form

Patient #: ____________________  Review period: ________________  
(Not sequentially 1–30 patients for each review period.)  Reviewer initials: ________________  

<table>
<thead>
<tr>
<th>List all medications</th>
<th>Info from home medication list (as identified from intake history, patient, family, prescription bottle)</th>
<th>Info from MD/prescriber order</th>
<th>Do all medication elements match?</th>
<th>Comments on data sources, omissions, variances, evidence of missing information at transfer</th>
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<tbody>
<tr>
<td>Drug</td>
<td>Dose</td>
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<td>Medication allergy information (optional)</td>
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<td>Last dose information (optional)</td>
<td>#</td>
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<td>Compliance information (optional)</td>
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</table>

- Are the allergies listed correctly on admission orders?  
- Are the allergies listed correctly on subsequent transfer orders?  
- Is the patient allergic to any ordered medications?  
- If medication allergies were detected during the hospitalization, was allergy info updated?  
- Is information on medication allergies consistent (e.g., history matches MAR, etc.)  
- #, % of medications with time “last taken” identified  
- #, % of medications with information on patient compliance  

Source: Massachusetts Coalition for the Prevention of Medical Errors. Reprinted with permission. For more information, visit www.macoalition.org.
Meet JCAHO requirements with a colorful solution
How one TN hospital uses colored bins to separate medications

Pharmacy technicians at Tennessee Christian Medical Center in Madison used to traverse the pharmacy to fill medication carts, often moving methodically from room to room to pick out different medications.

When pharmacy staff decided to place medications in alphabetical order in one location to expedite the order-fulfillment process, another problem arose—how to prevent technicians from reaching into the wrong bin and grabbing the wrong medication.

Colored plastic bins helped solve that problem. The different colors represent various drug types, from injectables to oral medications to extended-release versions of some medications, says David Kellogg, DPh, MS, the Tennessee Christian pharmacy director. “We were thinking about safety features for the Joint Commission,” Kellogg says. “We wanted something that might be outside of the box.”

The change helped the hospital reduce the risk of potential errors that could occur from technicians choosing the wrong drug in a hurry, Kellogg says, something that helps the hospital comply with JCAHO medication standard MM.8.10, which requires organizations to evaluate their medication management systems and take steps to improve safety.

Pick a color
The Tennessee Christian pharmacy divides medications in the following order:

- Beige bins for normal oral medications
- Green bins for extended-release versions of the drug they sit next to on the shelf
- Red bins for injectable forms of a drug
- Yellow bins for topicals, creams, and patches
- Blue bins for liquids
- Black bins for anesthesia drugs

The idea came about almost six months ago, when pharmacy staff wanted to stock drugs in alphabetical order but needed safeguards to prevent people from selecting the wrong drug. Staff first considered placing colored dots on the bins, and the idea grew from there, says pharmacy supervisor Amy Huffines, DPh.

“How are we going to make sure we can keep someone from pulling a tablet instead of an injectable [form of the drug]?” Huffines asks. “This way, we can keep them all together, but they are easily identifiable.”

The hospital spent about $2,000 for nearly 800 plastic bins, which vary in size from 3–6 in wide, Kellogg says. Bins for 1,000 mL IV bags are 16 in wide.

Many pharmaceutical supply vendors sell bins for drug storage, Huffines says.

Bin labels help compliance, too
Tennessee Christian will begin using a software system from the Kansas City, MO–based Cerner Corp. in January 2005, Kellogg says. The hospital aims to have a paperless records system in place with the new software.

The Cerner software will allow the pharmacy staff to label certain drug names with tall-man lettering, which capitalizes certain syllables in drug names to help pharmacists differentiate between look-alike and sound-alike drugs, a JCAHO National Patient Safety Goal that will take effect January 1, 2005.

Pharmacy staff will make the labels on the bins look exactly as they will appear on any document, including the medication administration record, Huffines says. This way, staff will be able to match the document to the printed label on the bins.

Please take a moment to complete the Hospital Pharmacy Regulation Report confidential training budget survey. This survey will help you benchmark your pharmacy training budget with your peers. Results will appear in a future issue of HPRR. To take the survey, visit www.zoomerang.com/survey.zgi?p=WEB2S4I.7KPGX.
Money makers: Results of HPRR’s salary survey

Editor’s note: In July, HPRR conducted its first salary survey. We received 29 anonymous responses, yielding the results presented in this story. Although the responses represent a slice of our readership, they reveal a lot about your colleagues. Check out future issues of HPRR for more about pharmacy staffing issues.

A majority of pharmacists believe they receive adequate financial compensation, and pharmacists overall are paid well, even as job responsibilities increase.

Fifty-nine percent of your colleagues reported that they are satisfied with their salary and believe they are financially compensated for the work they do, with the vast majority—76%—making $90,000 or more. One pharmacy director for a health system reported making $130,000 per year.

Overall, 66% said pharmacists in general are sufficiently compensated. However, there’s always room for improvement.

“We always feel as if we deserve more,” said one respondent. “If anything, I think I deserve call pay plus my salary, as I am a one-person department who is on call 24/7, except for three one-week vacations, which I must take out of town or I still get called.”

Despite increasing work demands, pharmacists understand that salaries reflect the current economic conditions.

“I have been a pharmacist for 21 years, and I feel we are compensated very well,” another respondent said. “However, the demand is so great and the supply is so small that supply and demand requires further escalation of salaries. If this changes, then expectations should change. But until then, it’s whatever the market can bear.”

2003 v. 2004

The good news is that salaries have changed over the past year, increasing

- 1%–3% for 48% of respondents

Figures 1 and 2

<table>
<thead>
<tr>
<th>Current Salary Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $20,000</td>
<td>0%</td>
</tr>
<tr>
<td>$20,000 to $29,000</td>
<td>0%</td>
</tr>
<tr>
<td>$30,000 to $39,000</td>
<td>7%</td>
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<td>3%</td>
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<td>0%</td>
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<tr>
<td>$80,000 to $89,000</td>
<td>14%</td>
</tr>
<tr>
<td>$90,000 or more</td>
<td>76%</td>
</tr>
</tbody>
</table>

- 4%–6% for 21% of respondents
- 7%–10% for 7% of respondents

Ten percent reported a salary increase of 15% or more in the past year. However, 14% also reported no change in their salary (see Figure 1 for salary breakdowns).

What you do at work

Most respondents are pharmacy directors working at a nonprofit, hospital-based pharmacy. Thirty-one percent work at a for-profit, hospital-based pharmacy. Three respondents—10%—reported working as clinical pharmacists. One was a pharmacy buyer and one was a pharmacy technician, both earning between $30,000 and $39,000.

One respondent worked in long-term care, and another worked at a state psychiatric hospital (See Figure 2).

All respondents have supervisory responsibilities, with 39% overseeing between one and five employees. Eighteen percent reported supervising more than 30 employees (See Figure 3).
A hard day’s work
You work hard for the money you earn. Most respondents report working between 41 and 50 hours each week. Twenty-four percent work more than 50 hours a week.

Some fail to receive compensation for the additional time. One respondent said some pharmacists work five to eight hours of overtime and do not receive additional compensation.

Five respondents said they supervise more than one department, including environmental services and nursing supervisors, separate retail pharmacies, outpatient pharmacies, and home-care pharmacies.

Newcomers to the game
Most respondents are fairly new to their position. Thirty-one percent have been in their current position for one to three years. Twenty-four percent have worked in the same position for four to six years, and 17% have held the same title for seven to 10 years.

Two respondents (7%) have worked in the same position for 11–20 years, and the same number has worked in the same place for more than 20 years.

Where do you come from?
Most of you reside in the Midwest (31%) and Southeast (28%). Only 7% live in the Mid-Atlantic, and no one reported living in New England. Fourteen percent live in the Southwest and West, and 7% live in the South.

Respondents from the Midwest reported earning $80,000 or more. Only two respondents from the South reported earning more than $90,000. All respondents from the Mid-Atlantic, Southeast, Southwest, and West reported making more than $80,000 a year.

The majority of respondents are between 36 and 55 years old. Twenty-four percent reported having a PharmD, and 45% have a RPh. Two respondents also have a master’s degree in business administration.

Both genders are almost equally represented by our respondents, with 55% males and 45% females.
Quick tip: Monitor prices to protect your hospital during flu vaccine shortage

Beware of price gouging this winter as some vendors may attempt to take advantage of the flu vaccine shortage.

The federal government is working with state and local governments to monitor and punish those who take advantage of the situation by dramatically raising prices, Julie Gerberding, MD, MPH, director of the Centers for Disease Control and Prevention (CDC), said during an October 12 press conference.

A physician at Children's Hospital of Orange (CA) County told The New York Times that a vendor asked $700 for a vial of 10 doses that usually costs $67. The hospital did not purchase the vaccine at that price, the physician said.

“Shame on the people who are price gouging,” said Gerberding. “This is a reprehensible thing to be doing. We need to pull together as a country to protect our vulnerable population.”

Price gouging definitions vary from state to state, Gerberding said.

Tip: Check with your state attorney general’s to determine the definition of price gouging and the appropriate agency to which you can report any cases. Visit the CDC Web site at www.cdc.gov/flu for more information.

The Department of Health and Human Services said between 1 million and 2 million doses of the nasal influenza vaccine FluMist—safe for use in healthy people between five and 49 years old—will be available as well as 54 million doses of vaccines from Aventis Pasteur. The agency established priority groups to receive the vaccine, including

- all children between six and 23 months
- adults older than 65
- women who will be pregnant this winter
- healthcare workers providing direct patient care

Quick tip: Monitor prices to protect your hospital during flu vaccine shortage

We want to hear from you . . .

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