Educating the healthcare community about safe medication practices

Acute Care

ISMP Medication Safety Alert!®

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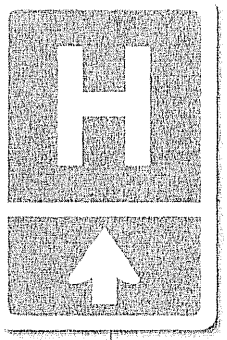
SafetyBriefs

JCAHO changes standard. A change in the Joint Commission standards, specifically the Element of Performance #2 for standard MM.4.50, will affect many organizations that do not provide round-the-clock pharmacy services. Previously, the Joint Commission allowed nursing access to a limited section of the pharmacy to retrieve medications after hours, when allowed by law and regulation, if other requirements in the Elements of Performance were met. After July 1, 2006, access to any part of the pharmacy by non-pharmacist personnel after hours is not allowed, even if permitted by law and regulation. All after-hours medications must be stored outside of the pharmacy (e.g., in a night cabinet, automated dispensing cabinet). If a needed drug is not available in that supply, an on-call pharmacist must come in to retrieve it or the medication must be obtained from an outside pharmacy that is open. This change was first announced in the February 2006 issue of *Perspectives* and was released in final form in the recent update to the *Comprehensive Accreditation Manual for Hospitals* that was sent to all accredited hospitals and Manual owners. Patients are at risk when non-pharmacists have complete access to a pharmacy after hours. With current technology, planning, and cooperation from medical and nursing staff, night access to the pharmacy can be eliminated, even in rural hospitals.



Read-back works. Physicians at Cincinnati Children's Hospital Medical Center recently studied error rates with and without the use of *read-back* of orders given verbally and then entered into the computerized prescriber order entry system. The Joint Commission National Patient Safety Goal 2A requires such a *read-back* process for both oral orders and oral critical test results. In the Cincinnati facility, the attending physician or chief resident typically communicates orders verbally during rounds and a resident physician then enters them into the computer system at a

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Tablet splitting: Do it only if you "half" to, and then do it safely

PROBLEM: Most oral medications are available commercially in the dosage strengths most commonly prescribed for patients. Occasionally, the patient's exact dose is not available commercially, so more than one tablet or just part of a tablet may be needed. While using more than one tablet for a single dose is customary, tablet splitting has become more commonplace in the past 5 years for several reasons:

- *Different tablet strengths often cost about the same. Patients who cannot afford their medications have received a higher strength tablet with directions to take ½ tablet (or even ¼ tablet) per dose.*[1]
- *Some health insurers have denied payment of prescriptions for the lower strength of certain drugs, thus requiring patients to receive the higher strength tablet and split it in half for each dose.*[1]
- *Some healthcare organizations have not purchased all commercially available strengths of oral medications. Thus, some of the drugs may require tablet splitting for patient-specific doses in the inpatient setting.*
- *Patients may not be able to swallow whole tablets.*[2]

A recent article in the Veterans Administration (VA) *Topics in Patient Safety* newsletter,[2] and a 2002 article on the American Society of Consultant Pharmacists website, *Tablet Splitting for Cost Containment*, authored by Thomas Clark,[1] offer several pitfalls with splitting tablets that clearly suggest it is not the safest option if the patient-specific dose is available commercially.

Patient factors. First, it is easy for patients to become confused about the correct dose. One woman learned this when she was admitted to the hospital with unstable angina and hypertension. Her physician found that she had been taking the wrong dose of lisinopril. She was supposed to be taking 5 mg BID, but the prescription label said there were 10 mg tablets in the bottle. When the physician looked inside, he saw both pink and peach tablets, some of which were split in half. Initially, the patient had been taking a 20 mg tablet BID. When her physician lowered the dose to 10 mg BID, she had the new prescription filled. The patient then cut the leftover 20 mg tablets in half and put them in the same bottle that held the 10 mg tablets. Later, her physician lowered the dose to 5 mg BID. Instead of filling the new prescription for 5 mg tablets, she tried to find all the 10 mg tablets to split them in half, but some remained whole.

In this case, no one could be certain of the dose the patient had been taking before she was hospitalized. But a study by the VA showed that most people took *too much* medication because they forgot to split their tablets.[2] Between January 2001 and April 2005, the VA's National Center for Patient Safety database included 442 reports related to pill splitting. Of those, 38% were considered adverse events, mostly occurring in outpatient settings (65%). Two-thirds of the patients received *more* than the intended dose. Pharmacists caught these errors because the patients came in too soon to refill their prescriptions. A quarter of the medications were high-alert drugs. About 9% of patients were harmed by these mistakes; 2% required hospitalization. In more than half of the events, the involved doses were available commercially.

Clark identified a few additional risks with tablet splitting:[1]

- *A pharmacist might misread a prescription written for 1/2 tablet as 1-2 tablets.*
- *Patients may assume the tablets have already been split when they have not, or split them again when they have been split already (especially if the pharmacy inconsistently splits the tablets upon refill).*
- *Patients may not have the visual acuity or manual dexterity needed to split the tablets.*
- *Patients may get confused and split the*

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SafetyBriefs continued

bedside terminal. In the first part of the study, the team on rounds accepted 70 consecutive oral orders and entered them into the computer. After rounds, they examined the orders and found a 9.1% error rate, mostly in drug dosages that would not have affected patient safety. However, in two instances, the resident ordered the wrong drug. In the second part of the study, before leaving a patient's room, the resident read back the order entered into the computer. The attending physician or chief resident then verified its accuracy. The researchers examined 75 orders and found that the error rate dropped from 9.1% to zero. The process added only seconds to each visit to a patient's room, so it did not slow down physician rounding. The data were presented last month at the Pediatric Academic Societies' annual meeting in San Francisco and will eventually be published (visit www.cincinnatichildrens.org/about/news/release/2006/5-verbal-order-errors.htm).

Special Announcements

Self-assessment data. Thanks to all who participated in the *2005 ISMP Medication Safety Self Assessment® for Antithrombotic Therapy in Hospitals.* Preliminary aggregate data are now available to those who anonymously submitted their findings to ISMP. Visit www.ismp.org/selfassessments/asa/Intro.asp and use the password provided during the data submission process to view the aggregate results. The self-assessment remains open to those who still want to participate. Results will be updated in real time as new participants join the study.

ISMP teleconference. Our next teleconference, ***The Impact of Clinical Decision Support Systems: Alerts and Standardized Order Sets***, will be held on June 29 from 1:30-3:00 p.m. EDT. The quantity and quality of safety alerts generated by computerized prescriber order entry (CPOE) systems is often problematic. Our guest speaker, **Eric Pifer**, MD, Chief Medical Informatics Officer at the University of Pennsylvania, will discuss how to best use safety alerts and order sets to augment decision making when prescribing drugs. **Peter Kilbridge**, MD, Associate Chief Information Officer for Patient Safety and Clinical Effectiveness at Duke University will moderate and discuss the Leapfrog initiative for evaluating hospital CPOE systems. For more information, visit: www.ismp.org/educational/teleconferences.asp.

Tablet splitting continued

wrong medication, or get tired of splitting the tablets and stop taking it.

- *To maximize cost savings, the patient may have been told to split the tablets in half, but the directions on the prescription may list "1 tablet" for each dose. These directions could mislead the patient or other healthcare providers who use the prescription label as a source of information when gathering a patient's medication history.*
- *Split tablets crumble more easily.*

Medication factors. Some medications or formulations are not suitable for splitting, including:

- *Enteric-coated/extended-release tablets*
- *Very small tablets*
- *Asymmetrical tablets*
- *Capsules*
- *Teratogenic medications (e.g., bosentan).*

Clark cites various studies that suggest that the accuracy of split tablets is questionable, even if the tablet is scored.[1] In one study, 94 volunteers were asked to split 10 tablets of hydrochlorothiazide 25 mg; 41% of the split tablets deviated by 10% of the correct weight, and 12% deviated by more than 20%. After the study, two-thirds of the volunteers said they would be willing to pay more for commercially available tablets in the correct strength. Other research cited by Clark corroborates the significant variation in tablet halves with rates of inaccuracy ranging from 5-72%.

SAFE PRACTICE RECOMMENDATIONS: Healthcare providers should make every effort to use commercially available oral tablets when available in both inpatient and outpatient settings. However, tablet splitting may still be necessary if the drug is not commercially available in the patient-specific dose, or if the patient's inability to afford the medication as an outpatient outweighs the risks involved with tablet splitting. Under these circumstances, consider the following suggestions from Clark, the VA, and ISMP:

Verify suitability. Before prescribing, dispensing, or administering half tablets, check drug references to ensure that it is safe. If unsure, contact the manufacturer.[2]

Select patients carefully. Establish criteria to screen patients before prescribing or dispensing half tablets to ensure they have the required level of understanding, ability, and motivation to split the tablets.[1,2] Ensure that the patient understands the risks associated with tablet splitting. If the patient cannot be expected to split his or her own tablets, enlist the aid of a qualified family member. (Note: It may not be legal in some states for a pharmacist to split tablets if the dose is available commercially.[1]).

Dispense split tablets for inpatients. For hospitalized patients, pharmacy staff should dispense exact doses by either splitting tablets and repackaging them or preparing an oral solution in a unit-dose oral syringe for each dose. Nurses should not be expected to split the tablets.

Keep it clean. Patients and healthcare providers who split tablets should wash their hands first. Healthcare providers should also wear gloves. If a tablet-splitting device is used, it should be washed afterwards to remove any powder or particles.

Prescribe by weight. Prescribers should order the medication strength and dose in "mg" when possible to avoid misreading an order for a "1/2" tablet as 1-2 tablets.

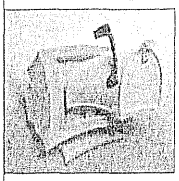
Counsel patients. Establish a system to ensure patient counseling when prescriptions for medications that require half tablets are picked up at community pharmacies, even if the pharmacist has split the tablets for the patient.[2]

Provide the right tools. If patients must split tablets at home, provide them with a tablet-splitting device to improve the accuracy.[2]

Provide discharge education. If patients are receiving half tablets while in the hospital, advise them regarding the dose they should take after discharge and whether this requires split or whole tablets.

References: 1) Clark TR. Tablet splitting for cost containment. August 2002. Available at www.ascp.com/advocacy/briefing/tabletsplittingcontainment.cfm 2) Sales MM, Cunningham FE. Tablet splitting. *Topics in Patient Safety* (HPS). 2006;6(3):1,4

Message in our mailbox



Vincristine in minibags. In our February 23, 2006 article, *IV vincristine survey shows safety improvements needed*, we recommended diluting IV vincristine before use. This makes it less likely to be administered intrathecally than undiluted drug in a syringe because the solution volume is increased. Use of a minibag offers further differentiation since intrathecal medications are often dispensed in a syringe. This week, our Australian colleagues let us know that the Australian Council for Safety and Quality in Health Care published a vincristine alert, which was developed in cooperation with the Hospital Pharmacy Society of Australia (visit www.safetyandquality.gov.au/council/vincristine/index.htm). The document (dated December 2005 but posted on the Internet earlier this month), was sent to Australian hospital chief executive officers and directors of nursing, pharmacy, and medical staff, as well as doctors, nurses and pharmacists. The alert calls for the immediate implementation of prevention strategies, including dilution in minibags to "design out the error" by preventing connection to a spinal needle. For adults, the alert recommends diluting vincristine in a 50 mL minibag and administering it over 5-10 minutes. For children, the alert suggests diluting vincristine in 20-50 mL of solution in a minibag to be given over 5-10 minutes. However, as John DiBona, PharmD, Director of Pharmacy at Sinai Hospital of Baltimore, correctly pointed out in response to our February article, as much as 15% of a 25 mL dilution may not reach the patient due to residual in the bag and tubing after the infusion stops. This needs to be factored in when using smaller volumes for children. For children age 10 years or less, if an individual risk assessment finds the use of a minibag inappropriate, dilution in at least 10 mL and administration from a syringe may be considered. Still, please note that inadvertent intrathecal administration of IV vincristine has occurred despite dilution to 10 mL and 20 mL in syringes. The recommended diluent is sodium chloride 0.9%. After administration, the line should be flushed to ensure no medication remains in the tubing.

Proactively eliminating the risk of "never" events

Despite the widespread increase in patient safety activities in the past decade, the importance of proactively reducing the risk of some of the most tragic medication errors has been minimized too often because the events have occurred infrequently, or the corresponding error reduction strategies have not been quantified scientifically. Yet, from the perspective of both patient safety and credibility in the eyes of patients who place their trust in our hands, the urgency for eradicating these "rare" events has never been greater.

Disturbing accounts of continued fatalities from accidentally administering IV vincristine by the intrathecal route of administration is just one of many examples of dramatic, preventable injuries that may have been side-lined as a priority because of their infrequency, despite relatively easy strategies that could prevent their occurrence. (See the *Message in our Mailbox* in the column to the right for more information on this topic.) Inadvertent administration of an oral solution or suspension by the IV route of administration is another example. The use of an inexpensive oral syringe could significantly reduce or eliminate such risks.

The desire to get the most out of allotted patient safety resources has perhaps increased our tolerance of "rare" but harmful events, knowing that, thankfully, they don't happen very often. We also may be too tolerant of practices that, if examined carefully, most would consider unsafe, simply because there are no quantifiable outcome data to confirm their danger, and no evidence-based proof about the effectiveness of seemingly safer practices that have face validity.

Moreover, consumers are unlikely to understand our tolerance of "rare" but harmful events when, rightfully, they should be considered "never" events in healthcare. We would not understand if the risk of an airplane crash was considered low priority because it happens infrequently, especially if it was caused by untrained or intimidating pilots, or a refusal to avoid dangerous abbreviations or repeat verbal commands to ensure understanding.

"Rare" but harmful events should not be discounted simply because of low frequency. Such an attitude of complacency or denial of the risk is indefensible. Prevalence should be one of many considerations when prioritizing patient safety efforts, but certainly not the only determinant of whether proactive steps must be taken.

When relatively simple actions could prevent "rare" but harmful events, but we do not implement these actions because they are not on our priority list, consumers have every right to doubt our ability to accomplish anything safely. After all, if we cannot eradicate vincristine misadministration after 30 years of knowing about its causes and prevention, how can we expect patients and their families to trust us?

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