

## Tablet Splitting

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### Background

TABLET SPLITTING is a common practice often recommended by providers and implemented by healthcare systems. Splitting a tablet allows for a lower dose than that manufactured by the pharmaceutical industries, can facilitate administration of large tablets that patients may find difficult to swallow whole, and can give patients access to more expensive medications.

Tablet splitting has many benefits, and consideration of both drug and patient characteristics ensures safe and appropriate use.

Certain physicochemical properties of a drug influence the decision to split. For example, drugs with enteric coatings, extended-release formulations, and some combination products can cause adverse outcomes if split.<sup>1-3</sup>

In one study, elongated tablets scored deeply on both sides broke easily when manually split.<sup>4</sup> Tablet splitting devices were shown to perform best with larger tablets, tablets with flat edges, and oblong tablets without pointed ends.<sup>5</sup>

Drugs with narrow therapeutic windows should only be split if the physicochemical properties are adequate and if the optimal therapeutic response depends on the dose being halved. Also, patients with severe physical or visual impairments may hinder precision in pill splitting.

Tablets come in all shapes and sizes and require sharp instruments to divide them. Patients or their caregivers must have good vision, manual dexterity, and the mental capacity to accurately split a tablet. Accuracy of tablet splitting also depends on one's technique or device.

An optimal tablet-splitting device should have a hard, steel blade that goes all the way into the base when the lid is depressed. This will ensure a clean cut without leaving unusable fragments or crumbs that break off from the tablet. Additional benefits are provided when using a non-slip surface with adjustable grips to firmly hold the tablet steady and an optional magnifying attachment to enlarge the view of small tablets.

Any alteration of a medication may result in an adverse event or close call; hence, tablet splitting may cause problems in the medication use process. Using a good tablet-splitting device, unambiguous directions listed on the prescription, and identification/recognition of non-splittable medications comprise steps that can help to prevent problems from developing.

VA NCPS and the VA Center for Medication Safety Patient Safety Center of Inquiry (PSCI) embarked on an effort to evaluate potential medication problems caused by tablet splitting. Data on tablet-splitting events were evaluated using the NCPS Patient Safety Information System database (nicknamed "SPOT"). This article describes the results of that analysis.

### Analyzing SPOT Data

#### Methods:

NCPS identified tablet splitting entries by querying the SPOT database for all RCA and safety reports involving tablet splitting from January 2001 to April 2005, forwarding the results to our Patient Safety Center of Inquiry for analysis. Search terms included: pill splitting, tablet splitting, half tablet, quarter tablet, ½ tab, and ¼ tab.

Data provided for each event included an anonymized case ID; date (year); free text description of event details; and record type (aggregate, safety report, RCA).

A complete evaluation of reports was conducted. Analysis of each individual case determined:

- ◆ Type of event (actual adverse event, close call, not enough information, or "other")
- ◆ Location of occurrence (inpatient or outpatient)
- ◆ Error type (overdose, underdose, incorrect directions, incorrect quantity, incorrect day supply, and incorrect strength dispensed)
- ◆ Medication characteristics (correct physicochemical properties, to include: non-extended release, no enteric coating and symmetric in shape; commercially available strengths; and high alert medications<sup>6</sup>)
- ◆ Documented patient outcomes (no harm, minor harm, hospitalization, and/or permanent harm/death)

#### Results:

We found 442 reports in SPOT related to pill splitting. Below are selected, notable statistics from these events:

- ◆ 38% were adverse events
- ◆ 66% of the adverse events involved patients receiving more than their intended dose
- ◆ 65% of the adverse events occurred in outpatient settings
- ◆ 51% of the adverse events involved medications that came in commercially available strengths
- ◆ 28% of the medications were high alert
- ◆ 9% of the adverse events resulted in causing harm to a patient, but only 2% required hospitalization; no deaths were reported

### Discussion

Limited literature suggests that manually or mechanically splitting tablets does not always produce equal portions.<sup>7-15</sup> The current evaluation of tablet splitting events within the VA revealed no problems regarding accuracy in splitting tablets to produce equal halves.

However, a potential source for problems was found in a number of areas: ordering, verifying, filling, and administering medications that require splitting.

# New Directive: Preventing Retained Surgical Items in Surgical Procedures

By Noel Eldridge, MS, NCPS executive officer, and Ed Dunn, MD, MPH, NCPS director of policy and clinical affairs

DURING A SURGICAL procedure, surgical teams employ standard “tools of the trade,” usually described in three categories: instruments, sharps, and sponges.

Infrequently, one of these items can be accidentally left inside a patient after a surgical procedure is concluded. Referred to as “retained items” or “retained foreign bodies,” they can become the source of infection, pain, or other serious issues. In many cases, another surgical procedure is required to remove a retained item.

Information on the incidence of retained surgical items in the VA varies, but available data suggest that it has happened from approximately 10-to-70 times annually in recent years. Efforts to prevent this type of adverse event have varied, but there has been no standardized approach to solving this problem across VHA. The same is true for private sector health systems.

Our review of RCA reports submitted by VAMCs to NCPS, 2000 to present, indicates that 80 percent of the retained items were sponges, 8 percent were towels, and 12 percent were other items, such as retractors. The post-operative count of items could be determined for two-thirds of these events: 48 percent of the reports ended with a “correct” count, 28 percent ended with an “incorrect” count, and 24 percent with the retained item *excluded* from the count.

To standardize a basic set of preventative procedures, NCPS collaborated with the VA Office of Patient Care Services to draft a new directive, *Prevention of Retained Surgical Items*. This directive was pilot-tested at six VAMCs.

The directive is based primarily upon previous work of experienced clinicians, processes established at VAMCs, standards established by the Association of Perioperative Registered Nurses (AORN), and root cause analysis findings submitted by VAMCs to NCPS.

The basic requirements of the directive are as follows:

- ◆ In every case, a methodical wound exploration must be performed before closing the surgical wound.
- ◆ Specific methods, following AORN standards, should be implemented for counting instruments, sharps, and sponges.

- ◆ During normal working hours, radiologists must interpret radiographs taken in the OR to locate a missing item, and provide findings to the surgical team within 30 minutes of the request.
- ◆ During other times, such as off-duty hours or weekends, VA radiologists may be provided electronic access to radiographs by VAMCs. Another option that may be provided is interpretation of a radiograph from a remote location by a radiologist who is not connected to a particular VAMC. (Increased capabilities for interpretation of radiographs from consolidated centers during off-hours has been approved by the National Leadership Board, but implementation will take time.)



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*This image is a perfect example of how difficult it can be, even for an experienced radiologist, to identify a sponge in the abdomen or pelvis.*

- ◆ VAMC management, purchasing, and logistics personnel will make available whenever possible:
  - ◆ X-ray-detectable sponges, laparotomy pads, towels, or other related materials for all surgical procedures
  - ◆ Adequate radiology department staffing to support timely intraoperative radiographs with interpretations reported to surgical team in the OR as required

- ◆ Access to teleradiology for OR support when necessary

In the past, the primary responsibility for preventing retained items has resided with OR nurses. The directive does not remove the OR nurses primacy in maintaining an accurate record and counting of surgical items. However, it does make clear that surgeons, radiologists, and administrators share the ultimate responsibility with nursing to prevent retained surgical items.

For instance, the directive indicates that surgeons have a responsibility to perform a methodical wound exploration prior to closing the surgical wound and again whenever an incorrect count is reported by the circulating nurse. When there is an incorrect count, the surgeon must support the circulating nurse’s request for an intraoperative radiograph to be performed and interpreted in a timely fashion.

The surgeon must also perform an initial review of an intraoperative radiograph during times when interpretations of radiographs are not available from the radiology department.

The surgeon must also allow adequate time for OR nurses to count and accurately record counts of surgical items prior to a procedure, before closing a wound, and after wound closure.

It should also be noted that VAMC directors have an important responsibility to prevent retained surgical items. In particular, they must ensure adequate staffing in radiology departments and to provide the OR with surgical sponges, instruments, and towels that are detectable by a radiograph whenever possible.

The directive allows for rare exceptions, such as for an unstable patient or when a surgeon decides it is in the best interest of a patient to expedite a procedure by forgoing final counts.

In summation, only a standardized approach that is consistently applied throughout VHA, as defined in the directive, can improve the accuracy of the counting process and reduce the incidence of retained surgical items.

The directive became effective on April 3, 2006. It can be viewed online: [www1.va.gov/vhapublications/](http://www1.va.gov/vhapublications/)



# Adverse Events Related to Do Not Resuscitate (DNR) Orders

By: Carol Samples, BGS, NCPS program analyst

DNR ORDERS COME with strong ethical implications. We would never want to withhold resuscitation when a patient and family have chosen to have resuscitation attempted. We also don't want to put patients and their families through the unnecessary stress of a code when DNR decisions have been conscientiously reached and agreed upon.

After reviewing reports in NCPS' Patient Safety Information System, nicknamed "SPOT," it appears it is sometimes difficult for us to determine a patient's DNR status: codes are called unnecessarily when patients are DNR, or not called when there is no active DNR order.

To clarify the term "DNR," the VA National Ethics Conference Call on June 28, 2005, noted the following guidelines: *"A DNR order is a medical order written by a healthcare provider that applies immediately. When the DNR order is entered into CPRS, the record is marked to alert other healthcare staff that the patient does not want CPR. A DNR order is clear and unequivocal. It instructs healthcare personnel not to initiate CPR in situations where the patient has no pulse. Personnel [are] to withhold CPR, which includes various types of interventions, but only when they are used in the setting of cardiopulmonary arrest. It is important to remember that a DNR order does not mean 'do not treat' or do not do other things beyond the setting of cardiopulmonary arrest and CPR interventions. Appropriate medical treatment and care is never withheld or withdrawn from a patient simply because a DNR order has been entered."*

This article summarizes a search of SPOT using the free text term "DNR." The search uncovered 25 RCAs and 55 safety reports pertaining to this issue. In addition to the events mentioned above, reports indicated the following:

- ◆ Delays in decisions regarding care when DNR orders were incomplete, such as when no note accompanied an order; or, when a note was written but not accompanied by an order.
- ◆ Problems also included limited availability of unequivocal code status, and confusion over colored wristbands. (Facilities used an array of colored arm bands to denote DNR status. See references.)

- ◆ Application of the DNR order was questioned when patients fell, were found choking, or experienced changes, such as cardiac or respiratory distress following falls.
- ◆ DNR status was erroneously communicated or not communicated during transfer within or between facilities.
- ◆ Discrepancies existed between various forms of documentation: paper, electronic, wristbands, and stickers.
- ◆ DNR and fall risk lists were posted side by side, causing confusion.
- ◆ DNRs were not promptly removed from the medical record when patients were discharged.
- ◆ DNR forms developed in a palliative care unit were inappropriate for other areas.

In response to the events listed above, RCA teams reinforced the standards and practices outlined in VHA policy on DNR orders and suggested other actions:

- ◆ A DNR order, its progress note, and signing of said progress note must conform to policy and be written by the attending physician (or with the attending's concurrence by house staff/resident for up to 24 hours).
- ◆ A progress note *must* accompany the DNR order.
- ◆ Flag records with a visual prompt as to DNR status and/or make DNR first on the active order list when an electronic record is accessed.
- ◆ Develop clinical reminders for inpatient admitting physicians to verify or re-verify the advanced directive and treatment wishes of the patient.
- ◆ Add a "Do Not Resuscitate" and/or "Advanced Directive" status template to interdisciplinary team treatment notes.
- ◆ Include a copy of the most current DNR order when nursing home patients are transferred.
- ◆ Standardize the documentation process: have the same person who verifies the order place any patient identifiers and confirm that these are, in fact, the patient's or family's wishes, as appropriate.
- ◆ When possible, make the patient and family aware of the purpose of the wristband when it is placed and confirm their understanding of it.
- ◆ Review mock codes routinely to include medical/surgical residents and medical students.

- ◆ Implement guidelines for verification of patient identification prior to reviewing the medical record with the code team.

A DNR order does not mean that a patient is not offered or provided other medical treatment and/or comfort care. It does not mean "do not treat." A DNR order is only applicable when there is no pulse. For example, should a DNR patient fall or choke, appropriate medical care must be initiated if there is a pulse.

Patient status should be addressed and documented whenever there is a transfer from unit to unit, person to person, specialty to specialty, or department to department. If wristbands are used, they should have patient-specific information for quick verification. Any color used to identify DNR status *must* be consistent throughout the facility.

The DNR status must always be updated with each admission, discontinued with each discharge, and changed as appropriate with the patient's condition.

Advance directives drafted by patients do not replace DNR orders initiated by physicians, yet advance directives, where legal, can help determine a patient's wishes "in case the patient loses decision-making capacity."

Standardized practices involving DNR orders are critical because staff must know what action to take. Patients, families, and caregivers also must feel secure about the decisions they have so painstakingly reached.

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## Special Note:

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## Tablet Splitting (continued from page 1)

The following examples show recurring issues that occurred due to splitting tablets in half:

- ◆ Most frequently, patients forgot to split the medication; providers often caught this problem when a patient came in early for a refill.
- ◆ Patients did not read the label properly.
- ◆ Healthcare personnel chose the wrong medications or formulations for splitting (i.e., enteric-coated, sustained-release, capsules).
- ◆ Complicated entries with strengths and additional instructions from providers not placed in the proper fields, resulting in incorrect directions, day supply and quantities in the final prescription.
- ◆ Tablet-splitting devices were not ordered or staff did not determine if patient had a device at home.
- ◆ Errors in the administration process occurred as staff no longer split medications per local policy, and patients did not get their correct dose.

Limitations of the analysis include: subjective interpretation secondary to raw data documented in SPOT; the voluntary nature of safety reports, potential underestimation of the frequency of adverse events; and the variability of reporting, resulting in some reports that contain detailed information and others with minimal data.

### Taking Action to Prevent Harm to Patients

Although tablet splitting remains a common practice in many settings, common elements of the cases reviewed demonstrate the need for increased awareness for both patients and providers. When tablets are split, the following should be considered:

- ◆ Practitioners must know the types of tablets that should *not* be split, such as: enteric-coated, extended release, and asymmetrical agents.
- ◆ Practitioners must be aware of patients or caregivers who are unable to split tablets.
- ◆ Practitioners must assure that all patients that are prescribed a tablet to split have a proper tablet-splitting device to do so.
- ◆ Provider and pharmacist must counsel patients; patients must have clear, concise directions describing how to take their medications — especially for new prescriptions or those with changes.
- ◆ A standardized process for entering prescriptions and directions involving tablet splitting should be in place.
- ◆ If pill splitting is desired, the facility's pharmacy and therapeutics committee (or equivalent) must instruct the automated data processing application coordinator (ADPAC), or designee, to ensure that possible dosages are configured

appropriately to support tablet splitting within VistA Pharmacy Data Management (PDM) software.

### Summation

Local procedures, such as those noted above concerning VistA PDM and patient counseling, are critical aspects of this patient safety effort.

Only consistent monitoring of tablet-splitting can allow leadership to assess how well the practice is being carried out at their facility and allow them to promote systematic improvements when needed.<sup>16-20</sup>

VA plans to include guidance on tablet splitting in its Formulary Management Process Handbook, due for release later this year.

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