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Multiple-Dose vs. Single-Dose Drug Delivery Systems: Which is More Economical and Safer?

By Keith W. Trettin, R.Ph., M.B.A., NCPS program manager

When determining whether to stock a multiple-dose vial (MDV) or a single-dose vial (SDV) of a medication, two issues are commonly evaluated: which option can reduce costs; and which option can improve patient safety. Let's explore both issues.

Business Case: MDVs vs. SDVs

The use of injectable medications in multiple-dose containers is often justified as an economical choice in health care systems. Cost per dose and storage costs are generally less for an MDV than for an SDV. However, the overall cost of delivering injectable medication is much more difficult to evaluate, because it can include the cost of treating cross-contaminated patients or those who have contracted a nosocomial infection secondary to MDV use and wastage.

The Centers for Disease Control (CDC) in 1996 estimated the risk of nosocomial infection caused by extrinsic contamination of MDVs was small, estimating it to be 0.5 per 1,000 vials.¹

The VA anticipated using more than four million MDVs in calendar year 2008. This represents 2,000 potentially new VA nosocomial infections related to MDV use. The cost to treat these patients is substantial. Press Ganey² reports the average cost of treating a nosocomial infection is \$13,973. Use of MDVs potentially increases annual VA health care costs by approximately \$28 million!

Another cost-related factor is the waste of medication. In a VA study by Sheth et. al.,³ in 90 percent of MDVs evaluated, 25 percent or less of the original volume was used prior to the vial's expiration date. The cost per dose delivered, including the cost of drug waste, was 86 percent higher than buying the product in an SDV.

When evaluating the use of an MDV vs. an SDV, the additional cost of cross-contamination and waste must be taken into consideration. When these parameters are added to the evaluation, an SDV may be determined to be the most cost-effective alternative.

MDVs vs. SDVs: Which is Safer?

There are many common misconceptions about MDVs and SDVs. To begin, let's test your knowledge of MDV and SDV usage:

1. MDVs are different from SDVs because they are sterilized by putting an inert gas in each vial. True or False?
2. If you have been careful to use a sterile technique when removing doses from an MDV, each manufacturer's expiration date is the last date the vial can be used. True or False?
3. MDVs are safe to use, even if slightly contaminated, because they contain a preservative. True or False?
4. All MDVs should be refrigerated after opening. True or False?
5. All medication vials size 10mls or less are SDVs. True or False?
6. All drugs are available as MDVs and SDVs. True or False?

1. FALSE. The United States Pharmacopeia (USP) has defined what constitutes an MDV and an SDV and their "beyond-use" dates. Regulatory agencies such as state boards of pharmacy and the Joint Commission have adopted these definitions into their regulations and standards.

MDVs are defined by the USP as a multiple-unit container for articles or preparations intended for parenteral administration only, and usually contain antimicrobial preservatives. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives.

SDVs are defined by the USP as a single-unit container for articles or preparations intended for parenteral administration. These containers are intended for a single use and labeled as such.

Examples of single-dose containers include: pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers, when so labeled. The USP further notes: "Opened or needle-punctured single-dose containers such as ampoules, bags, bottles, syringes, and vials of sterile products ... shall be used within 1 hour if opened in worse than ISO Class 5 (pharmacy IV room) air quality and any remaining contents must be discarded. Opened single-dose ampoules shall not be stored for any time period."⁴

2. FALSE. Unless otherwise specified by the manufacturer, the USP defines a beyond-use date as 28 days after initially entering or opening a multiple-dose container (e.g., needle-punctured). All MDVs

Delay in Outpatient Diagnosis and Care

By Paula Allstetter, NCPS program analyst

Background

A query of the NCPS Patient Safety Information System, commonly known as "SPOT," was completed in September 2008. The query searched for reports categorized with an event listing of "delay in treatment, diagnosis, surgery."

Of the 1,124 Root Cause Analyses (RCAs) associated with this category, 18 percent were linked to outpatient care. A variety of actions were implemented by RCA teams to reduce or eliminate future occurrences. The analysis was conducted on all outpatient events.

VA employees can click on a link offered at the end of this article for more detailed information.¹

In outpatient care, vulnerabilities could be identified in almost every step in the process of an outpatient appointment:

- Patient demographic information.
- Patient appointments.
- Scheduling tests or consults.
- Provider receiving and acting on results.
- Patient informed of results.
- Coordination of care.
- Misidentification.

Root causes and/or contributing factors resulting in outpatient delays shared common themes. These included:

- Lack of understanding of standard procedures, processes, protocols, policies.
- Absence of a clear delineation of responsibility (ownership) for follow-up.
- Inconsistent application (or absence) of a written protocol.
- Absence of a consistent procedure for hand-off and coordination of care.
- Problems with communication and documentation.
- Viewer alert process was seen as an obstacle to appropriate actions by staff and follow-up care for patients.
- Volume of patient workload and consults requested and size of staff.

Sample of the Data

Analysis of the data indicated problems and solutions that RCA teams noted in each of these categories; a sample of which is provided below.²

Please keep in mind that the root causes and contributing factors may apply to more than one step in an outpatient appointment process. The process steps may also vary between outpatient clinics.

VA employees can click on a link offered at the end of this article for a more thorough review of the action categories.³

Action Categories

The examples below show actions taken by the RCA teams. Actions can be thought of as stronger or weaker based upon the likelihood of reducing the vulnerability in question.

- Stronger actions are more likely to eliminate or greatly reduce the chance of an adverse event. This type of action applies human factors principles, and uses physical plant or architectural modifications and engineering controls or interlocks.
- Intermediate actions are likely to control the vulnerability and also employ human factors principles; however, they may rely upon individual actions only, such as a checklist or cognitive aid.
- Weaker actions are less likely to be effective at reducing the vulnerability because they are dependent upon the use of policies or procedures or an individual's choice of the most appropriate action.

Demographic Information Incorrect

Problem: Staff unable to reach some patients by telephone due to a lack of a systematic approach to gathering patient contact information, which led to delays in communicating test results to patients.

Solution (intermediate/staffing): Assign one staff member to support a clinic's administrative follow-up measures.

Patient Appointment

Problem: Using paper and electronic means in an other than systematic manner to document patient information decreased the probability that required information would be available to all departments. Communication drawbacks and limited documentation decreased the likelihood of a patient receiving timely notification of an appointment or subsequent care.

Solution (stronger/simplification of process): Enter all information into electronic progress notes *only*, so that the notes and orders are available for all to read.

Scheduling and Consult

Problem: Lack of understanding medical terminology decreased the likelihood of clerical staff scheduling an exam in the appropriate clinic, delaying patients from receiving care in a timely manner.

Solution (intermediate/enhanced information display): Generate a laminated list that provides names of exams performed by radiology, as well as synonyms for exams, and distribute it to all service lines to support clerical staff.

Provider Receiving and Acting on Results

Problem: Lack of appropriate assessment of patient test results and follow-up by staff resulted in delay of diagnoses and treatment.

Solution (stronger/standardize process): The ordering provider or designee will assume responsibility for appropriate follow-up of patient test results.

Patient Informed of Results

Problem: Lack of understanding by patients given verbal instructions and/or explanations about timelines for test results increased a *perception of delay* in follow-up. Patients with normal results still expect to hear something about their test results.

Solution (stronger/standardize process): Develop a form letter that will be sent to patients with normal biopsy results that includes phone contacts for them to call if they have further questions, even though they have normal results.

Coordination of Care

Problem: Lack of consistent documentation regarding canceling and rescheduling of patient appointments decreased the ability of staff to track trends in clinic cancellations. Without consistent documentation, it was difficult to measure clinic availability for patients who needed care at a specific time. This caused an ineffective use of clinics.

Solution (stronger/standardize process): Implement electronic alerts for cancelled appointments, as well as electronic requests for clinic cancellations to be routed through service chiefs for validation.

Misidentification

Problem: The wrong patient being scheduled for a test or procedure can result in a delay of care to the patient who requires the test or procedure. Sharing equipment, such as printers, among too many areas increased the likelihood of errors in paperwork or specimen labeling.

Solution (stronger/simplification of process): Schedulers will be required to have an electronic request in hand before scheduling any procedure. Removing all default options and allowing printing *only* to a specific printer can eliminate confusion over who printed which document.

Further Information

In a June 2008 article from *The Joint Commission Perspectives on Patient Safety*, “Creating a Backup System to Ensure Timely Reporting of Critical Test Results and Values,” the authors suggest several strategies to prevent delays, such as creating an effective tracking system to eliminate delays in reporting of critical labs.

For further information, click on: <http://www.jointcommission.org/library/newsletters/>

We are conducting an analysis of SPOT data regarding delays in inpatient care and delays due to events in the emergency department. We will provide VA employees more information when these analyses are complete.

References

1. The outpatient analysis is available to VA employees on the NCPS web site (Topic Summaries).

2. Research was also conducted to identify common elements of delays at two VA medical centers in Michigan: The John D. Dingell VA Medical Center, Detroit, and the Ann Arbor VA Health Care System. Both facilities graciously allowed on-site observation of their clinic process.
3. VA employees can review a more detailed presentation of RCA action categories.

Banning Tobacco Use in Acute Inpatient Psychiatric Units

By *Amanda M. Fore, R.N., M.S., NCPS nurse coordinator*

Smoking bans on locked, acute inpatient psychiatric units are feasible in the Veterans Health Administration (VHA) – and can offer many health and safety benefits to patients and staff.

Background

Missing patient events, or elopements, can occur in locked inpatient psychiatric units.

Many facilities in the VHA grant patients the ability to vacate locked units to smoke. Patients that stray beyond the normal view or control of employees may be at risk for injury and death.¹ Likewise, patients who leave a locked unit to smoke risk patient harm.

Based upon 91 individual Root Cause Analyses (RCAs), 16.5 percent of the missing patient events were reported by locked behavioral health (psych) units.² Root causes/contributing factors included:

- Ineffective use of an elopement risk assessment or lack of staff education on how to use the assessment.
- The level of observation that was ordered not being sufficient.
- Non-existent policies for high-risk patients.
- Unclear or inconsistent patient privileging or transport policies.
- Facility smoking policies that allow patients to walk to the smoking area unsupervised.²

Stronger actions included making changes to the physical plant or space layout and constricting smoking areas for inpatient psychiatric use.² However, according to VHA Directive 2008-052,³ all remaining indoor smoking areas were to be phased out by Feb. 1, 2009. Implementing a tobacco-free policy, or smoking ban, on locked psychiatric units can be done to prevent patient harm.

Patients on locked inpatient psychiatric units may not only reap the health benefits offered by a tobacco-free unit, but also the safety benefits.

A review of the literature suggests that total or partial smoking bans in inpatient psychiatric settings had no major long-standing or untoward effects in terms of behavioral indicators, unrest, or compliance.⁴

Similar studies have consistently found comparable evidence.

Taylor et. al.⁵ suggest that tobacco-free inpatient psychiatric units can be implemented without unit disruptions. In 2005, Mathews and colleagues⁶ also found that implementation of a smoking ban on an acute psychiatric unit did not result in any increase in aggressive behavior. It was also suggested that staff attitudes improved following the ban, and most believed the ban was ethical and beneficial to patients.⁶

Likewise, Haller⁷ suggests a total smoking ban may be less disruptive to the milieu of a locked unit than graduated restrictions, such as asking staff to take patients off the ward to smoke. Note, however, policies alone have had little or no effect on tobacco cessation. Tobacco cessation strategies should be an inherent component of smoking bans.⁴

Several inpatient psychiatric units in the VHA have implemented tobacco-free policies and, akin to the literature, say it was uncomplicated.

Successful Implementation

Nancy Sampson, R.N., M.S., associate chief nurse, ACNS, mental health, VA North Texas Health Care System (HCS), found the transition to a tobacco-free locked inpatient psychiatric unit was not as challenging as some may think. “The staff has told me that it is better now,” she said.

Sharon Muncrief, R.N., M.S., staff nurse, North Texas HCS, could not agree more. Muncrief said, “Staff were quite happy with the change.” Muncrief also agreed there has been no increase in aggressive behavior since implementation of the tobacco-free unit.

Implementation of a completely tobacco-free locked inpatient psychiatric unit means, with the exception of medical testing, no patients are given privileges to leave the unit.

“We have not had an elopement since we did this,” Sampson said, noting that there had been elopements when patients had been taken out to smoke. Muncrief added there has also been a decrease in patients found with lighters and other smoking-related contraband.

As part of the implementation, patients are educated, and tobacco cessation classes and nicotine replacement therapy is provided. “A couple of people grumbled, but the change has been better for both patients and staff,” Sampson stated.

The VA Ann Arbor Healthcare System also implemented a tobacco-free policy on the locked, acute care inpatient psychiatric unit.

Richard White R.N., M.S.N., acting nurse manager explains, “It was something that needed to be done for a long time. Staff were very much in favor of the change. It was very labor intensive for staff to constantly let patients off the unit.”

“Consistent with the literature, we have not had an increase in aggressive or disruptive behavior,” White continued. “We have not had any adverse events since going smoke-free.”

Like North Texas HCS, Ann Arbor implemented behavioral and pharmaceutical therapy for tobacco cessation prior to the smoking ban.

As White concluded: “It is the right thing to do for the patients.”

Additional information

VA Public Health Strategic Health Care Group: Smoking Cessation: <http://www.publichealth.va.gov/smoking/>

Americans for Nonsmokers’ Rights: <http://www.no-smoke.org/goingsmokefree.php?id=449>

References

Available in the online edition of TIPS: <http://www.patientsafety.gov/TIPS/tips.html>

Multiple-Dose vs. Single-Dose Drug Delivery Systems

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should be labeled with their expiration date.

3. FALSE. The antimicrobial agents used in an MDV require time to sterilize a vial that has been extrinsically contaminated. For this reason, cross-contamination can still occur with MDVs.

The highest risk is within the first 16 hours after contamination. A contributing risk factor is that vial contamination has low detectability, meaning it is difficult for users to identify when a vial is contaminated. This can lead to multiple patients being infected before the problem is identified. Several studies place the contamination rate of MDVs at 1 to 2.8 percent.³

The CDC estimates the risk of nosocomial infections caused by extrinsic contamination to be 0.5 per 1,000 vials. Because of this, the CDC recommends using SDVs whenever possible.

When MDVs are involved in cross-patient contamination, the vial is not necessarily the direct reason for iatrogenic infections. In most cases where cross-patient contamination is documented, poor aseptic technique is involved.

For example, the CDC reports that 1 to 3 percent of U.S. health care workers who provide medication through injection reused the same needle and/or syringe on multiple patients. This is an unsafe practice and should never occur.

4. FALSE. Once used, it is a common practice to store MDVs in a refrigerator. The assumption is that cool temperatures minimize the growth of bacteria. In a study done by Lehmann,⁵ it appeared that refrigeration actually slowed the bactericidal activity of the preservative; thus, refrigeration may be counterproductive.

The best advice is to follow each manufacturer's recommendation for storage after opening an MDV.

5. FALSE. The size of the vial does not determine if a product is an MDV or an SDV. For example, lidocaine hcl injections are available in 2ml, 5ml, and 30ml SDVs, as well as in MDVs in 10ml or 50ml sizes.

Some products, such as gentamycin injection, are available either as MDVs or SDVs in the same 2ml vial size.

Determining whether or not the vial is an MDV or an SDV, based on its size, is a significant human factors safety vulnerability. A label is the best determinant for vials containing an antimicrobial agent.

Unfortunately, the medication container labels can be printed in very small font size,

making them difficult to read.

For these reasons, the safest practice is not to rely on an end user identifying a vial as an MDV or an SDV.

6. FALSE. Not all products are available in both MDVs and SDVs. In a recent review of injectable medications, which represented 50 percent of all injectable drug costs in the VA, only one product (Procrit) was available in an MDV.

Recommended Actions

What can you do today to enhance the safe delivery of injectable medications?

- To minimize the risk of cross-contamination between patients, SDV containers in unit-of-use forms should be used whenever possible. This is consistent with the CDC's recommendations.
- If one is required to use an MDV, the smallest possible size should be stocked that will allow a single dose to be withdrawn (for example, if the drug is only available as an MDV).
- A vial of medication should never be used on more than one patient regardless of whether it is an MDV or an SDV. A simple human factors approach to this issue is to always discard vials that do not have the plastic safety cap installed by the manufacturer on the top of the vial. Exceptions to this recommendation may include: patient-specific allergy extracts, insulin, and vaccines. If exceptions are made, these should be based on explicit decisions by a pharmacy and therapeutics committee, and it should be communicated to all appropriate staff.
- Always use sterile technique when preparing injectable medications and inspect each container prior to use for contamination and discoloration.
- Do not administer medications from a common syringe to multiple patients, even if the needle has been replaced. A new syringe/needle should be used on each patient. Reuse of syringes is clearly in violation of CDC guidelines.

All syringes prepared from MDVs or SDVs, and not used immediately, are required to be fully labeled. The Joint Commission has specified labeling requirements, on and off the sterile field, in the Elements of Performance for National Patient Safety Goal 03.04.01.⁶ The nine elements read:

- Medications and solutions both on and off the sterile field are labeled even if

there is only one medication being used.

- Labeling occurs when any medication or solution is transferred from the original packaging to another container.
- Medication or solution labels include the medication name, strength, amount (if not apparent from the container), expiration date when not used within 24 hours, and time when expiration occurs if less than 24 hours.
- All medication or solution labels are verified both verbally and visually by two qualified individuals whenever the person preparing the medication or solution is not the person who will be administering it.
- No more than one medication or solution is labeled at one time.
- Any medications or solutions found unlabeled are immediately discarded.
- All original containers from medications or solutions remain available for reference in the perioperative or procedural area until the conclusion of the procedure.
- All labeled containers on the sterile field are discarded at the conclusion of the procedure.
- At shift change or break relief, all medications and solutions both on and off the sterile field and their labels are reviewed by entering and exiting personnel.

Conclusion

We should dedicate ourselves to enhancing patient safety through the appropriate selection of medication delivery containers and the appropriate labeling of each.

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