The Safe Use of Multi-Dose and Single-Dose Vials

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Myth: Because single-dose vials (SDVs) may be unavailable, the use of multi-dose vials (MDVs) for interventional pain procedures is a rational and efficient way to save time, money, and resources.

Fact: Regulations established by the Centers for Disease Control and Prevention (CDC) preclude the routine re-use of multi-dose vials for multiple patients in interventional pain procedures.

Definition

Physicians have traditionally been accustomed to tailoring the dose of a given medication to suit the specific needs of a patient. Whether or not the FDA considered a vial to contain single or multiple doses, in the past, a prescribing physician may have chosen to use any apportionment (½, ¼, etc.), thereby leaving behind a portion of the dose(s) unused. As an example, an interventionist may need 0.5 ml of contrast from a labeled SDV for an epidural injection, but may only have access to a manufacturer who supplies it in 50 ml SDVs. Although superficially logical, the reuse and conservation of agents labeled SDV is strictly prohibited due to safety concerns.

Multi-dose vials (MDVs) contain amounts of drug the physician may need for multiple doses. For a typical spine intervention, an MDV of local anesthetic contains enough “doses” to treat dozens of patients. However, CDC regulations state that all MDVs be reserved for a single patient “whenever possible”. The CDC does not support using MDVs on multiple patients simply because of financial concerns [1,2].

Recently, the FDA amended labeling to more closely mirror long-standing CDC recommendations by terming some “multi-dose” vials as “single patient dose” vials containing two or more doses. This designation has been applied primarily to certain oncology drugs. With this new labeling scheme, both the FDA and the CDC establish clear guidelines for limiting what was previously termed “multi-dose” vials to a one-time, single-patient use [3]. To date, that labeling has not been applied to local anesthetic vials, which continue to be labeled as MDV.

Rationale

Following a series of outbreaks of infections associated with parenteral injections and the reuse of SDVs, in 2007 the CDC included injection safety criteria as part of Standard Precautions [4]. Since that time there have been an additional 20 outbreaks attributed to either poor aseptic technique or unintended contamination of MDVs and SDVs, including outbreaks spread by tainted local anesthetic and contrast agents. Bacterial, viral, and fungal infections have resulted in death and disability [5-13]. The largest outbreak of healthcare-associated infections reported to date in the United States occurred as the result of contaminated MDVs of methylprednisolone acetate from a single compounding pharmacy [14]. Because of this, the CDC enacted new rules that supersede and obviate the FDA designation of MDVs. The CDC safe injection rules posed implementation problems for many pain practitioners [15].

Rare Exceptions

There are limited scenarios where MDVs and even SDVs may be used for multiple patients. The CDC allows for the partitioning of SDVs only under the following strict conditions: the USP 797 regulations require a laminar airflow in “First-Air” exiting a HEPA filter with an ISO Class 5 environment, including sterile gloves and mask and alcohol septum prep. Aliquots thus prepared are to be used within 6 hours [16].

Reuse of MDVs is slightly less onerous but still burdensome. If strict aseptic technique is employed, an MDV may be reused if it “remains in a clean environment that does not have any contact with patients,” such as in a dedicated medication preparation room. This precludes drawing up medication from MDVs in the OR, procedure room, or patient bedside. If an MDV is handled properly, after the first use a “beyond-use date” should be
written on the label (read the package insert for detailed instructions as duration of safe-use may vary) [4]. From a practical point of view, someone would have to draw-up medication for an injection in a room remote from the procedure room using sterile technique, transport it hygienically to the procedure room, and pass it off to the physician. This scenario introduces logistical concerns rendering the practice impractical in most circumstances.

National Drug Shortages

Concerns have been raised about whether the CDC guidelines and related policies contribute to drug shortages and increased medical costs to healthcare providers. The CDC recognizes the problem of drug shortages; however, it maintains such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines. CDC’s priority is protecting patients from harm [6]. In times of critical need, contents from unopened single–dose/single–use vials can be repackaged for multiple patients. However, this should only be performed by qualified healthcare personnel in accordance with standards in USP General Chapter 797 Pharmaceutical Compounding — Sterile Preparations. Following the USP standards is imperative, as medication contamination and patient harm can occur when repackaging (e.g. splitting doses) is not done properly [6].

Recommendations

1. Store all medications in a clean environment. Check the medication labels and inspect the contents.
2. Use standard aseptic procedures including hand washing, sterile gloves, and mask.
3. Clean vial septum with a new lint-free swab containing 70% alcohol or polyvinylpyrrolidone (PVP) and allow time to dry completely.
4. Puncture the septum only once with a new sterile needle attached to a new sterile syringe. Use one time on a single patient.
5. Promptly dispose of vial, needle, syringe, and any other materials used.
6. If, during the course of a single patient procedure, an additional dose is required from the same SDV or MDV, use a new sterile needle with a new sterile syringe through the septum that has been re-disinfected with a new alcohol pad.
7. Any SDV opened in less than ISO Class 5 conditions (such as in the OR, procedure room, etc.) must be used on a single patient within one hour.
8. Any MDV opened within a patient care area must be used on a single patient within six hours.
9. Make your institution aware of the One & Only Campaign from the CDC that emphasizes ONE needle, ONE syringe, ONLY one time [17].
10. Any potential savings from stretching the contents of an SDV or MDV by healthcare providers can be quickly offset by the costs associated with viral hepatitis, bloodstream infections, meningitis, discitis, epidural abscesses, and other infectious complications [6].

Conclusion

Medical societies do not make federal policies; they encourage adherence to them. Unless there are compelling or mitigating reasons, treat SDVs and MDVs as the same, and use them one time, on one patient, only once.

References


