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Single-Use Vials: Safety, Cost, and Availability

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Reusing Healthcare

The problem of reuse of single-use medical items and devices is not new. Almost as soon as healthcare began adopting single-use and disposable items in the 1970s for purposes of infection control, the reuse of such items began as a cost-saving measure. Despite infection control guidance to the contrary, in 2008, 20%-30% of US hospitals reported that they reused at least 1 type of single-use device.[1]

Evidence suggests that reuse practices extend to sterile vials of injectable drugs intended for one-time use. For example, some nurses and other healthcare providers admit to practices such as re-entering single-dose/single-use sterile vials after the initial access, either for the same or different patients, or inappropriately diluting contents of single-dose vials. A 2012 online survey[2] of 5446 healthcare practitioners found that 6% of respondents sometimes or always used single-dose/single-use vials for multiple patients, 15% used the same syringe to re-enter multidose vials, and 9% sometimes or always used a common bag or bottle of intravenous solution as a source of flushes and drug diluents for multiple patients. Comments made by respondents suggest that healthcare practitioners have many misconceptions about injection safety with single-use vials.

Why would educated healthcare professionals, committed to patient safety, do such a thing? The reasons are many. Efficiency, time constraints, conservation of resources, avoidance of waste, and cost considerations have all been cited to rationalize the misuse of single-dose vials. Of significance, however, most healthcare professionals who regularly use single-use vials inappropriately don't fully realize how dangerous it is to do so. If aseptic technique is maintained, they reason, what's the problem?

The Single-Use/Single-Dose Vial

According to the Institution for Safe Medication Practices (ISMP), "single-dose or single-use vials should be used clinically only for one dose for one patient, and then discarded after initial entry into the vial."[3]

Vials intended for single use are labeled "single use/single dose" for a very good reason. These vials contain no preservative or antimicrobial to prevent bacterial contamination. Because such contamination is not visible to the human eye, it must be assumed that once the stopper is penetrated or the ampule is broken, contamination may have occurred despite our best intentions, posing a risk for serious infection to the patient who next receives contents withdrawn from the vial.

The Risk Is Real

If a healthcare provider breaks infection control technique when preparing and giving a sterile injection (forgets to wash hands, fails to prepare the skin, accidentally touches the needle, etc.) the risk of introducing infection to that patient rises. This risk has always been present and probably happens more than we realize. Still, we hope that when this happens, only that patient will suffer the consequences of our lapse in proper technique. When a healthcare provider inadvertently contaminates a single-use vial and reuses that vial for more than 1 patient, it is not only a single infection that can follow, but an outbreak.

Two outbreaks of serious invasive staphylococcal infection were recently determined to be caused by the use of single-dose vials for more than 1 patient.[4] The first outbreak occurred in patients being treated at an outpatient pain clinic. It was a routine practice in this clinic to prepare a day's worth of injectable contrast doses used for radiologic imaging to guide needle placement for epidural steroid injections or nerve-block procedures. In a procedure room, contrast medium from single-dose vials was diluted with saline and then withdrawn and administered as needed, throughout the day, for different patients. Following their pain-remediation procedures, several of these patients developed severe infections (acute mediastinitis, bacterial meningitis, epidural abscess, and sepsis) with methicillin-resistant *Staphylococcus aureus* (MRSA) and required hospitalization.

What did these healthcare professionals do, or not do, that transmitted MRSA to these patients? Although the primary lapse in injection safety technique was determined to be the use of a single-dose vial for multiple patients, the investigation also found that staff were not wearing facemasks during spinal injection procedures.

The second outbreak occurred in a hospital-affiliated orthopedic clinic. Staff members withdrew doses of the anesthetic bupivacaine for use in joint injection procedures for multiple patients from 30-mL single-dose vials until the vial contents were depleted. Within days of their procedures, 7 patients required hospitalization, antibiotics, and debridement for

infections with an identical strain of methicillin-susceptible *S aureus*. Investigation by the state health department identified only the use of the single-dose vial for multiple patients as the root cause of this outbreak.

Probing the Why

Investigations into these 2 outbreaks aimed to determine why staff members used single-dose vials for multiple patients in violation of vial labeling. In the first outbreak, the rationale was the lack of an appropriately sized single-dose vial of contrast agent for patient need. A single 10-mL vial contained more than enough volume for 1 patient and, in fact, was sufficient for 6 or more patients. Withdrawing only a fraction of the vial contents for a single patient and discarding the remainder seemed unnecessarily wasteful. However, in this case, a smaller-volume single-dose vial was not available.

The national drug shortage was a factor in the unsafe injection practices of the outbreak involving bupivacaine. To conserve resources, staff used each 30-mL vial of anesthetic, as needed, for multiple patients, until the vial contents were depleted. If the 30-mL vial was not used in a single day, the vial was not discarded but saved for use the following day.

Centers for Disease Control and Prevention (CDC) Medical Officer Melissa Schaefer, MD, reflects on the reasons that staff in these 2 healthcare settings employed the unsafe injection practice of reusing single-dose vials for more than 1 patient. "One issue appeared to be access to an appropriate-size vial for clinical use, either because of the national drug shortage or because the manufacturer does not make that vial size. However, providers need to be reminded that difficulty in getting the vial size you feel is most appropriate is not an excuse to deviate from safe care."

One and Only One

CDC's position on the use of single-dose vials is simple, straightforward, and unequivocal: *Single-dose vials should be dedicated to an individual patient as part of an individual procedure.* Any contents not used for that patient should be discarded. Contents from single-dose vials should neither be used for additional patients nor stored for future use in the same patient. There is a very good reason for this: Single-dose vials contain no preservative agent to prevent bacterial growth that might be introduced upon vial entry. Once entered, the contents of these vials can support the growth of micro-organisms, with subsequent transmission to the same or multiple patients.

This policy is not new. Originally detailed in CDC's 2007 safe injection practice guidelines,[5] the policy was recently reiterated in a May 2012 position statement, "Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials."[6] An initiative known as the "One & Only Campaign" reminds providers to use "one needle, one syringe, only one time" when using single-use vials in patient care.

It is possible that, in a fast-paced healthcare environment, some healthcare providers are unaware of or forget the differences between single-dose and multidose vials, particularly if labels are not read carefully. The primary difference is the presence of an antimicrobial substance to minimize risk for bacterial contamination. Even multidose vials that contain preservatives, however, have been implicated in infectious outbreaks with transmission of both bacterial and viral infections. Dr. Schaefer emphasizes that "Providers shouldn't rely on a preservative as a safety net for lapses in aseptic technique."

The fact that some single-dose vials seem to contain more volume than may be required for a single patient use could be contributing to confusion about appropriate vial use. The volume of solution in the vial does not determine whether the vial is single-dose or multidose. CDC clarifies that even if a single-dose or single-use vial appears to contain multiple doses or contains more medication than is needed for a single patient, that vial should not be used for more than 1 patient or stored for future use in the same patient.

To prevent unnecessary waste or the temptation to use contents from single-dose or single-use vials for more than 1 patient, clinicians and purchasing personnel should select the smallest vial size necessary for an individual patient when making treatment and purchasing decisions. If desired vial sizes are not currently available, Dr. Schaefer encourages healthcare providers and pharmacies to communicate their needs directly to manufacturers and indicate that there is a market for smaller vials and prefilled syringes. When medication from single-dose or single-use vials must be divided, there are options to minimize patient risk.

Using a High-Quality Pharmacy

CDC recognizes that the issues that prompt healthcare providers to deviate from safe practice are real and unlikely to be resolved overnight. Although it is optimal for a medication vial to be used for only 1 patient, shortages of critical medications may justify the splitting and repackaging of vial contents *under strictly controlled conditions.* CDC's position on single-use vials extends the option of having the contents of a single-dose vial subdivided and repackaged into multiple single-use syringes or vials by high-quality pharmacies or pharmacy outsourcers that adhere to US Pharmacopeia (USP) 797 standards[7] for sterile preparation and storage of a medication outside of its original container. Clinical areas, including treatment, procedure, medication, or operating rooms (and patient bedsides) are inadequate for this purpose, no matter how carefully the provider attempts to adhere to sterile technique. For healthcare settings that lack on-site pharmacy facilities, a local high-quality compounding pharmacy can fulfill this function.

On June 15, 2012, the Centers for Medicare & Medicaid Services (CMS) sent a memorandum[8] to the directors of state survey agencies (the agencies that certify healthcare facilities and assess whether these facilities comply with CMS conditions of participation, conditions for coverage, and requirements) on "Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections." This memorandum made the key points that:

1. It is not acceptable, under CMS infection control regulations, to administer drugs from 1 single-dose vial to multiple patients without adhering to USP 797 standards[7] (Pharmaceutical Compounding -- Sterile Preparations)
2. Under certain conditions, it is permissible to repackage single-dose or single-use vials into smaller doses, each intended for a single patient. Subdividing and repackaging must follow USP 797 standards -- highly controlled environmental conditions, training and qualifications of personnel, and procedures for repackaging and labeling doses.
3. Healthcare facilities that reuse single-dose vials for multiple patients without adhering to USP 797 standards must be cited for deficiencies of practice.

Repackaging vs Reuse

To help healthcare providers distinguish between "repackaging" and "reuse" (the inappropriate subdivision of the contents of a single-dose vial for multiple patients that is not performed in accordance with USP 797 standards), CMS provides the following examples of *inappropriate* reuse of single-dose vials:

- Using a single-dose vial more than once, reaccessing it to provide injections for another patient;
- Preparing individual doses for multiple patients from 1 single-use vial on a patient or resident care unit; and
- Preparing a syringe of medication from a single-dose vial and using it more than 1 hour after preparation.

Neither patient care units nor operating rooms can fulfill the strict environmental conditions necessary for repackaging doses.

Facilities without on-site pharmacies may need to outsource this task. The American Society of Health-System Pharmacists (ASHP) Foundation offers a tool for assessing contractors who provide sterile products.

Stakeholders Speak

Reactions from the healthcare community to CDC's policy on single-use vials and CMS' reiteration of its oversight policy have been mixed. Although many professional organizations have verbalized support for these policies, certain groups believe that strict adherence to single-use vial recommendations has aggravated existing drug shortages and raised healthcare costs by requiring healthcare providers to unnecessarily waste drugs.

In its fact sheet "The Negative Effects of Single Dose Vial Implementation,"[9] the American Society of Interventional Pain Physicians (ASIPP) maintains that policies limiting the reuse of single-dose vials for purposes of infection control may lead to critical shortages of drugs and impede access to patient care, saying that, "the guidelines covering safe injection practices with single-dose vials and the requirement to use only one vial per patient may be overreaching, expensive, and burdensome to the practice of medicine and may ultimately result in reduced access." Furthermore, ASIPP states that "there is no evidence to date that single-dose vials, when used in multiple patients, are responsible for infections if proper infection control measures are applied."

Laxmaiah Manchikanti, MD, Chairman of the Board and Chief Executive Officer of ASIPP and the Society for Interventional Pain Management Surgery Centers, questions the findings and conclusions of the outbreak investigations reported in a recent *Morbidity and Mortality Weekly Report*[4] and suggests that breaches in sterile technique (in preparation of the anesthetic doses by office staff or failure to wear facemasks during spinal injection procedures) were likely responsible for transmitting infection to affected patients rather than factors inherent to the use of single-dose vials.

In response to the suggestion that clinics use compounding pharmacies to repackage the contents of single-dose vials, Dr. Manchikanti says that this practice is "expensive, tedious, and unnecessary, and that more cases of infections and increased risk are associated with compounding than with dividing the single doses into multiple doses in an office or surgery center. Repackaging will double or triple the price we would be paying when we use a single-dose vial on multiple patients."

Ray Baker, MD, President of the International Spine Intervention Society (ISIS), believes that the underlying problem is the lack of readily available, reasonably priced, single-dose vials, especially for injectable contrast media. The problem is exacerbated by the fact that smaller vials are relatively more expensive, often representing more than a doubling of the per-milliliter cost. "The lack of reasonable alternatives," writes Dr. Baker, "coupled with the recent decreases in reimbursement across the board for interventional pain procedures, has led many practitioners, believing that they are following a safe practice and one that helps curb rocketing healthcare costs and drug shortages, to reuse a 50-mL single-dose vial of contrast on multiple patients."

ISIS agrees with CDC policy on the reuse of single-dose vials because it is the correct policy to maintain the highest level of safety for patients. "As a professional medical society, ISIS wants to advocate for the highest standards of practice that lead

to the safest possible injection outcomes. At the same time, changes to community practice can only occur when appropriately sized and reasonably priced single-dose vials of commonly used medications become widely available," explains Dr. Baker.

ISIS has been working with CDC, other professional organizations, and manufacturers to provide healthcare professionals with safe and cost-effective single-dose contrast media alternatives. The organization also encourages its members to review and improve their injection safety practices as outlined by CDC, but Dr. Baker acknowledges that "rapid implementation may not be feasible for some providers. It is our concern that, unless the issues of availability and appropriately priced single-dose vials are addressed, drug shortages could occur, along with a reduction in the number of providers who would be able to continue to perform these procedures. This could create access-to-care issues for these patients who, by the very nature of their problems, are suffering greatly already." On its Website, in a message from Dr. Baker, ISIS explains its current position on the use of single-dose vials in interventional pain management.

The American Society of Anesthesiologists (ASA), in a statement on its Website, says, "ASA supports CDC's position and adopted CDC's Safe Injection Practices."

Expressions of support have also come from the professional pharmacist community. ASHP supports CDC's position on use of single-dose vials and endorses USP 797 requirements for preparation of sterile compounds. "In spite of increased cost, the risk of reusing single-dose vials is unacceptably high to justify this practice," says Bona E. Benjamin, BS Pharm, Director, Medication-Use Quality Improvement and Coordinator of the Drug Shortages Resource Center for the ASHP. Benjamin acknowledges that "healthcare providers face an extremely challenging dilemma when they must discard single-dose vials of expensive or hard-to-obtain injectable medications, especially when there is a possibility of negative outcome for their patients."

ASHP believes that this strong disincentive to compliance should not be underestimated. The healthcare community should be made aware that there are several options to counter it. One is a provision in the new US Food and Drug Administration (FDA) Safety and Innovation Act that allows health systems to centralize much of their sterile product compounding for their member hospitals in a single USP-compliant, system-owned facility. Another option is to request manufacturers to add more unit-of-use, single-dose injectables to their product lines or contract for unit-of-use products with an outsourcer. When using larger-volume, single-dose vials is unavoidable, they urge manufacturers of these products to develop containers for them that cannot be reused once opened.

The American Pharmacists Association "encourages pharmacists and other health professions to follow established CDC and FDA guidelines and to maintain open communication among all stakeholder groups to best meet the needs of their communities."

The ISMP also concurs with the positions of both CDC and CMS on the reuse of single-use vials. ISMP Executive Vice President Allen J. Vaida, PharmD, states that since the 1990s, the ISMP has been reporting on infections that have occurred following the inappropriate use of single-dose vials.

The Bottom Line: Patient Safety

In response to concerns that single-use vial policies contribute to drug shortages and increase costs to healthcare providers, CDC points to an FDA report indicating that drug shortages are a result of manufacturing, shipping, and other issues unrelated to the guidelines. The imperative to protect patients from harm resulting from the actions of healthcare professionals is foremost. The serious nature, and resulting expense and patient impact, of an outbreak cannot be ignored in this equation. Drug shortages, availability, and waste are issues that must be dealt with through appropriate channels and without endangering patients.

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