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Outsourcing Anesthesia Preparation, Part I: *Quality and Safety*

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Introduction

The economic downturn that has gripped the United States since early 2008 has placed added pressure on hospital administrators and medical staff already concerned about issues of cost containment and fiscal responsibility within health care. This, coupled with recent changes to United States Pharmacopeia (USP) Chapter <797> regarding compounded sterile preparations (CSPs), has led many health systems to consider outsourcing these functions.

USP is a nongovernmental, not-for-profit, public health organization that sets scientific standards for all prescription and over-the-counter medicines manufactured or sold in the United States. In 2004, supported by current data and developed in tandem with experts in drug contamination and infection control, USP introduced Chapter <797> to outline strict standards for proper sterile preparation of medications (or “compounding”). Although this process typically is performed by hospital pharmacists, the recommendations apply to all clinicians involved in the preparation of CSPs, including pharmacy technicians, nurses, anesthesiologists, and other physicians. Many hospitals have chosen to outsource the pharmaceutical preparation process as a way to meet these new strict standards, which include appropriate personal protective equipment, guidelines for cleaning the preparation area and laminar flow hoods, and environmental air-quality standards.

As with other USP standards, Chapter <797> is not a law, but rather a compendium of “best-practice” recommendations designed to provide health care providers a standard of practice in the preparation and delivery of CSPs (its recommendations may ultimately be adopted as law in individual states and, therefore, enforced by boards of pharmacy in those states). The decision to outsource these services affects not only these health care professionals, but health-system administrators as well. A 2006 survey of pharmacy practice in hospital settings showed that 42% of all hospitals and 78% of hospitals with 600 or more beds outsourced a portion of their preparation activities.¹ The health systems surveyed cited drug inventory and supply costs, environmental testing costs, and the capital investments required for USP Chapter <797> compliance (ie, clean room equipment and components, pharmacy staffing expenses, and proprietary vial and bag systems) as their main reasons for opting to outsource.

Since 2008, the Joint Commission has included Chapter <797> compliance in its evaluation criteria when surveying hospitals. A revision to Chapter <797> exempts medications expected to be administered within 12 hours of preparation, assuming compliance to all Joint Commission National Patient Safety Goals (NPSG). These would include the majority of pharmaceuticals prepared by the anesthesiologist for general or regional anesthesia. However, the preparation of all multiday infusions—including perineural, intra-articular, epidural, and intrathecal—must follow USP standards. For example,

contaminated infusate as a cause of infection in neuraxial anesthesia or peripheral nerve blockade is rare but may become more relevant as patients are discharged home with perineural catheters and portable pumps containing local anesthetic. No current guidelines exist citing the maximum length of time during which an admixture preparation such as an infusate can be administered without risk for microbiological or chemical instability.

The first installment of a 2-part series, this monograph will provide background information regarding medication errors in the operating room (OR) and will address error-reduction strategies by looking at quality, safety, and efficiency in the compounding of anesthesia preparations. Specifically, it will focus on how outsourcing anesthesia prepared drugs can assist health systems in meeting the requirements set by USP Chapter <797>, allowing them to better reach quality and patient safety standards. It also will provide health-system administrators, pharmacists, nurses, anesthesiologists, and physicians with the information needed to facilitate the outsourcing decision-making process. Part 2 of the series will focus on the workflow efficiency implications of USP Chapter <797> and how outsourcing vendors—and the ancillary services they provide (eg, standardized labeling, safety/quality assurance checks, extended expiration dating)—can assist health systems in streamlining the compounding process. This is a growing field and several companies already provide turn-key services in this area, including PharMedium and B. Braun/CAPS.

USP Chapter <797>: An Overview

Developed in response to patient illnesses and deaths reported in the 1990s and early 2000s and originally published in 2004, a revision of USP Chapter <797> was released in 2008 to further increase the rigor of quality and safety standards for compounding sterile preparations in health care settings. The Joint Commission considers this revised standard best practice.²

The revised USP Chapter <797> establishes quality controls for compounding methods and safety and accuracy checks—from compounding to the labeling, delivery, and storage of CSPs. Chapter <797> also provides general guidance on the compounding procedures, staff, and equipment requirements, and specifications for the compounding environment as well as the safe handling of the various types of CSPs.²

With regard to the storage of CSPs, for example, USP Chapter <797> offers guidance as to the limitations for beyond-use dates (BUDs) for certain CSPs (Table 1).² Although these dates can be exceeded based on the results of independent sterility testing—a service offered by most outsource compounding vendors—USP Chapter <797> guidelines offer health-system pharmacies a framework for CSP storage and highlight the importance of sterility testing, and the implementation of a system for beyond-use dating, for quality, and patient safety. The BUDs specified in USP Chapter <797> are

Table 1. Storage-Period Limitations Set by USP Chapter <797>^a

Storage Temperatures	Immediate-Use Preparations	Low-Risk Preparations	Low-Risk (<12 h BUD) Preparations	Medium-Risk Preparations	High-Risk Preparations
Controlled room temperature (<25°C/<77°F)	1 h	48 h	12 h	30 h	24 h
Refrigerator temperature (2-8°C/36-46°F)	1 h	14 d	12 h	9 d	3 d
Freezer temperature (<-10°C/<-4°F)	n/a	45 d	n/a	45 d	45 d

BUD, beyond-use date; **USP**, United States Pharmacopeia

^a Note: Limitations apply in the absence of stability testing.

Adapted from reference 2.

applicable to drugs prepared under the conditions described in USP Chapter <797>. Otherwise, drugs compounded at the point of care (POC) in the OR are for immediate use only; they must be administered within 1 hour after preparation begins.²

To comply with the requirements of USP Chapter <797>, health systems must ensure that the CSPs they dispense are prepared appropriately (in a sterile environment) by well-trained staff and tested for sterility and stability prior to dispensing, and that documentation of these processes is in place in the event of a problem. To safeguard the pharmacy from liability, standard operating procedures should be developed, updated, and rigorously followed. Facilities also must be monitored and/or maintained to ensure that they continue to meet USP Chapter <797> standards.^{3,5}

Because of these requirements, compliance with USP Chapter <797> can be challenging and costly for health-system pharmacies. As a result, health systems unable to meet the requirements may need to make alternative arrangements for their compounding services, and many, as noted above,

have opted for outsourcing. Additionally, even those facilities that meet the revised USP Chapter <797> requirements may choose to reduce their on-site admixture compounding volume and burden through outsourcing in order to better allocate pharmacy resources for more clinical tasks, as well as to potentially decrease their quality and environmental testing costs.^{1,5,6}

Anesthesia and the Operating Room

According to the 2009 hospital pharmacy survey, analgesics are among the more commonly outsourced preparations.¹ Many medications are unique to the perioperative setting in terms of their type, use, and delivery, including anesthesia. Historically, the anesthesia provider may have prescribed, retrieved, prepared, and administered these medications, all without the aid of a “double-check” for accuracy of drug and dose. It was the need to ensure the quality and accuracy of sterile compounded products that prompted creation of USP <797>.

According to the *MEDMARX Data Report*, which examined 11,239 perioperative errors submitted voluntarily to the MEDMARX system (a database of more than 400 hospital systems

Table 2. Medication Errors in Perioperative Units

Perioperative Unit	Errors (No.)	Errors Resulting in Harm (%)	Facilities Reporting Errors (No.)
Outpatient surgery department	3,427	2.9	422
Preoperative holding area	779	2.8	177
Operating room	3,773	7.2	447
Postanesthesia care unit	3,260	5.6	397

Adapted from reference 7.

Table 3. Common Medication Errors in Anesthesia Preparation^a

Incorrect dose, 44% ^b
Substitution/swap, 30% ^c
Contraindication, 10%
Incorrect schedule, 8%
Other, 8% ^d
^a Total medication error claims: 80.
^b Incorrect dose claims broken down by type of preparations: halogenated gas (17%), antihypertensive (17%), local anesthetic (11%), and induction agent (11%).
^c "Substitution/swap" broken down by delivery device (80% syringe, 20% infusion pump) and drug type (46% muscle relaxant, 21% vasopressor).
^d "Other" might include errors such as "omission" or incorrect route of administration

Adapted from reference 13.

nationwide) between 1998 and 2005, the OR generates the highest percentage of medication errors resulting in patient harm (Table 2).⁷ Moreover, a review of error data by Webster et al found that 1 medication error occurs for every 130 anesthetics administered.⁸

In contrast to the error rate found by Webster et al, a retrospective analysis of medication errors in a Japanese teaching hospital found an error incidence of 0.078% (50 out of 64,285 cases), with 0 medication errors leading to serious sequelae. The most common error was incorrect medication (with syringe or drug vial swap accounting for 75%). The second most common error was overdose due to misunderstanding or pre-conception of the dose (53%), pump misuse (21%), and dilution errors (5%). Another important finding was that errors were most likely to be made by anesthesiologists with little experience.⁹

Three studies presented at the 2008 International Anesthesiology Research Society meeting examined medication errors within the context of staff training and case complexity. The overall medication error incidence was 0.49% (52 out of 10,574 cases). The error incidence for trainees was twice that of nontrainees (ie, experienced providers; 0.66% vs. 0.34%). Not surprisingly, medication errors were more often made in more complex cases.¹⁰⁻¹²

These studies support what many experts have suspected: that anesthesia-related medication error incidence is not nearly as high as was reported in *MEDMARX*, that medication error incidence is higher for trainees, and that medication error incidence is higher in complex cases. Prefilled labeled anesthesia syringes could potentially decrease or eliminate these errors and help to standardize protocols reduce provider stress in more complex cases.

Common Medication Errors in Anesthesiology

In a presentation entitled "The American Society of Anesthesiologists (ASA) Closed Claims Project: Lessons Learned," Robert Caplan, MD, medical director-quality and staff anesthesiologist at Virginia Mason Medical Center in Seattle, suggested to an audience gathered for an Anesthesia Patient Safety Foundation (APSF) Board of Directors Workshop on medication safety in 2008, that the ultimate goal of those responsible for the administration of anesthesia in the OR is "the right patient and the right drug, at the right dose, right concentration, and right time."¹³

This concept of "The 5 Rights" has existed for some time, and has been expanded to include 2 additional "rights": right indication and right documentation.¹⁴ Anesthesia care providers—including anesthesiologists, nurses, nurse anesthetists, and pharmacists—must have a broad-based knowledge of the medications most commonly encountered in their practice setting and maintain this knowledge through frequent updates and use of current resources that are readily accessible at the POC. Identifying and achieving competence related to medication compounding and administration in the perioperative and peri-anesthesia settings can be difficult unless special attention is directed to these specialty practice areas by all anesthesia personnel, including nursing.¹⁵

In his analysis of the ASA Closed Claims Project, which reviewed the medication-error claims against one-third to one-half of the anesthesiologists in the United States between 1990 and 2001, Dr. Caplan noted that of the 80 medication-error claims studied, 44% were the result of anesthesia administered at the wrong dose (Table 3).¹³ Additionally, a survey published in the *Canadian Journal of Anaesthesia* found that most anesthesiologists had experienced more than one drug error in their practice, with syringe swap (the selection of the wrong syringe and the erroneous administration of its contents, usually due to incorrect labeling or inconsistent labeling procedures) being the most prevalent category of errors.¹⁶ Syringe-swap error was again listed as the third most frequent error in a study that reviewed 359 incidents.¹⁷

Efforts To Reduce Medication Errors in Anesthesiology

Regulatory agencies and voluntary safety groups such as the Institute for Healthcare Improvement, Centers for Medicaid & Medicare Services, Institute for Safe Medication Practices (ISMP), and the Joint Commission have focused on medication-error reduction and recommended safety goals or error-reduction techniques to address medication errors in anesthesiology. The Joint Commission views the OR as a high-risk location and has published standards and goals to address medication safety.

In particular, a goal addressing the issue of syringe swap, unlabeled syringes, or mislabeling of syringes was added to The National Patient Safety Goals (NPSG) in 2005.¹⁸ NPSG.03.04.01 states: "Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and

off the sterile field.” This applies to any surgical or other procedural setting and includes pre-, intra-, and postoperative/procedural areas and is applicable to the following¹⁸:

“Medications and solutions both on and off the sterile field, even if there is only one medication being used.... Any medication or solution transferred from the original packaging to a secondary container prior to administration. The Joint Commission does not approve of the use of prelabeled syringes manufactured prior to transfer of the drug to the syringe.”

The NPSG also recommends that drug/packaging labels include the medication name, strength, amount (if not apparent from the container), expiration date when not used within 24 hours, and expiration time (when expiration occurs in less than 24 hours). Additionally, the Joint Commission’s Medication Management (MM) standard MM.05.01.09 adds that drug/packaging labels should include the date prepared and the diluent for all compounded IV admixtures to be listed. For reasons of safety, the standards recommend that all drug/packaging labels be verified both verbally and visually by 2 qualified individuals whenever the person preparing the medication or solution is not the person who will be administering it.¹⁸ These recommendations also have been supported by the Association of Operating Room Nurses.¹⁹

Furthermore, the Joint Commission has 2 MM standards that address the safe storage and dispensing of medications²⁰:

MM.2.20, EP 12: *“Medications in care areas are stored in the most ready-to-administer forms available from the manufacturer, or in unit doses repackaged by the pharmacy or a licensed repackager.”*

MM.4.40, EP 4: *“Medications are dispensed in the most ready-to-administer forms available from the manufacturer, or if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackager.”*

The literature also contains research studies and reviews on medication safety strategies in the OR. These include standardization (drug preparation procedures, layout of work space, syringe sizes, IV drug concentrations), prefilled and labeled syringes, distinctive and colored labels, separate storage areas for hazardous medications, bar coding, etc.²¹⁻²³ Webster and Grieve outline “strong safety recommendations”—highlighting the importance of labeling, organization, and the involvement of pharmacists in the OR—based on a systematic review of publications and validated against actual error reports.²⁴

Outsourcing Medication Preparation

Outsourcing vendors can assist health systems with medication preparation services that meet the new regulatory

requirements and, in so doing, presumably enhance safety. Standardized labeling and safety checks, among others, aim to reduce drug errors. However, the decision to outsource is not an easy one, as each facility needs to weigh pros and cons. Not all compounding vendors are alike and, indeed, the services offered by the vendor selected must ultimately match well with a specific health system’s needs.⁶

Outsourced pharmacy compounding services that offer admixing and “drawing up” of prefilled syringes for the anesthesia care provider or the surgical team may provide an advantage in the OR. The fast-paced and frequently emergent OR environment can be a distracting and undesirable setting to carefully arrange, organize, aseptically prepare, and label medications for the surgical patient using traditional vials or syringes. Additionally, drugs prepared in anticipation of an emergency are not always used, increasing the potential for drug waste. With the limited resources in the pharmacy, the time needed to properly prepare prefilled syringes and admixtures, and the volume inherent in a busy hospital, the pharmacy sterile compounding room can be overwhelmed. Some facilities have addressed this by outsourcing these services.

Some studies have recommended using prefilled syringes to decrease errors in drug administration.²⁵ By using a standard dose of a prefilled syringe, the risk for a medication error can be decreased. Outsourcing the preparation of these drugs might decrease drug dose and/or concentration errors in the OR by eliminating the need for the anesthesia provider to dilute medication while simultaneously addressing direct patient-care activities, improving workflow and efficiency. (Part 2 of this series will explore this area in further detail.) Also, by having someone other than the anesthesia provider prepare the drugs, a “second pair of eyes” (ie, the pharmacist or nurse) can independently check the dose and concentration.

Outsourcing vendors can provide the following services:

Standardized labeling: As noted above, the risk for mix-ups of unlabeled containers in the OR is well documented in the literature.²⁶ A quality outsource vendor should provide consistent labeling of medication containers (syringes, basins, vials, etc) that includes “TALL MAN” lettering (Figures 1 and 2)—designed to reduce medication errors by allowing the user to easily identify medications and distinguish between those with similar names^{27,28}—as well as other conventions recommended by the ISMP and the American Society for Testing and Materials (ASTM).²⁹

Color differentiation: Color-differentiated preparations sorted by class (ie, orange for sedatives, red for neuromuscular blocking agents, blue for narcotics, etc), as recommended by ASTM and widely accepted and endorsed by the ASA, enables anesthesia care providers to differentiate between drugs quickly (Figures 1 and 2).²⁹ A study presented at the 2008 ASA annual meeting found that clinicians made fewer medication errors when a system of color-coded labeling was



Figure 1. Color-coded and “TALL MAN” labeling on syringes.

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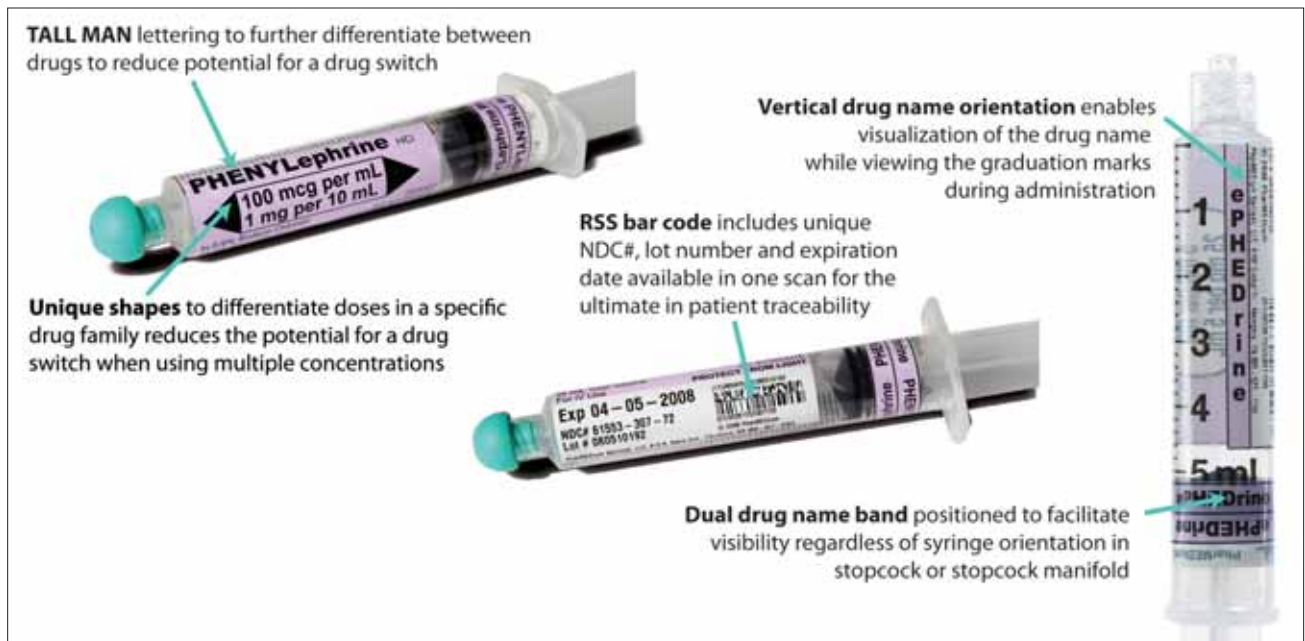


Figure 2. Explanation of standardized labeling on syringes.

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used.³⁰ It should be noted, however, that the use of color-coded labels can actually increase risk for error if the user becomes dependent on the color and size of syringe to identify the contents and does not habitually read the label to determine the medication it contains; as a result, education also is vital. It is possible that a color-coding system should only be undertaken by an experienced compounding facility, employing advanced label designs with the critical information such as the drug name, clearly visible from any potential viewing angle during administration. Additionally, compounding facilities should focus their efforts on issues of safety and compliance with the USP, Joint Commission, and other standards.³¹

Bar-coded labels: Bar codes for medications have been implemented in some hospitals to improve documentation and billing (Figure 2). However, the workflow for OR anesthesia providers is different than those for anesthesia providers in the patient ward, where medication is typically ordered by a physician and administered by a nurse. The OR anesthesia provider prepares the dose, administers it, and monitors the drug's effects. As a result, traditional bedside verification via bar codes that are used on inpatient units has not been implemented in the OR. However, the same forces that are motivating bar codes outside the surgical suite may reach the OR. Several studies recommend a check of drug labels by a second person or device before administration to decrease drug errors.²² Bar coding is one method of double-checking a syringe via device or computer before administering a drug.

Along with bar coding, improved easier-to-read labeling also may help the anesthesia provider reduce the risk for medication errors, including inadvertent drug swap. In fact, in 2004 the ASA released a statement supporting the manufacture and use of pharmaceuticals with labels meeting ASTM international standards. In the future, it is likely that anesthesia providers will swipe a prefilled, labeled, bar-coded syringe across a scanner prior to administration, thus inputting the drug into the electronic anesthesia record keeper.

In general, labels with a Reduced Space Symbology composite bar code—which includes the National Drug Code number, lot, and expiration date—may allow hospitals to better track and reconcile controlled substances or high-risk drugs, improve inventory control, and reduce unused or wasted drug admixtures, in addition to the obvious benefit of improved readability.³²

Beyond-use dating and real-time stability: Ready-to-use and POC-activated IV admixtures often allow an extended shelf life. For example, many POC products allow at least 30-day BUD once the product is assembled, but not activated, according to the manufacturer's package insert. If compounded by pharmacy staff in a clean room, these same medications generally would be subject to a 14-day refrigerated BUD—or 48 hours at room temperature.^{2,33} By extending the BUD, hospital

pharmacies can reduce waste and eliminate the staff time necessary to re-compound expired medications. Many on-site pharmacies lack the testing capacity and staff training needed to properly implement these systems; however, outsource vendors can offer this service.

Potency testing, for example, is limited as it typically only measures the concentration of drug in a compounded preparation at the time of administering the testing. Also, depending on the method used for potency testing, degradants may go undetected, meaning that the true drug concentration could change before the BUD has been reached. Conversely, real-time stability testing can be used to accurately determine the BUD because it essentially involves re-creating a facility's entire compounding and shipping process to ensure accuracy and quality aseptic technique and it evaluates the true drug concentration change over time. Effective stability tests (ie, method development and method validation) separate the drug from any degradants and excipients, usually via heat or ultraviolet radiation. These tests are difficult to perform in an on-site pharmacy.

Reporting: Communication and vigilance continue to be essential to the safe care of patients during anesthesia. Any outsourced admixture provider should readily make available a detailed monthly or quarterly quality report that summarizes key areas, such as environmental testing, media-fill results, equipment validation, and any other indicators that would normally be monitored if the compounding were not being outsourced. Hospital pharmacies should also review outsourced documentation for the preparations to be outsourced for stability, sterility, and pyrogenicity testing, when required.³¹

Conclusion

Many hospital pharmacies are already outsourcing preparation of sterile medications such as IV patient-controlled analgesia pumps, cardioplegia, vasoactive drug drips, and epidural solutions. This is because orders for them come in randomly during the day, disrupting the pharmacist's other duties; preparing them also can be labor-intensive and difficult. Their preparation might be performed more efficiently in a controlled environment offered by an outside company, allowing for easier record keeping especially for controlled medications.

Outsourcing the preparation of anesthetic drugs for prefilled syringes and infusions presents other potential benefits, such as decreasing concentration and dosing errors, decreasing labeling errors, and reducing anesthesia provider workload. However, outsourced prepared drugs are not a complete solution to medication administration errors. Substitution or syringe-swap errors still can occur, and drugs still can be given at the wrong time. Clinicians need to read the label and have either a manual or bar-code double-check.

Central to outsourcing drug preparations is the quality of the prepared drugs. Anesthesia providers must have confidence that the premade infusions and prefilled syringes they

use contain the correct drug, dose, and concentration. Before deciding to outsource the preparation of anesthesia drugs to compounding centers, pharmacy and anesthesia departments must thoroughly evaluate the outsource vendor and trust that the vendor will provide safe and quality preparations.

Is it practical to outsource all anesthetic preparations or just certain drugs such as high-risk medications, including

neuromuscular blocking agents? The answer depends on the needs of a specific health system, but a systematic approach may be more beneficial than a piecemeal solution that leaves opportunity for error. Overall costs of outsourcing, including the many direct and indirect costs, as well as the effect of outsourcing on workflow in the OR, also must be considered. These areas will be explored in further detail in Part 2 of this series.

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