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# Special REPORT

JANUARY 2010

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## Outsourcing Anesthesia Preparations, Part II: Balancing Costs, Efficiency, and Quality Care

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## Introduction

Making sure that the correct drug, in the correct dose and concentration, is administered to the right patient at the right time is the primary responsibility of all members of the anesthesia care team, including anesthesiologists, pharmacists, and nurses. Known as the “5 rights” (or “7 rights”—with right indication and right documentation),<sup>1</sup> this fundamental professional obligation and typically manual task may soon be automated, as a result of the growing use of prepackaged, predrawn, and pre-labeled bar-coded syringes in routine clinical practice. However, this technology does not absolve anesthesia care providers from responsibility. If hospitals need to consider outsourcing to supplement their compounding needs, they need to be diligent in choosing a quality outsourcer.

Today, new focus has been placed on the most cost-efficient methods to ensure that the “5 rights” remain fully enforced in the operating room (OR). Recent changes to the Joint Commission and United States Pharmacopeia (USP) standards (Chapter <797>) regarding the safe and accurate preparation of compounded sterile preparations (CSPs)—including anesthesia drugs—are essentially aimed at reinforcing many of the considerations covered under the “5 rights.” But what impact have these new standards had on the cost-effective operation and management of health-system pharmacies?

In all, 75.1% of hospitals responding to a national survey commissioned by American Society of Health-System Pharmacists (ASHP) reported the need to increase pharmacy budgets in an effort to implement the changes needed for compliance with the new USP standards.<sup>2</sup> Table 1 summarizes cost considerations inherent in anesthesia drug purchasing and preparation and USP Chapter <797>, in brief, stipulates the following<sup>3,4</sup>:

- Health-system pharmacies must ensure that the CSPs they dispense are prepared appropriately (in a sterile environment) by well-trained staff.
- Medications must be verified prior to dispensing.
- Procedures and facilities must be monitored and/or maintained to ensure that they continue to meet currently accepted standards in order to safeguard the pharmacy from liability, and to increase safety during preparation of medications.

Because of these requirements, compliance with USP Chapter <797> can be challenging and costly for health-system pharmacies. To lessen the burden, many health systems have opted to outsource some of their compounding services.<sup>5</sup> But some question whether this is the most cost-effective option.

**Table 1. Costs of Anesthesia Drug Preparation**

Material costs	Drug, diluents, syringe, needle to draw, cap to close, label, alcohol prep pads, compounding waste
Labor costs	Preparation of the syringe by the anesthesiologist or CRNA, stocking the drug cart, collecting and disposing of unused syringes and vial medications, training on aseptic technique
Overhead costs	General overhead for the surgical suite, including waste management (eg, if partially filled syringe inadvertently placed in red sharps container) Satellite pharmacy clean-room design and construction, maintenance, periodic certification per USP Chapter <797> requirements, utilities, insurance, etc.
Safety costs	Medication errors (eg, inadvertent drug swap), hospital-associated infection
Compliance costs	Initiatives needed to meet Joint Commission standards for OR medications, controlled substance reconciliation

**CRNA**, certified registered nurse anesthetists; **OR**, operating room; **USP**, United States Pharmacopeia

The second installment of a 2-part series, this monograph will discuss drug waste and workflow efficiency in the setting of the anesthesia OR work environment and guide providers regarding what options to consider (including outsourcing), with the goal of maximizing efficiency and improving patient safety and quality of care in the increasingly complex economic and regulatory climate.

## Chapter <797> and Workflow

As Candy et al noted in analyzing the data from an ASHP survey, pharmacy directors under pressure to improve productivity and efficiency don't necessarily have a favorable view of the recommendations made in USP Chapter <797>. Indeed, in general, respondents to the survey believe that implementation of USP Chapter <797> recommendations will adversely affect the workload of pharmacy technicians and pharmacists, as well as the overall efficiency of drug preparation and delivery.<sup>2</sup>

In all, 22.6% of survey respondents said they changed staff—either by hiring new employees or reallocating existing ones to perform functions related to CSPs—in order to comply with USP Chapter <797>. Candy et al note that USP Chapter <797> has “resulted in more human resources being assigned to CSPs [without] a compensatory decrease in other budgetary items.”<sup>2</sup>

Indeed, the significant staffing and staff training needs associated with on-site compounding have led many health systems to consider outsourcing. More than half the participants (29 out of 49) at the Second Consensus Development Conference said they considered outsourcing IV admixtures cost effective.<sup>5</sup>

### OR Workflow

In a recent article in *Pharmacy Purchasing & Products*, the pharmacist author characterizes anesthesia drug preparation and administration as “not only labor-intensive...but time-interruptive.”<sup>6</sup> Indeed, data indicate the use of prefilled syringes has the potential to reduce drug preparation time in the OR, freeing up anesthesia care providers and pharmacy staff for other direct patient care.

At the University of California-San Diego Medical Center Thornton Hospital, Weinger and colleagues found that it takes anesthesia providers approximately 35 seconds to draw up a “completely unprepared emergency drug (ie, with everything available in the anesthesia cart).” The authors concluded that by adopting certain preparation strategies (including the use of prefilled syringes) anesthesia care providers could reduce preparation time “at least by half.”<sup>7</sup>

In another study evaluating a prefilled saline syringe system, the authors found that the prefilled system reduced syringe preparation time by approximately 70%.<sup>8</sup> The findings were based on a survey of nurses involved in the daily preparation of injections for administration and pharmacists involved in the preparation of these admixtures.

Finally, Webster et al evaluated the use of prefilled syringes for anesthesia—as part of a new injectable drug administration system that used specialized trays with color- and bar-coded syringes—against conventional methods, with the goal of reducing medication errors. The authors found that the use of prefilled syringes in the new system decreased preparation time (when compared to conventional methods of drawing up the drug by the anesthetist) and eliminated hazards associated with drug preparation (ie, cuts from glass amps, needle-stick injury, violation of sterile technique, drug errors caused by mislabeled syringes). The authors concluded that when evaluated for safety and efficiency the potential increased cost of prefilled syringes is justified, adding that “a safe anaesthetic is in fact a cost-effective anaesthetic.” However, they also wrote that it is “unwise to present potentially very dangerous drugs, such as protamine,

potassium and metaraminol in a prefilled format, because of the possible increased risk of inadvertent administration.”<sup>9</sup>

### USP Chapter <797> and Waste

All health systems have a certain amount of drug waste. In a recent study presented at the ASHP 2009 summer meeting, Chiu, using a custom-designed bar-code system, analyzed drug waste at the University of Cincinnati Medical Center. According to Chiu’s analysis, the average cost of IV drug waste per month was \$47,977 hospital wide.<sup>10</sup>

Weinger et al studied “waste” in the operating room and defined “drug wastage” as vials and/or syringes unused or unopened that had to be discarded. In their analysis, they collected all opened and unused or unusable IV anesthesia drugs left over at the end of each workday during the 2-week period. During the study period, 166 procedures were performed and 157 syringes and 139 ampoules were collected. Based on actual hospital drug acquisition costs, \$1,802 worth of drugs was wasted during the study period. On a cost basis, 75% of the total wastage was attributed to 6 anesthesia drugs: phenylephrine, propofol, vecuronium, midazolam, labetalol, and ephedrine. The authors believe that their findings may actually underestimate the cost of wastage because incompletely used syringes or vials that were discarded in the trash were not included.<sup>7</sup>

The results of the Weinger study are similar to those of previous studies that employed electronic record-keeping techniques to calculate drug waste. In a 1997 study, for example, Lubarsky et al programmed an automated database to perform drug cost calculations at Duke University Medical Center, and found that a few anesthesia drugs—atracurium, vecuronium, rocuronium, propofol, midazolam, fentanyl, labetalol, and isoflurane—accounted for approximately 67% of all anesthesia drug costs at the hospital during the 1-month period studied. The amount of drug waste was defined as the difference between that depleted from pharmacy supplies and that reported as administered to the patient in the electronic anesthesia record-keeping system. Discard rates for the study drugs ranged from 44% (midazolam) to 78% (labetalol), although the latter figure can be attributed, at least in part, to the fact that labetalol is not available in a single-use vial.<sup>11</sup>

Overall, 77.6% of the respondents to the ASHP survey on the potential impact of USP Chapter <797> feel that waste of sterile products will increase because of the beyond-use dating (BUD) standards established in the guidelines.<sup>2</sup> Much of this drug waste occurs because anesthesia care providers routinely

**Table 2. ASTM Standard Background Colors for User-Applied Syringe Drug Labels<sup>a</sup>**

Drug Class	Examples	Pantone Color, All Uncoated
Induction agents	Thiopental, methohexital, etomidate, ketamine	Yellow
Benzodiazapenes/Sedatives	Diazepam, midazolam	Orange 151
Muscle relaxants	Succinylcholine, <sup>b</sup> rocuronium, vecuromum pancuronium, atracurium, cisatracurium	Fluorescent red 805
Relaxant antagonists	Neostigmine, edrophonium, pyridostigmine	Fluorescent red 805 or warm red <sup>c</sup> and white diagonal stripes
Narcotics	Morphine, fentanyl, alfentanil, sufentanil, remifentanil	Blue 297
Narcotic antagonists	Naloxone	Blue 297 and white diagonal stripes
Major sedatives	Droperidol, chlorpromazine	Salmon 156
Vasopressors	Epinephrine, <sup>b</sup> ephedrine, phenylephrine	Violet 256
Hypotensive agents	Nitroprusside, nitroglycerine, phentolamine	Violet 256 and white diagonal stripes
Local anesthetics	Bupivacaine, lidocaine	Gray 401
Anticholinergic agents	Atropine, glycopyrrolate	Green 367

<sup>a</sup> Drugs that do not fit into these classes should be labeled with black printing on a white background. The examples shown are representative, not restrictive.

<sup>b</sup> All printing is to be in black bold type, with the exception that “succinylcholine” and “epinephrine” shall be printed against the background color as reversed plate letters within a black bar running from edge to edge of the label.

<sup>c</sup> Warm red may be used if the printing of 805 fluorescent red stripes presents insurmountable difficulties.

Adapted from reference 4.

prepare syringes that ultimately go unused. These might include emergency agents (ie, ephedrine, atropine, and phenylephrine) for cardiac cases in the OR; often the BUDs for these medications (as established by USP Chapter <797>) will expire before they can be administered to patients.

Still, some drug waste can be reduced or eliminated. Jensen et al conducted a systematic review of the literature on drug errors in the OR and developed a list of “reasonable and sensible” measures, which included the use of prefilled syringes, rather than ampoules, to avoid administration of the incorrect agent during an emergency.<sup>12</sup> Many of their recommendations also have the added benefit of reducing drug waste. Jensen et al addressed the following:

- Drug labeling. Syringes should be labeled legibly and standards should be established as to font, size, color, and the information included.<sup>12</sup> Initiatives such as “TALL MAN” lettering, color coding, and expanded content (ie, adding detailed drug concentration and patient information), as well as bar coding, can help prevent the incorrect prefilled packaging from being opened (and thus discarded) at bedside.<sup>7,13</sup> In 2004, the American Society of Anesthesiologists released a statement supporting the manufacture and use

of pharmaceuticals with labels meeting standards set forth by the American Society for Testing and Materials International (Table 2).<sup>14</sup>

- Bar-coding of syringes. Before a drug is drawn up or administered, a second care provider or device (such as a bar-code reader linked to a computer) should be used to double-check the labels. Bar-coding systems have been implemented in some hospitals to improve documentation and billing; these systems also can serve as a valuable “safety check,” without additional staff burden.<sup>15,16</sup>
- Organizing the anesthesia cart. Organize drug drawers and work spaces with attention to tidiness, position of ampoules and syringes, separation of similar or dangerous drugs, and removal of dangerous drugs from the operating theaters.<sup>12</sup>
- Reporting and reviewing all errors in IV drug administration during anaesthesia.<sup>12</sup>
- Managing inventory to minimize risk (ie, appointing a drug safety officer or pharmacist in the OR).<sup>12</sup>
- Avoiding similar packaging and presentation of drugs (“look-alike/sound-alike”).<sup>12</sup>
- Color-coding vials by class of drug according to national or international standards.<sup>12</sup>

The overall theme is that providers need to return to the basics. It is interesting to note that 4 of the 7 recommendations made by Jensen et al could be adopted by using pre-filled syringes prepared by pharmacy, a qualified outsourcer, or a commercial manufacturer. The authors acknowledge, however, that much of the evidence used to support their recommendations is based on opinion (as opposed to being “experimental”) and urge readers to consult referenced studies and conduct similar analyses in their own health systems.<sup>12</sup> While many of these approaches are considered “best practice” within the health-system pharmacy, health systems should also demand that they be standard operating procedure by any and all vendors if they have opted to outsource these services. USP Chapter <797> does not address the issue of drug waste specifically; however, many of the Chapter’s recommendations, when implemented, have potential to reduce drug waste in the OR.

## Dispensing Logistics

The adoption of the USP Chapter <797> guidelines for compounding sterile products has presented numerous challenges to departments of pharmacy—not just in the design, construction, and costs associated with complying to the Chapter’s complex facility requirements, but also in the ongoing maintenance, training, documentation, oversight, and changes to daily practice.

The Joint Commission and the Centers for Medicare & Medicaid Services (CMS) have developed standards for pharmacy concerning the admixture of most sterile products. Although very appropriate, the standards do add to the already high-volume workload of the “IV room.” The Joint Commission’s Medication Standard (MM.05.01.07)<sup>17</sup> states: “A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product’s stability is short.” Additionally, the CMS condition of participation 482.25(b) (1)<sup>18</sup> states: “All compounding, packaging and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws. ... Only Pharmacy compounds or admixes all sterile medications, intravenous admixtures or other drugs except when not feasible.”

Consistent with Joint Commission medication management standards, clinicians working in areas such as the perioperative setting appreciate the value and safety of prefilled preparations and are increasingly requesting pre-labeled, ready-to-administer

forms of drips and syringes, adding to the volume of IV admixtures prepared in the sterile compounding room in the central pharmacy and/or the satellite OR pharmacy. Many facilities do not have a dedicated OR pharmacist who guides medication use; however, the regulatory groups have an expectation that pharmacy oversight and monitoring exist, regardless of the setting. These challenges and the need to comply with the regulatory group standards, combined with the national shortage of pharmacists and the level of training needed for pharmacy technicians, has forced pharmacy directors to consider alternatives to manage the workload of the IV sterile admixture area, including the implementation of new technologies or outsourcing some or all the services.<sup>19</sup>

In general, studies have found that having medications 1) accessible at the point of care<sup>20</sup>, 2) ready to use<sup>21</sup>, and 3) appropriately labeled<sup>22</sup> enhances the ability of the care team to provide safe, quality care. Processes that interfere with the flow of care cause inefficiencies and frustration among the team and potentially compromise patient care. Assembling medications to be compounded, having adequate work space, and minimizing distractions are necessary components for preparing medications.<sup>13,23</sup>

Automated dispensing machines (ADMs) and automated information management systems (AIMS) are among the new technologies being used to improve workflow in the increasingly complex health-system OR environment. ADMs and AIMS allow for improved workflow, inventory control, controlled substance management and security, and record keeping, without the need for additional nursing staff.<sup>24</sup> Some AIMS provide alerts for patient allergies and dosing schedule conflicts, but none can prevent the wrong drug from being administered. Using anesthesia-specific ADMs would require pharmacy to restock each machine daily and each machine would need to be housed in an OR, which is difficult because ADMs are in use during usual business hours. Thus, anesthesia-specific ADMs are still in their infancy and are not widely used. Most health systems still use an anesthesia tray stocked by pharmacy and exchanged daily (or for each new case).

## Outsourcing

Many hospital pharmacies already are outsourcing preparation of sterile medications such as IV patient-controlled analgesia pump syringes, cardioplegia, vasoactive drug drips, and epidural solutions. This is because orders for these products often come in at random times throughout the day, disrupting

**Table 3. Cost Considerations in Outsourcing Anesthesia Drug Preparation**

<b>Material costs</b>	<b>Waste<sup>a</sup></b>
Drug	Percent compounding scrap for pharmacy-prepared doses (generally around 8%-10% produced based on materials + labor + overhead)
Diluent	Percent compounding scrap for anesthesia-prepared doses (generally lower than pharmacy 1%-5% of all syringes produced based on materials + labor + overhead)
Syringe cap and/or tamper-evident caps	Percent of syringes wasted due to expiration of BUD
Syringe(s): multiple syringes may be used depending on preparation process and drug	Pharmacy technician labor to collect and dispose of unused syringes and vial medications
Quantity of syringes used in preparation process	Disposal of syringes prepared but not used due to expired dating; red bag cost of disposal
IV piggyback transfer set for batch volume preparations (pharmacy-prepared batches)	<b>Medication error cost</b>
Quantity of admixtures produced for pharmacy-prepared syringes	AE cost resulting from a medication error occurring at a fixed error rate of 0.68% (or 1 in 149), for example <sup>25</sup>
Labeling and packaging	<b>Total cost</b>
Miscellaneous supplies most commonly associated with pharmacy-prepared medications, including alcohol prep pads, sterile gloves, sterile gowns, etc.	Total cost of the preparation including the materials, labor, incidental costs of scrap/waste and AEs resulting from a medication error prevented by using a fully labeled and ready-to-use syringe preparation
<b>Labor costs (choose appropriate categories depending on preparation method)</b>	
The estimated time it takes for the anesthesiologist to prepare the syringe (where appropriate)	
The estimated time it takes for the CRNA to prepare the syringe	
Estimated time it takes for the RN to gather the drugs and supply the syringes (anesthesiologist prepared)	
Pharmacists time to prepare or check the admixture	
<b>Overhead costs</b>	
General overhead cost per syringe (for pharmacy-prepared): clean-room design and construction, maintenance, cleaning, periodic certification per USP Chapter <797> requirements, utilities, insurance, disposal, etc.	
Sterility container/closure testing to ensure the container and closure system (eg, syringe and syringe cap) are capable of maintaining sterility over the life of the BUD (relevant to pharmacy-prepared doses with extended BUDs).	
Ongoing sterility monitoring to ensure the ongoing integrity of the process, operator, facility, and container to maintain the sterility of the syringe admixture. This includes daily media fill testing of compounding personnel, daily/weekly/monthly testing of the various surfaces in the Laminar Flow Work Bench and clean-room and daily/weekly testing of the compounding equipment and fixtures (where appropriate).	
Real-time stability testing is specific to drug, drug concentration, fill volume, diluent, container, container manufacturer, etc. and is completed prior to a syringe being offered to a customer	
Ongoing potency and ID testing is systematic daily testing to ensure the correct admixture is present at the correct concentration throughout the BUD of the syringe	

AE, adverse event; BUD, beyond use date; CRNA, certified registered nurse anesthetists; ID, identification; IV, intravenous; RN, registered nurse; USP, United States Pharmacopeia

<sup>a</sup> Compounding scrap for either anesthesia or anesthesia-prepared doses refers to medications drawn-up or reconstituted from a vial where a provider or pharmacist immediately realizes there was an error in the compounding or labeling process and discards it. It can also include medication left over from a pharmacy-prepared source container that does not get completely used or to an odd amount of drug left over; both scenarios are accounted for.

the pharmacists' other duties. Preparing them can be labor-intensive. The ASHP national survey of pharmacy practice in hospital settings reported that more than 42% of hospitals outsourced some drug preparation activities. Larger hospitals were more likely to outsource than smaller hospitals.<sup>19</sup>

Typically, cost of medication preparation is a significant factor in the decision to outsource. When comparing in-house costs with the cost of outsourcing, it is important to account for all expenses incurred by the hospital pharmacy, including costs of the drugs, mini-bags, diluents, needles, syringes, and labeling supplies (Table 3).<sup>25</sup> Costs associated with compounding equipment (ie, purchasing, installation, and training)—as well as the sets and controls used with the equipment—should also be considered, as should staffing expenses. Given these considerations, outsourcing may be a more cost-effective option.

Another potential benefit of outsourcing is extended expiration dates, which enable the hospital to reduce waste of prepared but unused pharmaceuticals. Quality outsourcers conduct "real-time" stability studies when determining expiration dates and can readily provide proof of testing by an FDA-registered laboratory.<sup>26</sup>

In general, outsourcing compounding services means that health-system pharmacies can provide standardized drug concentrations of prefilled syringes and infusion medications without the pharmacy equipment and manpower requirements associated with conducting these procedures on-site. Outsourcing also can improve workflow by reducing staff time needed to mix or dilute drugs or to calculate concentrations, enabling care providers to spend more time on other activities, including patient care. Finally, outsourcing vendors also can limit the risk for medication compounding and/or administration errors by performing regular safety checks and offering standardized labeling that includes date, time, practitioner identification, and bar coding, among other safety elements. Some vendors may even have the sophistication to produce high-quality labeling normally associated with pharmaceutical manufacturers.

In an audience-response poll conducted during the 2008 Second Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems, 57% of respondents agreed that "outsourcing IV admixtures is a safe practice"; 59% agreed that "outsourcing IV admixtures is cost-effective."<sup>5</sup>

## Challenges to Outsourcing

Logistics may be an issue when selecting an outsource vendor. For example, the location of the compounding facility, in

relation to the hospital, may not allow for timely delivery of CSPs (before BUD expiration). This may be particularly problematic if a health system is ordering controlled substances from an outsource vendor; these drugs require special filings with the Drug Enforcement Agency, and if a vendor does not have a system in place to streamline this process, delivery can be problematic.<sup>27</sup> Outsourcers should have electronic online CII ordering capabilities that may expedite delivery.

Pharmacists must carefully monitor BUDs and remove expired doses from inventory in the pharmacy and nursing units. One way to avoid drug waste is to recycle doses nearing expiration to higher-volume nursing units. Routine inventory analysis should be implemented so that pharmacists can identify potential waste issues and alter orders from outsource vendors accordingly.<sup>27</sup>

Outsourcing does not eliminate drug waste because there will always be unused "emergency" agents and/or partially used syringes in the OR setting; however, it may reduce it. Each institution should evaluate the practice of their anesthesia care providers from the perspective of safety.

One final challenge is that few if any outsource vendors can fulfill all the needs of a health system, making working with multiple vendors a necessity. Monitoring orders and inventory from more than one vendor can be challenging, thus it is best to identify one that can handle the bulk of the work.

## Conclusion

As anesthesiologist, David M. Gaba, MD, wrote in the spring 2003 issue of the Anesthesia Patient Safety Foundation newsletter, "In health care a prime challenge to a culture of safety is 'production pressure,' the overt or covert pressure to put production (as in throughput and efficiency) [ahead of safety]. ... This has been shown to be a real problem in the operating room. ... Yet [effective organizations] have established mechanisms to ensure that these pressures do not overcome real safety concerns. They have evolved formal mission rules, checklists, milestones, and a system whereby even the most junior person feels empowered and obligated to halt production for a credible safety threat. Developing such mechanisms will be important for health care."<sup>28</sup>

As more and more health systems turn to outsourcing vendors as an alternative to on-site compounding, benefits are being reported in improved safety, reduction of medication waste, increased quality, improved efficiency, and enhanced compliance with current regulatory standards.

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## Clarification

In Part I of this Special Report series—entitled “Outsourcing Anesthesia Preparation, Part I: Quality and Safety”—the term “sterility” was used incorrectly in several instances as a result of an editing error. Sterility is the time (or period) that a container (multidose vial, SDV, syringe, etc) retains its quality, as long as the container is unaltered and remains in its originally manufactured state. The editors apologize for any confusion.