



Critical Considerations for Outsourcing Pharmacy Compounding Services

ASHP Advantage E-Newsletter

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Outsourcing Sterile Compounding Services and Prefilled Anesthesia Syringes

A midday symposium entitled Critical Considerations for Outsourcing Pharmacy Compounding Services was conducted at the 44th ASHP Midyear Clinical Meeting and Exhibition on December 7, 2009, in Las Vegas, Nevada. Attendees at the symposium submitted questions that were later addressed by the faculty in a live webinar conducted on January 28, 2010. This newsletter features highlights from this webinar and practical tips for making the decision to outsource sterile compounding services and prefilled anesthesia syringes. Other highlights and practical tips for conducting site visits to and evaluating prospective suppliers of outsourced sterile compounding services and other aspects of the contract sourcing process will be described in another newsletter to be released this spring.

The prevalence of outsourcing of medication preparations has increased in recent years, and nearly one in four hospitals plan to increase their outsourcing of sterile compounding services in the future.^{1,2} The ASHP Board of Directors recently approved new guidelines on outsourcing sterile compounding services that will be published soon in the *American Journal of Health-System Pharmacy*.³

Outsourced Compounded Sterile Preparations

Ready-to-use (RTU) compounded sterile preparations obtained through outsourcing are one of several intravenous (i.v.) drug delivery systems used in health systems (Table 1).^{4,5} In most cases, no one system can meet an institution's needs, and a combination of systems is required. The primary goal in choosing the optimal combination of i.v. drug delivery systems in an institution is ensuring patient safety.

The role of outsourced sterile compounding services in health systems depends on several institution-specific factors (e.g., patient mix, type of institution, staff size, storage space). Health systems with contractual arrangements with group purchasing organizations that have established contracts for outsourcing sterile compounding services may not need to establish direct contracts with suppliers of such services.

At the University of Illinois Medical Center (UIMC), all five types of i.v. drug delivery systems listed in Table 1 are used, although manufacturer RTU and pharmacy compounded preparations are relied on heavily. Use of point-of-care (POC) activated preparations at UIMC is minimal. The use of non-pharmacy compounded POC preparations

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Table 1. Advantages and Disadvantages of Intravenous Drug Delivery Systems^{4,5}

<i>Types of System</i>	<i>Advantages</i>	<i>Disadvantages</i>
Manufacturer RTU	<ul style="list-style-type: none"> • Low risk for contamination • Ease of use • Long expiration dates 	<ul style="list-style-type: none"> • Difficulty accommodating special patient populations • Frozen preparations require thawing
Outsourced RTU	<ul style="list-style-type: none"> • Doses can be customized for patient • Low risk for contamination 	<ul style="list-style-type: none"> • High cost • Need for contracting
POC activated	<ul style="list-style-type: none"> • Suitable for ADC's • Long expiration dates 	<ul style="list-style-type: none"> • Difficulty accommodating special patient populations • High cost • Potential for error related to inactivation
Pharmacy compounded	<ul style="list-style-type: none"> • Dose can be customized for patient • Appropriate labeling • Quality control procedures are established 	<ul style="list-style-type: none"> • High risk of contamination • Difficulty complying with USP-Chapter <797> requirements
Non-pharmacy compounded at POC	<ul style="list-style-type: none"> • Dose can be customized for patient • Immediate availability 	<ul style="list-style-type: none"> • High risk of compounding error • Inconsistent labeling practices • High risk for contamination • Difficulty achieving regulatory compliance

ADCs = automated dispensing cabinets; POC = point of care; RTU = ready to use; USP = United States Pharmacopeia

also is minimal because of safety concerns. Outsourced RTU preparations are used selectively for various reasons at UIMC, including a need to minimize the risk for harm associated with complex preparations used in high-risk patients (e.g., cardioplegia solution), reduce the workload involved in preparation of commonly used admixtures, avoid waste in compounding sterile preparations, circumvent shortages of manufacturer RTU preparations, or minimize institutional paperwork.

“ The use of sterile preparations that are non-pharmacy compounded at the point-of-care should be minimized to the extent possible because of the safety risk from a lack of checks and balances. ”

— Andrew J. Donnelly, Pharm.D., M.B.A., FASHP

A variety of costs other than the acquisition cost should be taken into consideration when making decisions about the use of outsourced RTU preparations (e.g., supplies, labor, equipment, waste, sterility testing, managing medication errors). These costs offset the high acquisition cost of these preparations and may be substantial.

Some institutions recently began using i.v. robots to “insource” compounded sterile preparations that previously were outsourced. Most i.v. robots can be used to prepare both i.v. syringes and bags. Vendors of robotic equipment may offer “fee for product” payment arrangements instead of requiring leasing or purchase

agreements. Currently, the number of institutions using i.v. robots in the United States is small, but the number could grow in the future.

Prefilled Syringes for Anesthesia Care

The medication-use process in the operating room (OR) differs from that in other hospital areas. The pace of drug therapy decisions and dose preparation and administration is faster in this setting than elsewhere in hospitals because of rapid changes in patient status, with a need for decisions and medication administration within seconds or minutes instead of the minutes or hours that usually suffice in other areas of the hospital. A lack of pharmacy involvement in the preparation of most of these medications is also unique to the OR setting.

Outsourcing of the preparation of prefilled syringes for use in anesthesia care has become increasingly popular in health systems. In some health systems, the use of prefilled syringes was implemented in response to a request from anesthesia care providers. The market for prefilled syringes is expected to grow by 12.8% per year in the future because of many potential benefits (Table 2).⁶ Improved patient safety is a major benefit of prefilled syringes. The double checks inherent in the processes used to prepare the syringes eliminate errors attributed to a lack of such checks when anesthesia care providers draw up doses from vials. Dose measurement errors, wrong drug errors related to “syringe swaps,” and contamination from failure to adhere to proper aseptic technique in dose preparation are among the problems that can be avoided when prefilled syringes are used.⁷⁻¹¹ Convenience and reduced dose preparation time and waste are among the other benefits of prefilled anesthesia syringes.¹²

Table 2. Reasons for Outsourcing Prefilled Anesthesia Syringes

- Frees up pharmacist time for clinical duties
- Facilitates compliance with regulatory and accreditation requirements
- Avoids dose measurement errors
- Avoids wrong drug errors due to “syringe swaps”
- Avoids errors related to lack of double checking by anesthesiology staff
- Circumvents problems related to failure to use proper aseptic technique
- Improves labeling/use of bar coding
- Provides for extended beyond-use dates
- Reduces waste of routinely-used drugs
- Improves controlled substance reconciliation

The use of prefilled syringes helps institutions meet The Joint Commission medication management standards and National Patient Safety Goal (NPSG) pertaining to labeling (Table 3). This NPSG (03.04.01) requires labeling of all medications, medication containers (including syringes, medicine cups, and basins), and other solutions on and off the sterile field in perioperative and other procedural settings.¹³ The labeling

requirements apply to all surgical and other procedural settings, including preoperative, intraoperative, and postoperative areas (i.e., preoperative holding areas, postanesthesia care units).¹⁴ Surveyors from The Joint Commission often encounter problems in compliance with NPSG 03.04.01 in OR areas (Table 4). Failure to affix labels directly to the drug container (e.g., labeling bins containing drug syringes instead of the syringe itself) can result in medication errors. The use of prelabeled drug containers also can lead to errors if the container is later filled with the wrong drug, dose, or concentration.

“ Medication labeling during procedures was the most challenging medication-related NPSG that was scored noncompliant by the Joint Commission in 2009. ”

—Tricia A. Meyer, Pharm.D., M.S., FASHP

Table 3. The Joint Commission Medication Management Standards and National Patient Safety Goal Pertaining to Compounded Sterile Preparations¹³

<i>MM.05.01.07:</i>	Sterile preparations are prepared by pharmacy except in emergent situations
<i>MM.05.01.09:</i>	Medications are appropriately labeled unless prepared and immediately administered
<i>NPSG 03.04.01:</i>	Appropriate medication labeling in perioperative and procedural settings

MM = medication management; NPSG = National Patient Safety Goal

Table 4. Common Problems in Complying with NPSG 03.04.01^a Encountered During Joint Commission Surveys of Operating Room Areas

- Lack of compliance in all procedural areas
- Failure to label all solutions
- Failure to indicate the drug strength on labels
- Failure to affix labels directly to drug containers
- Use of prelabeled drug containers

NPSG = National Patient Safety Goal

^aLabel all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. Medication containers include syringes, medicine cups, and basins.

The labels of outsourced prefilled anesthesia syringes are designed with features that improve readability and promote ease of use for health care personnel and patient safety (e.g., standardized background colors for drug classes, TALL man lettering). Labels with bar codes reduce the risk for error and can be used for tracking purposes (e.g., for narcotic reconciliation).¹⁵ Some labels on outsourced prefilled syringes provide information both horizontally and vertically permitting reading from more than one perspective without turning the syringe.

The benefits of outsourcing prefilled anesthesia syringes must be weighed against various potential disadvantages and concerns. Cost is a major concern. A variety of direct (e.g., materials, labor) and indirect (e.g., overhead, safety, compliance) costs enter into decisions to outsource prefilled anesthesia syringes.

For More Information

If you missed the midday symposium about outsourcing pharmacy compounding services at the 2009 ASHP Midyear Clinical Meeting and Exhibition and want to learn more about this topic, a web-based activity based on the symposium is available, offering two hours (0.2 CEUs) of continuing pharmacy education credit. Podcast interviews with the faculty, which were conducted after the live program in Las Vegas, are also available. These activities are available on the activity website (www.ashpadvantage.com/outsourc).

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