

Outsourcing the Compounding of Sterile Preparations

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INTRODUCTION

New laws, regulations, and professional guidelines make compounding sterile preparations very complex (Chapter 2). Faced with these challenges, pharmacists have decided to outsource sterile compounding to pharmacies that claim to have the trained staff, facilities, and supply of ingredients to make the pharmaceuticals needed by their patients.

NATIONAL TRENDS

According to a 2012 survey of 298 hospitals by the U.S. Office of Inspector General (OIG), ensuring an adequate supply of compounded sterile preparations (CSPs) was very important to hospitals when determining whether to outsource them. Many hospitals cited shortages of commercial products (68%), the availability of CSPs with extended shelf lives (62%), and CSP stability (69%) as very important factors in their decision to outsource. However, hospitals took limited steps to ensure the quality of outsourced CSPs but had few problems (that they knew about) with the quality of products from outside pharmacies.¹

Pedersen et al. reported in 2014, that 70% of hospitals outsourced some of their sterile preparation activities (**Table 32-1**).² A greater percentage of larger hospitals outsourced some sterile preparation activities as compared to smaller hospitals. For example, 90.9% of hospitals with 600 or more staffed beds outsourced some preparation activities, compared with 59% of hospitals with fewer than 50 staffed beds. Of hospitals that outsourced some preparation activities, 69.1% outsourced patient-controlled analgesia (PCA) and epidurals, 53% outsourced oxytocin preparations, 31.1% outsourced total parenteral nutrition (TPN), and 28.3% outsourced syringe-based anesthesia medications (see further discussion of syringes as containers below). Less than 25% of hospitals outsourced routine intravenous admixtures, high-risk products made from nonsterile components, or cardioplegia.

Why would so many hospitals choose an outside pharmacy to provide a variety of CSPs? In addition to the reasons in the OIG survey, other reasons include shortages or reallocations of pharmacist and pharmacy technician staff; costs of space, equipment, and

Table 32-1.
Preparation Activities Partially or Completely Outsourced

Characteristic	n	% Hospitals								
		Patient-Controlled Analgesia and Epidural	Oxytocin	Total Parenteral Nutrition Solutions	Syringe-Based Anesthesia Medications	IV Admixtures and Piggybacks	Unit-Dose Repackaging—Drug Only	High-Risk Preparations from Nonsterile Sources	Cardioplegia	Unit-Dose Repackaging for Barcoding
No. staffed beds										
<50	48	62.5	43.8	25	12.5	12.5	10.4	12.5	0	4.2
50–99	35	74.3	62.9	28.6	17.1	34.3	14.3	5.7	2.9	2.9
100–199	32	78.1	56.3	21.9	34.4	12.5	15.6	12.5	3.1	6.3
200–299	63	68.3	52.4	39.7	31.7	25.4	17.5	14.3	30.2	17.5
300–399	48	72.9	62.5	52.1	50	25	22.9	20.8	29.2	16.7
400–599	50	64	54	34	58	36	26	24	34	16
≥600	39	56.4	51.3	46.2	38.5	41	38.5	23.1	53.8	23.1
All hospitals—2014	315	69.1	53	31.1	28.3 ^a	21.4 ^b	16.4	13.8	12.9 ^c	9.3 ^d
All hospitals—2011 ³	441	73.3	65.2	23.6	24.1	38.3	16	NS ^e	18.3	10.4
All hospitals—2008 ⁶	270	64	NS	32.8	NS	37.3	13.4	NS	NS	14.6
All hospitals—2005 ⁹	186	40.2	NS	39.8	NS	31.4	11.6	NS	NS	9.6
All hospitals—2002 ¹²	137	16.7	NS	52.4	NS	15.7	12.1	NS	NS	8.9

^aUncorrected $\chi^2 = 31.9980$, $df = 6$, design-based $F(4.26, 1311.06) = 5.5411$, $p = 0.0001$.

^bUncorrected $\chi^2 = 17.7174$, $df = 6$, design-based $F(4.21, 1295.48) = 3.0251$, $p = 0.0152$.

^cUncorrected $\chi^2 = 68.8310$, $df = 6$, design-based $F(3.83, 1180.28) = 13.9121$, $p = 0.0001$.

^dUncorrected $\chi^2 = 15.4463$, $df = 6$, design-based $F(4.28, 1317.36) = 2.5724$, $p = 0.0328$.

^eNS = not surveyed.

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quality assurance; and lack of expertise within the pharmacy to compound the more complex sterile preparations.³

Pharmacists and technicians are often poorly trained to compound sterile preparations, especially those that are made from nonsterile components (Chapters 23 and 24).⁴ In fact, Pedersen et al. determined that only 13.8% of hospitals even

prepare high-risk (nonsterile to sterile) CSPs (Table 32-1). New technologies such as specialty pharmaceuticals, genetically engineered pharmaceuticals, and individualized dosing based on pharmacogenomics, are creating an increased need for trained compounding pharmacists and technicians, thereby raising the probability of greater CSP outsourcing in the future.