ARTICLE

Survey of Sterile Admixture Practices in Canadian Hospital Pharmacies: Part 1. Methods and Results

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ABSTRACT

Background: The 1996 *Guidelines for Preparation of Sterile Products in Pharmacies* of the Canadian Society of Hospital Pharmacists (CSHP) represent the current standard of practice for sterile compounding in Canada. However, these guidelines are practice recommendations, not enforceable standards. Previous surveys of sterile compounding practices have shown that actual practice deviates markedly from voluntary practice recommendations. In 2004, the United States Pharmacopeia (USP) published its "General Chapter <797> Pharmaceutical Compounding—Sterile Preparations", which set a more rigorous and enforceable standard for sterile compounding in the United States.

Objectives: To assess sterile compounding practices in Canadian hospital pharmacies and to compare them with current CSHP recommendations and USP chapter <797> standards.

Methods: An online survey, based on previous studies of sterile compounding practices, the CSHP guidelines, and the chapter <797> standards, was created and distributed to 193 Canadian hospital pharmacies.

Results: A total of 133 pharmacies completed at least part of the survey, for a response rate of 68.9%. All respondents reported the preparation of sterile products. Various degrees of deviation from the practice recommendations were noted for virtually all areas of the CSHP guidelines and the USP standards. Low levels of compliance were most notable in the areas of facilities and equipment, process validation, and product testing. Availability in the central pharmacy of a clean room facility meeting or exceeding the criteria of International Organization for Standardization (ISO) class 8 is a requirement of the chapter <797> standards, but more than 40% of responding pharmacies reported that they did not have such a facility. Higher levels of compliance were noted for policies and procedures, garbing requirements, aseptic technique, and handling of hazardous products. Part 1 of this series reports the survey methods and results relating to policies, personnel, raw materials, storage and handling, facilities and equipment, and garments. Part 2 will report results relating to preparation of aseptic products, expiry dating, labelling, process validation, product testing and release, documentation, records, and disposal of hazardous pharmaceuticals. It will also highlight some of the key areas where there is considerable opportunity for improvement.

Conclusion: This survey identified numerous deficiences in sterile compounding practices in Canadian hospital pharmacies. Awareness of these deficiencies may create an impetus for critical assessment and improvements in practice.

RÉSUMÉ

Contexte : Les Lignes directrices sur la préparation des produits stériles dans les pharmacies de la Société canadienne des pharmaciens d'hôpitaux (SCPH) publiées en 1996 représentent la norme actuelle de pratique en matière de préparation de produits stériles au Canada. En revanche, ces lignes directrices sont des recommandations en matière de pratique et non pas des normes coercitives. Des sondages menés sur la préparation des produits stériles ont révélé une non-observance marquée de ces recommandations de pratique à conformité volontaire. En 2004, la United States Pharmacopeia (USP) publiait son « General Chapter <797> Pharmaceutical Compounding—Sterile Preparations », qui met de l'avant une norme plus rigoureuse et coercitive en matière de préparation des produits stériles aux États-Unis.

Objectifs : Évaluer les pratiques de préparation des produits stériles dans les pharmacies hospitalières canadiennes et les comparer aux recommandations actuelles de la SCPH et aux normes du chapitre <797> de l'USP.

Méthodes : Un sondage en ligne fondé sur des études antérieures des pratiques en matière de préparation des produits stériles, les lignes directrices de la SCPH et les normes du chapitre <797> a été créé et distribué à 193 pharmacies hospitalières au Canada.

Résultats : Un total de 133 pharmacies ont répondu au sondage, soit un taux de réponse de 68,9 %. Tous les répondants ont déclaré préparer des produits stériles. Divers degrés de non-observance ont été notés dans presque toutes les sphères des lignes directrices de la SCPH et des normes de l'USP. Un faible taux d'observance était particulièrement remarquable en matière d'installations et d'équipement, de validation de la procédure et de contrôle des produits. L'accès à une salle blanche de classe 8 ou supérieure selon l'Organisation internationale de normalisation (ISO) dans la pharmacie centrale est une exigence du chapitre <797>, mais plus de 40 % des répondants ont déclaré ne pas disposer d'une telle salle. De meilleurs taux d'observance ont été notés au chapitre des politiques et procédures, des vêtements de protection, des techniques aseptiques et de la manipulation des produits dangereux. La première partie de cette série décrit la méthodologie du sondage et les résultats concernant les politiques, le personnel, les matières premières, l'entreposage et la manipulation, les installations et l'équipement, et les vêtements. La deuxième partie traitera des résultats portant sur la préparation des produits aseptiques, l'attribution de la date de péremption, l'étiquetage, la validation de la procédure, le contrôle et la délivrance des produits, les registres, et l'élimination des produits pharmaceutiques dangereux. Elle soulignera aussi certains des domaines clés qui méritent une attention considérable.

Key words: chapter <797>, sterile compounding, aseptic technique

Conclusion : Ce sondage a mis au jour de nombreuses lacunes dans les pratiques de préparation des produits stériles dans les pharmacies hospitalières au Canada. La sensibilisation à ces lacunes pourrait donner l'élan nécessaire à une évaluation critique et à des améliorations de la pratique.

Mots clés : chapitre <797>, préparation de produits stériles, techniques aseptiques

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INTRODUCTION

As illustrated by a large and ever-growing number of reports, poor aseptic compounding practices may result in significant patient morbidity and mortality.[1-8] For the past decade, the 1996 G*uidelines for Preparation of Sterile Products in Pharmacies* of the Canadian Society of Hospital Pharmacists (CSHP)[9] have served as the standard of practice for the preparation of sterile admixtures in Canadian hospital pharmacies. These guidelines provide recommendations that pharmacists and their organizations can use to safely guide sterile compounding practices.

Unfortunately, current compliance with the CSHP guidelines is unknown. One study that evaluated sterile compounding practices in Canada before 1993 revealed substantial variation in practices across the country, with a significant proportion of facilities reporting inadequately trained personnel and suboptimal sterile compounding practices.[10] No subsequent studies of this type have been conducted in Canada, and therefore data are lacking to indicate what impact, if any, the 1996 CSHP guidelines have had on aseptic compounding practices in this country. However, evidence from the United States indicates that voluntary implementation of guidelines has had little effect on the quality of sterile compounding practices in that country.[11-13] Like the 1993[14] and 2000[15] guidelines of the American Society of Health-System Pharmacists (ASHP), the 1996 CSHP *Guidelines for Preparation of Sterile Products in Pharmacies*[9] do not constitute a legal or accreditation requirement. In addition, the content of the ASHP and CSHP guidelines have many similarities. As such, there is little reason to expect that widespread, comprehensive adoption of the 1996 CSHP guidelines has occurred in Canada.

In January 2004, the United States Pharmacopeia (USP) published the first mandatory, enforceable standard relating to the compounding of sterile preparations ("General Chapter <797> Pharmaceutical Compounding—Sterile Preparations").[16] The requirements in these standards are more demanding than recommendations in previous guidelines and are now used by the Joint Commission (formerly the Joint Commission on the Accreditation of Healthcare Organizations) for surveying hospitals.[17] A recent study has shown that chapter <797> is having a significant impact on sterile compounding practices in the United States.[18]

In light of the institution of new standards in the United States and the historically ineffective nature of voluntary guidelines, it is likely that some form of enforceable sterile compounding standards similar to those in the United States will soon be introduced in Canada. The aim of the survey described in this 2-part series (conducted in conjunction with CSHP), was to determine the extent of compliance of Canadian hospital pharmacies with current CSHP and USP chapter <797> standards of practice for the preparation of sterile products. The current article provides methodologic details and results for 6 categories of requirements (policies, personnel, raw materials, storage and handling, facilities and equipment, and garments). The second article[19] will present results for 8 additional categories of requirements (preparation of aseptic products, expiry dating, labelling, process validation, product testing and release, documentation, records, and disposal of hazardous pharmaceuticals), and will highlight some of the areas where there is opportunity for improving sterile compounding practices.

METHODS

Survey Design

The CSHP guidelines,[9] USP chapter <797>,[16] the ASHP guidelines,[14,15] and the ASHP self-assessment tool[20] for determining compliance with USP chapter <797> were used to identify the sterile compounding practices that would be assessed in the current survey. Survey questions were modelled on those in previous Canadian and US studies evaluating compliance with sterile compounding recommendations.[10-13] The version of the survey sent to respondents did not indicate the standard or standards to which each question was related, but the investigators' version of the survey did contain this

information, for analysis purposes. The survey was initially field-tested with regional pharmacy managers of the Winnipeg Regional Health Authority, was modified on the basis of their feedback, and was subsequently used in a pilot study of 9 hospitals within the regional health authority.[21] The survey was further modified on the basis of the results of the pilot study and additional comments and suggestions received thereafter from practitioners consulted by CSHP. The final version of the survey was then formatted within online survey software (SurveyMonkey.com, Portland, Oregon).

Study Sample

An e-mail message with an embedded link to the survey was sent to hospital pharmacy managers practising in all Canadian acute care hospitals with at least 50 acute care beds and at least 100 beds in total (both acute and non-acute care) in January 2007. The message included a covering letter from CSHP, which described the reasons for the survey and requested the recipient's participation in the study. Respondents were tracked by comparing the e-mail addresses through which they accessed the online survey against the list of e-mail addresses to which the initial invitation had been sent. Reminder e-mail messages were sent at 1-week intervals to potential respondents who had not completed the survey.

Data Collection

Survey responses were recorded and tabulated automatically by the survey software. The survey was officially closed to respondents 4 weeks after the initial distribution.

Data Analysis

The investigators accessed the survey data through the survey host website. Descriptive statistics were assembled using online data analysis software (SurveyMonkey.com).

RESULTS

Characteristics of Responding Hospitals

A total of 133 hospitals responded to the survey, for a 68.9% response rate. The criteria used to establish the initial distribution list for this study were identical with those of the 2005/2006 Hospital Pharmacy in Canada survey,[22] the number of surveys circulated by the 2 studies was similar (190 and 193, respectively), and the number of respondents was also similar (133 and 142, respectively). The report of the 2005/2006 Hospital Pharmacy in Canada survey stated that its respondents represented over half of the total hospital beds in Canada,[22] and it is therefore probable that the current survey similarly represented a large and representative sampling of the Canadian hospitals that were eligible to participate in the survey.

All respondents indicated that their pharmacies prepared sterile products. Two respondents answered only the first question on the survey, regarding sterile product preparation, and failed to complete the rest of the survey; these 2 surveys were excluded from further analysis. Forty-five of the respondents were from hospitals with fewer than 200 beds, 64 were from facilities with 200 to 500 beds, and 22 were from facilities with more than 500 beds (Table 1). Of the 127

Table 1. Sterile Admixture Practices by Hospital Size

	Hospital Size; No. (%) of Respondents*			
Practice	**All Hospitals**	**< 200 Beds**	**200–500 Beds**	**> 500 Beds**
Preparation of sterile products	131 (100)	45 (100)	64 (100)	22 (100)
Approximate % of sterile admixtures prepared by disciplines other than pharmacy	(*n* = 124)	(*n* = 45)	(*n* = 58)	(*n* = 21)
0–25	42 (33.9)	13 (29)	21 (36.2)	8 (38)
25–50	31 (25.0)	10 (22)	14 (24.1)	7 (33)
50–75	29 (23.4)	9 (20)	15 (25.9)	5 (24)
75–100	22 (17.7)	13 (29)	8 (13.8)	1 (5)
No response	7	NA	6	1
No. of sterile products made per day	(*n* = 127)	(*n* = 45)	(*n* = 63)	(*n* = 21)
<10	16 (12.6)	14 (31)	2 (3.2)	0 (0)
10–100	52 (40.9)	23 (51)	27 (42.9)	3 (14)
101–500	50 (39.4)	7 (16)	32 (50.8)	12 (57)
>500	9 (7.1)	1 (2)	2 (3.2)	6 (29)
No response	4	NA	1	1

*Percentages are calculated using number of responses as the denominator (i.e., excluding surveys with no response for the particular question).

respondents who provided data on the number of sterile products produced in their pharmacies per day, 16 (12.6%) indicated that their pharmacies produced fewer than 10 sterile products per day, 52 (40.9%) reported preparing 10 to 100 sterile products per day, 50 (39.4%) reported preparing 101 to 500 products per day, and 9 (7.1%) prepared more than 500 sterile products per day (Table 1). Fifty-one (41.1%) of 124 respondents reported that professions other than pharmacy prepared 50% or more of sterile products (Table 1). There was a slight trend toward greater nonpharmacy involvement in sterile admixture preparation in smaller hospitals (fewer than 200 beds) than in larger hospitals (200 beds or more). The respondents were located mainly in Ontario and Quebec, with some respondents in all of the other provinces, but no responses from any of the territories (Table 2).

Of the 118 respondents reporting the involvement of pharmacy staff in sterile compounding, 21 (17.8%) indicated that pharmacists routinely compound sterile products prepared for immediate dispensing; only 3 (2.5%) indicated that pharmacists routinely compound batch products. In contrast, 29 (24.6%) of respondents reported technician involvement in sterile product preparation for immediate dispensing with certain limitations on what products the technicians could prepare, and 86 (72.9%) reported technician involvement in sterile product preparation for immediate dispensing without any limitations. These numbers were similar to those for technician involvement in batch preparation: 32 (27.1%) of respondents reported technician involvement with limitations, and 87 (73.7%) reported technician involvement without limitations.

The most frequently reported types of sterile products prepared by respondents were antineoplastics (121/130 or 93.1%), total parenteral nutrition products and IV antibiotics (each 113/130 or 86.9%), and IV analgesics (103/130 or 79.2%) (Table 3). Thirty-one sites (23.8%) reported preparing "other" products (i.e., not specifically listed in the survey), such as solutions for sterile bladder instillation, solutions for intrathecal administration, and sterile talc for pleurodesis.

Table 2. Response Rate by Province or Territory

Province or Territory	No. (%) of Respondents (*n* = 131)	
British Columbia	16	(12.2)
Alberta	14	(10.7)
Saskatchewan	4	(3.1)
Manitoba	7	(5.3)
Ontario	45	(34.4)
Quebec*	29	(22.1)
Nova Scotia	6	(4.6)
New Brunswick	6	(4.6)
Newfoundland	2	(1.5)
Prince Edward Island	2	(1.5)
Northwest Territories, Yukon Territory, Nunavut	0	(0)

*Some of the results for the 29 survey respondents from Quebec were published previously.[23]

Table 3. Types of Sterile Admixtures Prepared

Type of Sterile Admixture	No. (%) of respondents (*n* = 130)	
Antineoplastics	121	(93.1)
Total parenteral nutrition	113	(86.9)
Epidural analgesic solutions	99	(76.2)
Other epidural solutions	35	(26.9)
IV antibiotics	113	(86.9)
IV analgesics	103	(79.2)
Subcutaneous products	78	(60.0)
Ophthalmic and otic products	95	(73.1)
Sterile nebulizer solutions	19	(14.6)
Large-volume parenteral solutions (e.g., KCl)	85	(65.4)
Dialysate solutions	11	(8.5)
Irrigation solutions	34	(26.2)
Other*	31	(23.8)

*Includes sterile solutions for bladder instillation, solutions for intrathecal administration, and sterile talc for pleurodesis.

Comparison of Survey Results with 1996 CSHP Guidelines and USP Chapter <797>

Policies and Procedures

Summary of CSHP Guidelines and USP Chapter <797>

Both the CSHP guidelines and USP chapter <797> require the presence and maintenance of up-to-date policies and procedures at sites where compounded sterile preparations are produced. CSHP recommends that these policies and procedures be available to everyone involved in the production of compounded sterile preparations, and that policies and procedures be reviewed, revised, and updated at least annually. Chapter <797> requires, more generally, that policies, procedures, and operational guidance be maintained, communicated, and adhered to by all personnel responsible for compounding sterile preparations. It also recommends an ongoing, systematic program for monitoring, evaluating, correcting, and improving all activities associated with compounded sterile preparations. Table 4 summarizes the aspects of sterile compounding that policies and procedures should address, as set out in the CSHP guidelines.[9]

Survey Results

Nearly 90% (110/124 or 88.7%) of respondents indicated that their institutions had written policies and procedures governing the preparation of sterile products. Of these, 97.3% (107/110) indicated that the policies and procedures were

readily available to all pharmacy staff who participated in sterile compounding. A total of 89.1% of respondents (98/110) indicated that all staff participating in sterile compounding are required to read their respective sites' policies and procedures as part of their orientation, and 63.9% (69/108) reported that staff are required to review these policies regularly (for 54% [25/46] of these, this review occurs annually). Almost three-quarters of respondents (78/109 or 71.6%) reported that their policies and procedures are updated less frequently than every 2 years. The areas covered by the policies and procedures of responding sites generally matched the CSHP recommendations,[9] except for testing and release of end products (38/108 or 35.2%) and process validation (57/108 or 52.8%) (Table 4). Only 27.3% (27/99) of respondents reported the existence of a formal system to monitor, evaluate, correct, and improve activities associated with preparing sterile products.

Table 4. Policies and Procedures Related to Preparation of Sterile Admixtures*

Areas Covered by Policies and Procedures	No. (%) of Respondents (*n* = 108)	
Training and knowledge requirements	97	(89.8)
Storage and handling requirements for raw materials and finished products	89	(82.4)
Facilities, equipment, sanitation	96	(88.9)
Garment requirements	98	(90.7)
Techniques for preparation of aseptic products	100	(92.6)
Expiry dating (beyond-use dating)	91	(84.3)
Labelling	99	(91.7)
Process validation	57	(52.8)
Testing and release of end products	38	(35.2)
Documentation	78	(72.2)

*As specified in the guidelines of the Canadian Society of Hospital Pharmacists.[9]

Personnel

Summary of CSHP Guidelines and USP Chapter <797>

CSHP recommends that a pharmacist with sufficient training and/or expertise be assigned responsibility for overseeing sterile production operations. Pharmacy personnel who prepare sterile products must receive adequate orientation; must undergo suitable didactic and experiential training in aseptic techniques, proper gowning and gloving, and clean room procedures; and must demonstrate competence through written and practical testing. Furthermore, regular, ongoing training programs and evaluations should be available to all personnel to ensure maintenance of expertise in sterile product preparation. CSHP also recommends that the aseptic technique of personnel involved in producing compounded sterile preparations be evaluated, at least annually, through direct observation, media fill testing, or microbiological monitoring of work surfaces. Chapter <797> states that personnel must be oriented and trained and must demonstrate competency in compounding sterile preparations (including hazardous drugs) and in packaging and labelling the resulting preparations. Chapter <797> also states that pharmacy staff must perform a didactic review and pass written and media-fill validation testing of aseptic technique, at least annually for those involved in preparing low- to moderate-risk compounded sterile preparations and at least semiannually for those involved in preparing high-risk compounded sterile preparations.

Survey Results

The survey results indicated a substantially greater level of formal training in sterile compounding for pharmacy technicians than for pharmacists (Table 5). Roughly half of respondents indicated that pharmacists received training in each of the areas listed in Table 5, with the exception of operation and procedures for automated compounding devices, for which only 14.2% (16/113) reported formal training for pharmacists. Nearly all respondents reported high levels of compliance with the requirement for formal training of pharmacy technicians in every area listed in Table 5, with the exception of operation and procedures for automated compounding devices, for which only 51.3% (58/113) indicated formal training for pharmacy technicians. Seventy (60.9%) of 115 respondents reported that a designated individual was responsible for the training and evaluation of all pharmacy staff members involved in preparing sterile products. Lectures or videotapes, review of written policies and procedures, and supervised laboratory exercises were the most commonly used training and testing methods reported for both pharmacists and technicians. A total of 51 (44.3%) of 115 respondents reported a requirement that staff undergo regular refresher programs and/or evaluations related to sterile product policies and procedures. Nearly two-thirds (33/51 or 64.7%) of these respondents reported the use of annual evaluations, and roughly half of them (25/51 or 49.0%) reported annual refresher training programs.

Raw Materials

Summary of CSHP Guidelines and USP Chapter <797>

CSHP states that any raw materials (i.e., materials that are not finished sterile pharmaceuticals obtained from a licensed manufacturer) require further testing to determine the content of each lot before they are used in the production of compounded sterile preparations. Nonsterile raw materials that are not compendial grade (USP, British Pharmacopoeia, etc.)

Table 5. Formal Training of Staff Members

Area of Formal Training*	Staff Group Receiving Training; No. (%) of Respondents (*n* = 113)			
	Pharmacists		Pharmacy Technicians	
Aseptic technique	64	(56.6)	111	(98.2)
Proper gowning and gloving	70	(61.9)	109	(96.5)
Clean room procedures	56	(49.6)	103	(91.2)
Packaging, handling, and transporting sterile preparations†	50	(44.2)	101	(89.4)
Labeling sterile preparations†	64	(56.6)	106	(93.8)
Measuring, mixing, and diluting ingredients (in correct sequence)†	48	(42.5)	101	(89.4)
Preparing antineoplastics and other hazardous products	48	(42.5)	103	(91.2)
Operation of and procedures for automated compounding devices	16	(14.2)	58	(51.3)
Operating principles and procedures for laminar airflow hood	52	(46.0)	106	(93.8)
Handling and disposing of hazardous pharmaceuticals	64	(56.6)	107	(94.7)

*Included in guidelines of the Canadian Society of Hospital Pharmacists,[9] except where indicated otherwise.
†Included in United States Pharmacopeia chapter <797>.[16]

or better must either be validated by a vendor's certificate of analysis for each lot or be quarantined and assayed by a competent laboratory before being used in the preparation of compounded sterile preparations. Chapter <797> similarly states that pharmacists must verify that nonsterile components meet USP standards for identity, purity, and endotoxin levels before being used in compounded sterile preparations. Non-official ingredients used in compounded sterile preparations must be accompanied by certificates of analysis from their suppliers indicating identity, quality, and purity. USP also recommends that products be tested for sterility, pyrogens, and potency before release.

Survey Results

Thirty-one (27.0%) of 115 respondents reported using nonsterile raw materials in the preparation of sterile products. About two-thirds of respondents (15/23 or 65%) reported using the vendor's certificate of analysis as the means of validating the identity, purity, and potency of each lot of non–compendial-grade, nonsterile raw materials; the remainder used laboratory assays or did not validate the material. Twenty-five (81%) of 31 respondents reported that preliminary preparation of nonsterile raw materials (measuring, handling, weighing, and dissolving) occurred outside the clean room. Testing of final products for sterility, pyrogens, and potency was reported by 29% (9/31), 16% (5/31), and 3% (1/31) of respondents, respectively. Nineteen (61%) of 31 respondents indicated that preliminary preparation of components occurs in an area where equipment and work surfaces are cleaned and disinfected, generally on a daily basis. Expiry dates for products prepared from nonsterile raw materials (see Table 6) were reported to be based on product stability data from published literature references by 64% of respondents (14/22); 45% of respondents (10/22) reported using stability as reported from another IV admixture program (i.e., unpublished data), and 27% (6/22) assigned an arbitrary expiry date.

Storage and Handling

Summary of CSHP Guidelines and USP Chapter <797>

Table 7 summarizes the storage and handling conditions recommended in the CSHP guidelines for all components used in compounded sterile preparations. Chapter <797> includes provisions that items must be stored according to manufacturer or USP requirements. Packing materials must maintain the physical integrity, sterility, and stability of products, and all sterile products that are not immediately administered or dispensed should be stored in the refrigerator, unless otherwise specified by the manufacturer of the raw material. For compounded sterile preparations prepared for outpatient use, staff must select appropriate modes of transport, periodically review the delivery performance of couriers, and ensure that each patient or other recipient is able to store the compounded sterile preparations properly. Also, labels must have clearly readable expiry dates, and storage and disposal instructions.

Survey Results

For 4 of the 5 recommendations listed in Table 7, a large majority of the 112 respondents (94 [83.9%] to 103 [92.0%])

Table 6. Expiry Dating of Sterile Products Produced with Nonsterile Raw Materials

Expiry Dating*	No. (%) of Respondents	
Storage at room temperature (*n* = 27)		
24 h or less	11	(41)
>24 h	7	(26)
No storage at room temperature	9	(33)
Refrigerated (2°C to 8°C) (*n* = 24)		
<3 days or less	7	(29)
>3 days	11	(46)
No refrigerated storage	6	(25)
Frozen storage (–20°C or colder) (*n* = 23)		
<45 days or less	2	(9)
>45 days	2	(9)
No frozen storage	19	(83)

*Included in United States Pharmacopeia chapter <797>.[16]

reported meeting the recommendation. A lower proportion of respondents (79/112 or 70.5%) reported ensuring that storage containers in which sterile products are packaged are not interactive with, and are appropriately protective of, the sterile products they contain. A total of 96 (85.0%) of 113 respondents indicated that sterile products that are not immediately dispensed or administered, and that are not adversely affected by cold temperatures, are immediately stored in a refrigerator following preparation. Fifty-one (44.7%) of 114 respondents reported transporting sterile products outside of their facilities. Of these, nearly all reported that the packing containers and modes of transport were selected to appropriately maintain the overall integrity of the sterile products, and that labels were verified to ensure that they included clearly readable expiry dates as well as storage and disposal instructions. Slightly more than one-third of respondents reported periodically evaluating courier performance. About three-quarters of respondents (41/57 or 71.9%) reported preparing sterile products for use in the home setting. Of these, 87.5% (35/40) reported ensuring that the patients receiving the products were able to properly store them (i.e., had working refrigerators or freezers, as appropriate).

Facilities and Equipment

Summary of CSHP Guidelines and USP Chapter <797>

CSHP recommends that sterile products be prepared in an aseptic preparation area that is designed and maintained in a manner that minimizes microbial and particulate contamination. Specific air quality requirements for the aseptic preparation area are not listed in the guidelines; however, the guidelines do recommend use of a Federal Standard 209E class 100[24] (International Organization for Standardization [ISO] class 5[25]) laminar airflow hood for sterile compounding and also recommend that the laminar airflow hood should be run continuously. If not run continuously, the hood should be run for at least 30 min before use or as specified by the manufacturer. Chapter <797> similarly requires that sterile compounding activities take place in an ISO class 5 environment (i.e., horizontal or vertical laminar airflow hood, class II or III biological safety cabinet, or barrier isolator), but goes further, by requiring that the equipment be located in a buffer zone or buffer room (i.e., clean room) that meets ISO class 8 clean room standards. High-efficiency particulate air (HEPA) filters are listed as a necessity for the clean room, as are humidity control and air conditioning. The presence and use of an anteroom or ante-area are also recommended by CSHP and required by chapter <797>. The CSHP guidelines, while not requiring the presence of clean room facilities, include the specifications necessary for "clean room" designation, including Federal Standard 209E class 100 000 or better (ISO class 8 or better) air quality and the presence of anterooms and changing areas.

Both CSHP and chapter <797> state that floors, walls or partitions, and ceilings of the aseptic preparation area must be

Table 7. Storage and Handling Procedures*

Procedure	No. (%) of Respondents (*n* = 112)	
Items received are inspected for expiry date, contamination, or damage	95	(84.8)
Storage under conditions that ensure cleanliness	103	(92.0)
Storage under conditions that allow for easy inspection and rotation	99	(88.4)
Items removed from outer shipping cartons before introduction into aseptic preparation area	94	(83.9)
Containers in which sterile products are packaged do not interact with the products they contain, and protect the sterility and chemical and physical integrity of the products	79	(70.5)

*As presented in guidelines of the Canadian Society of Hospital Pharmacists.[9]

nonporous and washable. All smooth, exposed surfaces should be impervious and unbroken, to minimize shedding and accumulation of particles and microorganisms. Sinks and drains should not be present in the aseptic preparation area. Chapter <797> also describes a number of restrictions regarding clean rooms and anterooms or ante-areas. Only furniture, equipment, supplies, and other goods required for the tasks to be performed are to be brought into the buffer zone or room. Objects that shed particles should not be permitted in the clean room. Carts used to supply the anteroom or ante-area should not cross the demarcation line in the anteroom or ante-area, and carts used in the clean room must not be removed unless cleaned and sanitized before being returned. Hand-washing and gowning should occur in the anteroom or ante-area.

The CSHP guidelines state that work surfaces should be cleaned daily and before each product sequence. Floors in the clean room and anteroom areas should be cleaned daily, adjacent work surfaces such as shelves, tables, and stools should be cleaned weekly, and ceilings and walls should be cleaned monthly or as required to maintain cleanliness. Both USP chapter <797> and CSHP recommend that laminar airflow hoods be disinfected before starting sterile product preparation each day and between product sequences. CSHP also recommends that laminar airflow hoods be cleaned after being powered on. The guidelines also include recommendations on appropriate methods for waste removal. USP chapter <797> recommends daily floor cleaning, weekly cleaning of anterooms and shelving, and daily removal of trash. USP chapter <797> also states that floor cleaning should not occur while aseptic compounding is in progress, and that floor cleaning should start in the aseptic preparation area and proceed out to the anteroom. CSHP and USP chapter <797> both make reference to the disinfectants used within the aseptic compounding area. Disinfectants should be chosen after consideration of compatibilities, effectiveness, and the presence of inappropriate residues. Also, a facility should reserve certain cleaning tools for use exclusively within the aseptic preparation area. CSHP recommends that partially empty bottles of disinfectant should not be topped up and that sites should have procedures in place to ensure that waste is removed regularly.

Survey Results

Twenty-six (27.1%) of 96 respondents reported that their facilities did not have a clean room in the central pharmacy, and 16 (16.7%) reported that the clean room in the central pharmacy was "less than ISO class 8" (i.e., lower standard than class 8) (Table 8). The total percentage of respondents without a compliant clean room in the central pharmacy was therefore 43.8%. Twenty-three (24.0%) respondents reported an ISO class 8 clean room and 31 (32.3%) reported an ISO class 1 to 7 clean room (i.e., meeting a higher standard than class 8), for a total of 56.3% with a compliant clean room (Table 8). Twenty-nine (29.6%) of 98 sites reported no air filtration in the central pharmacy's clean room. Of these, 19 (66%) also indicated the presence of an ISO class 8 clean room in the central pharmacy, which would, by definition, require the presence of HEPA filtration. Similarly contradictory responses were noted for the presence of HEPA filtration in oncology IV preparation areas. The number of respondents reporting a class 1 to 7 clean room in the central pharmacy was also higher than expected, which may suggest confusion on the part of respondents between the environment within the hoods they use (ISO class 5) and the environment within the clean room itself. Overall, these results suggest that a number of the respondents lacked a solid understanding of the terminology used to describe air handling and filtration requirements for clean rooms.

Roughly half of the respondents indicated the presence of an anteroom in the central pharmacy and oncology IV preparation area (Table 8). Slightly more than one-third had no anteroom or ante-area in these locations, and the remainder had only ante-areas (Table 8), with the exception of 2 respondents, who reported both an anteroom and an ante-area. The work surfaces used in central pharmacy preparation areas consisted of horizontal laminar airflow hoods, vertical laminar airflow hoods, and/or biological safety cabinets, with 100% of respondents reporting the use of one or more of these devices. Biological safety cabinets accounted for a large majority of work surfaces for oncology IV preparation areas (Table 8). Among the few respondents who reported on the work surfaces used in satellite pharmacies, 79% (11/14) indicated the use of horizontal and/or vertical laminar airflow hoods, and 29% (4/14) indicated the presence of biological safety cabinets.

Contrary to recommendations, more than half of respondents reported the presence of sinks and/or drains in the aseptic preparation areas of central pharmacies (47/81 or 58.0%) and oncology IV preparation areas (37/69 or 53.6%). Procedures for the use and maintenance of sinks were in place for only 22.2% (18/81) of central pharmacies and 26.1% (18/69) of oncology IV preparation areas. A majority of sites were compliant with USP requirements relating to furniture, equipment, and supplies. Thirty-three (40.2%) of 82 respondents reported the presence of refrigerators and/or freezers in the clean room in the central pharmacy. Greater proportions reported the presence of such equipment in oncology and satellite pharmacy areas (Table 8). More than half of respondents reported compliance with recommendations regarding particle-shedding objects in central pharmacies and oncology IV preparation areas, but only 17% (2/12) reported compliance in satellite pharmacies (Table 8). Relatively few sites were compliant with recommendations regarding the cleaning and disinfection of carts (Table 8). Forty-six (96%)

Table 8. Compounding Facilities and Equipment

Compounding Facilities and Equipment*	Hospital Area; No. (%) of Respondents Reporting Compliance		
	Central Pharmacy	IV Prep Areas (Oncology)	Satellite Pharmacies
Clean room	(*n* = 96)	(*n* = 82)	(*n* = 18)
No clean room	26 (27.1)	24 (29.3)	12 (67)
ISO class 3–7 clean room (i.e., higher standard than class 8)	31 (32.3)	22 (26.8)	3 (17)
ISO class 8 clean room	23 (24.0)	23 (28.0)	1 (6)
Lower standard than ISO class 8 clean room	16 (16.7)	13 (15.9)	2 (11)
Anteroom area	(*n* = 90)	(*n* = 77)	(*n* = 17)
Use of anteroom	46 (51.1)	36 (46.8)	3 (18)
Use of ante-area	10 (11.1)	10 (13.0)	1 (6)
No anteroom or ante-area	34 (37.8)	31 (40.3)	13 (76)
Air filtration in clean room	(*n* = 98)	(*n* = 84)	(*n* = 12)
No air filtration	29 (29.6)	21 (25.0)	9 (75)
HEPA filtered air circulated within room†	45 (45.9)	43 (51.2)	3 (25)
Humidity control for air circulated within room†	22 (22.4)	14 (16.7)	0 (0)
Other	2 (2.0)	6 (7.1)	0 (0)
Work surface	(*n* = 104)	(*n* = 90)	(*n* = 14)
Clean surface	14 (13.5)	10 (11.1)	1 (7)
Horizontal laminar airflow hood (ISO class 5)	54 (51.9)	2 (2.2)	5 (36)
Vertical laminar airflow hood (ISO class 5)	52 (50.0)	16 (17.8)	6 (43)
Biological safety cabinet (class II/III)†	35 (33.7)	75 (83.3)	4 (29)
Barrier isolator	3 (2.9)	5 (5.6)	0 (0)
Environment	(*n* = 81)	(*n* = 69)	(*n* = 4)
Floors, walls, partitions, and ceilings are nonporous and washable	49 (60.5)	49 (71.0)	1 (25)
All smooth surfaces are impervious and unbroken	49 (60.5)	44 (63.8)	2 (50)
Sinks and drains present in aseptic preparation area	47 (58.0)	37 (53.6)	3 (75)
Procedures in place for use and maintenance of sinks	18 (22.2)	18 (26.1)	2 (50)
Restrictions and other	(*n* = 82)	(*n* = 77)	(*n* = 12)
Area contains only furniture, equipment, and supplies necessary for tasks to be performed	73 (89.0)	62 (80.5)	7 (58)
Refrigerator and/or freezer available for storage of supplies and products	33 (40.2)	46 (59.7)	9 (75)
Particle-shedding objects not brought into clean room†	48 (58.5)	43 (55.8)	2 (17)
Carts cleaned and disinfected before they are brought into clean room†	36 (43.9)	31 (40.3)	2 (17)
Clean room has demarcation line that must not be crossed by cart†	7 (8.5)	9 (11.7)	2 (17)

HEPA = high-efficiency particulate air, ISO = International Organization for Standardization.
*Included in guidelines of the Canadian Society of Hospital Pharmacists,[9] except where indicated otherwise.
†Included in United States Pharmacopeia chapter <797>.[16]

of 48 respondents reported that hand-washing, gowning, and gloving occur in the anteroom in central pharmacy areas, compared to 84% (32/38) in oncology IV preparation areas with anterooms, and 100% (4/4) in satellite pharmacies with anterooms.

A total of 75.0% (75/100) of respondents reported cleaning the floors of the clean room daily, and 20.0% (20/100) reported weekly cleaning. The remainder cleaned their clean room floors monthly or less frequently than monthly (Table 9). Fifty-eight (82.9%) of 70 respondents reported cleaning anteroom floors daily, and 12.9% (9/70) reported weekly cleaning. Three (4.3%) reported cleaning anteroom floors less frequently than monthly. Seventy-one (67.0%) of 106 respondents indicated that they had standardized floor-cleaning procedures. Of those with standardized floor-cleaning procedures, 64 (90.1%) stated that floor cleaning did not occur when aseptic compounding was in progress, and 48 (67.6%) reported that floor cleaning began in the clean room and proceeded to the anteroom.

For central pharmacy areas, 93.0% of respondents (80/86) reported "always" cleaning and disinfecting laminar airflow hoods after turning them on, whereas 4.7% (4/86) reported "never" doing this (Table 10). One hundred and one (98.1%) of 103 respondents reported always cleaning and disinfecting their hoods before work each day. Only 52.7% (49/93)

Table 9. Frequency of Cleaning and Disinfection

Frequency of Disinfection*	Item Disinfected or Cleaning Activity; No. (%) of Respondents				
	Floors	Counters and Work Surfaces	Ceilings and Walls	Trash Collection	Storage Shelving
In aseptic preparation area and clean room	(*n* = 100)	(*n* = 99)	(*n* = 96)		
Daily	75 (75.0)	81 (81.8)	2 (2.1)		
Weekly	20 (20.0)	12 (12.1)	8 (8.3)		
Monthly	1 (1.0)	3 (3.0)	28 (29.2)		
> Monthly	4 (4.0)	2 (2.0)	30 (31.3)		
Not done	0 (0)	1 (1.0)	28 (29.2)		
In anteroom or ante-area†	(*n* = 70)	(*n* = 73)	(*n* = 69)		
Daily	58 (82.9)	48 (65.7)	1 (1.4)		
Weekly	9 (12.9)	19 (26.0)	5 (7.2)		
Monthly	0 (0)	3 (4.1)	19 (27.5)		
> Monthly	3 (4.3)	1 (1.4)	22 (31.9)		
Not done	0 (0)	2 (2.7)	22 (31.9)		
In aseptic preparation area, anteroom, ante-area, clean room				(*n* = 102)	(*n* = 99)
Daily				94 (92.2)	19 (19.2)
Weekly				6 (5.9)	8 (8.1)
Monthly				1 (1.0)	21 (21.2)
> Monthly				1 (1.0)	39 (39.4)
Not done				0 (0)	12 (12.1)

HEPA = high-efficiency particulate air, ISO = International Organization for Standardization.
*Included in guidelines of the Canadian Society of Hospital Pharmacists,[9] except where indicated otherwise.
†Included in United States Pharmacopeia chapter <797>.[16]

indicated that hoods are always cleaned and sanitized before each product sequence is begun in the central pharmacy. Forty-nine (53.8%) of 91 respondents reported always cleaning and sanitizing the laminar airflow hood after completion of each batch product sequence. The proportions were similar for laminar airflow hoods located in satellite pharmacy areas (Table 10).

Sixty-six (63.5%) of 104 respondents indicated that the choice of disinfectants and detergents was outside the control of the pharmacy department (i.e., the decision was up to infection control, housekeeping, logistics, or another department). Another 38 (36.5%) reported choosing disinfectants and detergents on the basis of compatibilities, effectiveness, and residues. The remaining respondents indicated that the decision was either made on a hospital-wide level with input from pharmacy and other areas, on the basis of guidelines set by the Alberta Cancer Board pharmacy, or was based on USP recommendations. Only 50 (47.6%) of 105 respondents indicated that there were cleaning tools, such as wipers, sponges and mops, designated to be used only in the clean room. A majority of sites (62/104 or 59.6%) reported that their facilities regularly topped up detergent or disinfectant bottles when partially empty, contrary to recommendations. Ninety-three (87.7%) of 106 respondents reported the existence of procedures to dispose of waste such as needles, bottles, vials, or other supplies from the aseptic preparation area.

Garments

Summary of CSHP Guidelines and USP Chapter <797>

CSHP recommends that closed gowns or coats and hair and facial hair coverings be worn inside the aseptic preparation area and removed upon exiting the area. When working within the critical area (i.e., within a laminar airflow hood or biological safety cabinet), gloves are recommended; a mask is recommended if there is no vertical glass barrier. Foot coverings should be worn within the clean room. It is also recommended that cosmetics and jewellery be removed before entering the aseptic preparation area. USP chapter <797> contains similar restrictions and also recommends the use of eye protection if there is no vertical glass barrier.

Survey Results

In central pharmacy areas, 69.9% of respondents (72/103) reported that staff were required to remove certain garments before entering the preparation area. One hundred (97.1%) of 103 respondents reported that there were approved gowns or outer garments that had to be worn in the preparation area of the central pharmacy. Similar garbing requirements were reported for oncology preparation areas, but lower percentages of respondents reported having these garment requirements in place in their satellite pharmacies. In addition, 31.1% (32/103)

Table 10. Frequency of Cleaning of Laminar Airflow Hood

Frequency of Cleaning*	Type of Pharmacy; No. (%) of Respondents	
	Central pharmacies	Satellite pharmacies
When hood is turned on	(*n* = 86)	(*n* = 30)
Always	80 (93.0)	29 (97)
Sometimes	2 (2.3)	0 (0)
Never	4 (4.7)	1 (3)
Before work begins each day	(*n* = 103)	(*n* = 31)
Always	101 (98.1)	31 (100)
Sometimes	1 (1.0)	0 (0)
Never	1 (1.0)	0 (0)
Before each product sequence	(*n* = 93)	(*n* = 27)
Always	49 (52.7)	13 (48)
Sometimes	38 (40.9)	12 (44)
Never	6 (6.5)	2 (7)
Following completion of product sequence	(*n* = 91)	(*n* = 24)
Always	49 (53.8)	12 (50)
Sometimes	38 (41.8)	10 (42)
Never	4 (4.4)	2 (8)

*Included in guidelines of the Canadian Society of Hospital Pharmacists.[9]

Table 11. Garment Restrictions and Requirements

Requirement*	Hospital Area; No. (%) Reporting Requirement		
	Central Pharmacy (*n* = 103)	IV Prep Areas (Oncology) (*n* = 88)	Satellite Pharmacy (*n* = 13)
Approved gowns or outer garments must be worn	100 (97.1)	85 (96.6)	11 (85)
Garments that are restricted must be removed while in the sterile room†	72 (69.9)	64 (72.7)	6 (46)
Mask at all times	67 (65.0)	55 (62.5)	5 (38)
Mask under certain circumstances	34 (33.0)	27 (30.7)	4 (31)
Gloves at all times	93 (90.3)	85 (96.6)	12 (92)
Gloves under certain circumstances	11 (10.7)	4 (4.5)	1 (8)
Jewelry and wristwatch restrictions	93 (90.3)	77 (87.5)	11 (85)
Makeup restrictions	32 (31.1)	25 (28.4)	5 (38)
Hair covers at all times	87 (84.5)	71 (80.7)	7 (54)
Hair covers under certain circumstances	9 (8.7)	9 (10.2)	1 (8)
Leg coverings	29 (28.2)	22 (25.0)	3 (23)
Foot coverings‡	52 (50.5)	44 (50.0)	4 (31)
Eye protection†	19 (18.4)	20 (22.7)	3 (23)
Other	2 (1.9)	1 (1.1)	0 (0)

*Included in guidelines of the Canadian Society of Hospital Pharmacists,[9] except where indicated otherwise.
†Included in United States Pharmacopeia (USP) chapter <797>.[16]
‡Not mentioned in either the guidelines of the Canadian Society of Hospital Pharmacists[9] or USP chapter <797>.[16]

reported makeup restrictions, and 28.2% (29/103), 50.5% (52/103), and 18.4% (19/103) reported restrictions or requirements relating to leg coverings, foot coverings, and eye protection, respectively, in the central pharmacy area (Table 11). The proportions reported for oncology IV preparation areas were similar to those for central pharmacies (Table 11). Most of the respondents who reported on satellite pharmacies indicated the presence of requirements or restrictions similar to those in place in the central pharmacy, the most notable exception being the lower proportions reporting that a mask or hair cover must be worn while compounding sterile products in satellite pharmacy areas (Table 11).

CONCLUSION FOR PART 1

Additional results relating to expiry dating, labelling, process validation, product testing and release, documentation, records, and disposal of hazardous pharmaceuticals will be published in part 2 of this series.[19] The closing discussion will

highlight some of the key areas where there is considerable opportunity for improving sterile compounding practices in Canadian hospital pharmacies.

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