

Inventory of Drug Samples in a Health Care Institution

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ABSTRACT

Background: Few data exist on the presence of drug samples in health care facilities. Although the use of drug samples has potential benefits, this practice is also controversial, as it can contribute to non-optimal drug use. The objective of this study was to evaluate the inventory of drug samples in a health care institution and to determine compliance with existing policies and procedures.

Methods: This descriptive observational study was conducted in a university hospital centre from October 18 to November 1, 2007. A standardized data collection form was used for a physical inventory, which was intended to identify all drug samples available in the institution. The following information was recorded: number of locations where drug samples were found, primary patient care activity performed at each location, number of storage areas in the location, type of storage, presence of a lock, location of the key (if a lock was present), medical specialty, number of physicians and nurses likely to use the samples, reasons given for handing out samples, presence of a designated person to manage the samples, physical inventory (i.e., various details for each distribution unit), and declaration of samples to the pharmacy department. The inventory was conducted by 2 research assistants during day shifts.

Results: A total of 84 locations were included in the inventory, and drug samples were found in 21 locations (with a total of 31 storage areas). All of the locations were intended for ambulatory patients (outpatient clinics and day centres). No drug samples were found in inpatient care units. The drug samples, which came from 62 different pharmaceutical companies, represented a total of 159 generic entities and 266 different brands. Of the distribution units for drug samples that were identified during this inventory, 59% were not on the hospital's local formulary. Furthermore, only 3.5% of the distribution units had been declared to the pharmacy department, in accordance with established policy. The sample distribution units, including expired units, totalled 78 955 doses, with a total value of Can\$48 783 (based on unit prices in effect in October 2007).

Conclusion: This study presents an inventory of drug samples in an urban health care institution and reports compliance with the institution's policies and procedures regarding drug samples. Samples were found only in outpatient clinics and represented 2.4 times the hospital's floor stock of medications. Most of the samples inventoried were not listed on the hospital's formulary. It appears that the use of drug samples is underestimated in hospital settings. Further studies are needed to evaluate the importance of drug samples and the risks associated with their use.

RÉSUMÉ

Contexte : On ne dispose que peu de données sur la présence d'échantillons de médicaments dans les établissements de santé. Bien que l'utilisation des échantillons de médicaments ait des bienfaits potentiels, le recours à ces échantillons est également controversé, car il pourrait contribuer à l'utilisation non optimale des médicaments.

Objectif : Évaluer les stocks d'échantillons de médicaments dans un établissement de santé et déterminer la conformité avec les politiques et procédures de l'établissement.

Méthodes : Une étude d'observation descriptive a été menée dans un centre hospitalier universitaire entre le 18 octobre et le 1^{er} novembre 2007. Un formulaire standardisé de collecte de données a été utilisé pour procéder à l'inventaire matériel de tous les échantillons de médicaments sur place. Les renseignements suivants ont été enregistrés : le nombre d'emplacements où les échantillons se trouvaient, l'activité primaire de soins aux patients réalisée à chaque emplacement, le nombre de points d'entreposage à l'emplacement, le type d'entreposage, la présence d'un dispositif de verrouillage, l'emplacement de la clé (si verrouillage), la spécialité médicale, le nombre de médecins et d'infirmières et infirmiers susceptibles d'utiliser les échantillons, les raisons motivant l'utilisation des échantillons, la présence d'une personne désignée à la gestion des échantillons, les stocks physiques (c.-à-d. divers détails pour chaque unité de conditionnement), et la déclaration des échantillons au service de pharmacie. L'inventaire a été réalisé par deux assistants de recherche durant les quarts de jour.

Résultats : Au total, 84 emplacements ont fait l'objet de l'inventaire et on a trouvé des échantillons de médicaments dans 21 de ces emplacements (avec un total de 31 points d'entreposage). Tous les emplacements étaient destinés aux patients ambulatoires (consultations externes et centres de jour). Aucun échantillon de médicament n'a été retrouvé dans les unités de soins aux patients hospitalisés. Les échantillons de médicaments, qui provenaient de 62 sociétés pharmaceutiques différentes, représentaient en tout 159 entités génériques et 266 marques de commerce différentes. Des unités de conditionnement pour les échantillons de médicaments dénombrées durant l'inventaire, 59 % n'étaient pas sur la liste de médicaments de l'hôpital. De plus, seulement 3,5 % des unités de conditionnement avaient été déclarées au service de pharmacie, conformément aux politiques de l'établissement. Les unités de conditionnement d'échantillons, y compris les unités périmées, totalisaient 78 955 doses, pour une valeur globale de 48 783 \$ (calculée sur le prix unitaire en vigueur en octobre 2007).

Conclusion : Cette étude présente les stocks des échantillons de médicaments dans un établissement de soins de santé urbain et fait état de la conformité avec les politiques et procédures de l'établissement relativement aux échantillons de médicaments. Les échantillons n'ont été retrouvés que dans les cliniques externes et représentaient 2,4 fois les stocks de médicaments au commun de l'hôpital. La plupart des

INTRODUCTION

The distribution of drug samples by the pharmaceutical industry and by physicians and certain other health care professionals is permitted, in certain situations, under Canadian¹ and US² federal laws. In Canada, under the Food and Drugs Act, the distribution of drug samples is generally banned, with certain exceptions allowing physicians, dentists, veterinarians, or pharmacists who are duly registered and authorized to practise their profession in a given province to request drug samples from manufacturers, by specifying the brand name, proper name or usual name, and quantity of a drug to be used as a sample. The pharmaceutical representative who receives such a request may distribute the drug as a sample to the physician, dentist, veterinarian, or pharmacist, if the drug is labelled in accordance with the regulations. In Canada, professional practice falls under provincial jurisdiction, such that the provincial bodies governing each profession may also govern the use of drug samples. In the province of Quebec, both the Collège des médecins du Québec and the Ordre des pharmaciens du Québec (the provincial regulatory bodies for physicians and pharmacists, respectively) condemn the inappropriate use of samples, especially for resale to patients or for personal use, while recognizing their suitability for patients who could not otherwise afford the medications.³

The distribution of drug samples is widespread in Canada and the United States. According to Intercontinental Medical Statistics Health (also known as IMS Health), expenditures for prescription drugs being promoted by the pharmaceutical industry in the United States doubled from US\$12.4 billion in 1998 to US\$25.3 billion in 2003, including US\$16 billion in distributed drug samples.⁴ In a national survey of 3167 US physicians conducted in late 2003 and early 2004, 78% of respondents stated that they had received samples.⁵ In a similar survey in 2001, 92% of responding physicians indicated that they had received drug samples.⁶ In 2000, nearly 800 million drug samples were distributed in the United States, equivalent to 1500 samples per physician.⁷ In a descriptive study of 53 general practitioners in 18 offices, a total of 1588 patient visits were observed, 20% of which involved the distribution of drug samples.⁸

Many reasons are given for physicians distributing drug samples rather than writing prescriptions that would necessitate a visit to the pharmacy.⁹⁻¹² According to physicians and other individuals polled (e.g., medical residents, nurses, pharmacists, participants in medical continuing education, pharmaceutical sale representatives), samples save the patient from having to go to the drugstore; reduce the cost of treatment; allow the patient to gain access to new treatments while allowing the physician to develop clinical experience and use new drugs that may not yet be covered by public or private plans; allow rapid initiation of therapy, which may be needed for clinical reasons; and allow the physician to verify short-term tolerance or efficacy before writing a prescription for the usual duration of therapy. The use of samples may even increase the patient's level of satisfaction.

Distributing samples also has perceived disadvantages.^{9-11,13-15} For example, the distribution of drug samples may jeopardize the continuity of care, especially as the patient's medication record at the retail pharmacy will be incomplete and the pharmacist is unlikely to meet the patient during the course of therapy with drug samples. These omissions can lead to unintended therapeutic duplication, allergic reactions, intolerances or interactions, doses that are too low or too high, use of contraindicated drugs, and missed opportunities to counsel patients. The use of samples by a patient who also has a prescription to be dispensed by a pharmacy can create confusion or may lead to unexpected clinical results or interruption or discontinuation of treatment before the planned course of therapy is complete. Documentation of the distribution of drug samples by physicians varies, with only 9% to 30% of drug samples being recorded in the patient's chart, which makes it difficult to monitor and solve potential pharmacotherapy-related issues.^{16,17} When physicians or nurses distribute samples, they are unable to supply specific instructions to the patient, who may forget the individual dosage or other details about using the medication. Similarly, the packaging of certain samples is unsafe (e.g., can be opened easily by children or may have incomplete or illegible labelling), which may increase the risk of accidental ingestion.¹⁸ Although samples are intended for use by patients, studies have shown that 30% to 54% of samples are handed out to health care staff or are used by pharmaceutical representatives.^{8,19} Finally, there

have been reports of disciplinary decisions against physicians who have engaged in the illegal practice of selling drug samples.²⁰

The management of drug samples in medical offices is not optimal. Pharmaceutical representatives often fill or update medication supplies without completing any written records or periodic documentation. The methods used for disposing of expired samples are unknown, although it is likely that samples are discarded with the regular garbage in some cases, rather than being disposed of safely, as required by pharmacists' codes of practice (by incineration or burial, according to the relevant environmental laws).

Besides the advantages described above, the real justification for drug samples is the desire to influence prescribers and to increase the market share for recently approved products.²¹ No samples are offered for medications that have been on the market for many years, nor are there any generic drug samples. Groves and others⁹ conducted a literature review on the impact of drug samples and gathered more than 15 articles documenting the influence of samples on prescribers' behaviour. They found that of all the resources invested by the pharmaceutical industry in drug promotion, drug samples accounted for more than two-thirds.⁹ The use of drug samples, therefore, has the effect of promoting the sale of medications that are not necessarily first-line agents,^{11,14} the use of brand name drugs rather than generic formulations (which would be less costly for the health care system,^{10,22,23} and the use of medications that are not listed on the local institution's formulary.^{15,24} Although using drug samples may appear to save the health care system and the patient money, the short-term advantages can turn into much higher ongoing costs.^{21,25-27}

Many institutions, including integrated health care management groups (e.g., Puget Sound Health Alliance²⁸) and learned societies (e.g., the Association of American Medical Colleges²⁹), have recommended eliminating or limiting the use of drug samples within the health care network. Within the context of consultations on legislative renewal, the Canadian Pharmacists Association suggested that drug samples be distributed by pharmacies. The Council of Pharmacy Registrars of Canada has proposed various solutions, including blocking the distribution of drug samples, distributing samples through pharmacists, strictly applying the Code of Marketing Practices of Canada's Research-Based Pharmaceutical Companies, and entrusting the distribution of drug samples to third parties. More generally, many institutions hold the view that current practices must be changed.³⁰

Few data exist on the presence of drug samples in health care facilities. The objective of this study was to evaluate the inventory of drug samples in a health care institution and to assess compliance with existing policies and procedures.

METHODS

This descriptive observational study was conducted in an urban university hospital centre. The Centre Hospitalier Universitaire Sainte-Justine in Montréal, Quebec, has 500 mother-child beds in 2 locations (450 beds at the main site and 50 beds at a rehabilitation site). The study was carried out at the main site, which has 21 inpatient locations (which together had 18 324 admissions in 2006/2007) and 63 outpatient locations (which had 198 227 outpatient visits and 67 580 emergency visits in 2006/2007). At the time of the study, which was conducted from October 18 to November 1, 2007, the institution had about 1000 nurses, about 350 physicians, and 34 pharmacists.

For the planned physical inventory of all drug samples available in the hospital, a data collection form was designed, which had the following variables: number of locations where drug samples were found, primary patient care activity performed at each location, number of storage areas in each location, type of storage, presence of a lock, location of the key (if a lock was present), medical specialty, number of physicians and nurses likely to use the samples, reasons given for handing out samples, presence of a designated person to manage the samples, physical inventory (i.e., for each distribution unit, the trade name, generic name, content or form, number of distribution units, number of doses per distribution unit, and expiration date), and declaration of samples to the pharmacy department.

The risk management consultant contacted all of the unit heads or clinical administrative managers, identified from an administrative list of all sectors within the institution, by phone and e-mail during the study period, with a request to identify a suitable contact person for the inventory and to request access to the areas likely to contain drug samples. However, no advance notice was given of the study or the visits at each location. Two research assistants (G.S., L.T.), working independently, took the inventories during the day shift. On arrival in a health care unit, the research assistant asked the contact person (typically a nurse, clerk, or receptionist) to provide access to all storage areas likely to contain samples. The research assistant completed the data collection form by taking a physical inventory (on the basis of visual observation) and questioning the contact person. Any expired drug samples (with expiration dates of November 1, 2007, or earlier) were immediately removed and destroyed according to operational procedures. The proportion of distribution units that had been declared to the pharmacy department was determined with reference to declarations archived in the department. A distribution unit was deemed "compliant" if the unit, its lot number, and its expiration date were recorded in the declaration register. According to policies in effect since January

2004, the pharmaceutical sales representative must hand the requested stock to a physician or nurse. The physician, the nurse, or the pharmaceutical sales representative must then complete a paper declaration (with information such as the commercial name, drug strength, formulation, quantity given, expiration date, manufacturer's name, and representative's name), which is sent by fax or delivered by hand to the pharmacy department. Finally, the drug sample stock was compared with authorized floor stock of medications in the unit (drugs purchased and dispensed by the pharmacy department through floor stock policies and procedures).

The data were entered into an Excel 2007 spreadsheet (Microsoft, Seattle, Washington), and descriptive statistics were calculated (average, standard deviation, median, minimum, and maximum). Data included the numbers of individual companies, generic entities, brands, distribution units, and doses; the total cost and cost per dose; and the proportions of expired distribution units and of distribution units not recorded on the local list by therapeutic class or location, as applicable. In the case of multidose formats, a scale was established to estimate the number of doses per format: 5 mL/dose for syrup, 1 g/dose for cream, and 1 mL/dose for lotion. The monetary value of the drug samples was calculated from prices on the October 2007 price list for insured drugs, prepared by the Régie de l'assurance maladie du Québec (Quebec's health insurance board). The distribution of the number of drug sample doses was compared with the number of doses of drug floor stock for each location. For drug floor stock, the estimated number of distribution doses was based on authorized quotas rather than physical inventory. The main products used as antiseptics or disinfectants (including isopropyl alcohol, ethyl alcohol, methyl alcohol, hydrogen peroxide, sodium hypochlorite, acetone, acetic acid, and all solutions containing chlorhexidine) were excluded from the drug floor stock. Staff from the pharmacy department were responsible for managing the drug floor stock, refilling the stock daily using a bar code system; therefore, the quotas established were assumed to be representative of usual stock levels.

Because this project involved quality and risk assessment, it was conducted under the auspices of the hospital's Pharmacology Committee and the Professional Services Directorate.

RESULTS

Of the 84 identified locations, drug samples were found in 21 locations, all intended for ambulatory patients (i.e., outpatient clinics and day centres). No drug samples were found in inpatient care units.

Overall, the number of doses of drug samples ($n = 78\,955$ doses) was 2.4 times greater than the number of doses of drug floor stock ($n = 32\,987$ doses) (Table 1). The outpatient clinics

with the largest stocks of drug samples were (in decreasing order) pneumology, obstetrics and gynecology, pediatrics, dermatology, and otorhinolaryngology, and these clinics accounted for 80% of the sample doses. The distribution of drug floor stock among the various clinics differed from that for the drug samples (Table 1).

At least 1 person was identified as being in charge of managing drug samples in 11 of the 21 locations. A total of 13 different types of storage areas were identified: examination rooms ($n = 7$), nurses' offices ($n = 5$), nursing stations ($n = 4$), doctors' rooms or offices ($n = 3$), rooms for measuring patients' weight and height ($n = 2$), reception areas ($n = 2$), storerooms ($n = 2$), floor pharmacy ($n = 1$), photocopy room ($n = 1$), common work room ($n = 1$), test room ($n = 1$), corridor ($n = 1$), and recovery room ($n = 1$). Fourteen of these 31 storage areas did not have a lock. Six types of storage were identified: cabinet ($n = 20$), office area ($n = 3$), drawer ($n = 3$), storage shelf ($n = 3$), pantry ($n = 1$), and refrigerator ($n = 1$).

According to interviews with the contact person at each location, the reasons for handing out samples included (in decreasing order) avoiding costs for the patients ($n = 8$), trying a treatment ($n = 7$), starting a treatment ($n = 5$), facilitating a treatment ($n = 4$), alleviating pain or fever ($n = 4$), providing patient education ($n = 3$), treating health care staff ($n = 3$), deciding between 2 treatments ($n = 1$), evaluating side effects ($n = 1$), providing a quantity of medication sufficient to last until the next planned prescription renewal ($n = 1$), responding to a relative's request ($n = 1$), and using the sample simply because it was available ($n = 1$).

The drug samples were classified in 23 therapeutic classes (Table 2) and came from 62 different pharmaceutical companies. The companies represented by the greatest number of samples were Wyeth Ayerst (25 different products), Stiefel (17), Sanofi-Aventis (10), Novo Nordisk (10), Eli Lilly (10), and Glaxo-Smith Kline (10). The companies represented by the greatest number of distribution units and number of therapeutic classes were Wyeth Ayerst (28.5% of distribution units, in 6 therapeutic classes), Stiefel (7.4% of distribution units, in 1 therapeutic class), Merck Frosst (5.3% of distribution units, in 2 therapeutic classes), Galderma (4.7% of distribution units, in 1 therapeutic class), Johnson & Johnson (3.3% of distribution units, in 4 therapeutic classes), and Baush & Lomb (3.3% of distribution units in 2 therapeutic classes).

A comparison of inventoried stock with declarations archived in the pharmacy revealed that only 3.5% ($n = 302$) of the drug sample distribution units had been declared to the pharmacy department according to established policy. Generally speaking, the samples were given to physicians, nurses, or clerks or were dropped off by pharmaceutical sales representatives in locations where samples were already present, or they were sent by regular mail, sometimes at the request of hospital staff.

Table 1. Comparative Profile of Drug Samples and Drug Floor Stock by Location*

Location (Clinic)	Drug Samples				Drug Floor Stock		
	No. of Storage Areas with Drug Samples	No. of Doses	Annual No. of Outpatient Visits	No. of Doses Per Visit	No. of Storage Areas with Drug Samples	No. of Doses	No. of Doses Per Visit
Pneumology	1	19 553	3 788	5.16	2	1 505	0.40
Obstetrics and gynecology	5	16 383	31 557	0.52	2	1 621	0.05
Pediatrics	2	11 977	9 475	1.26	1	1 452	0.15
Dermatology	3	9 131	6 112	1.49	1	2 648	0.43
Otorhinolaryngology	1	6 056	9 451	0.64	1	5 575	0.59
Hepatology and gastroenterology	1	2 450	5 431	0.45	1	1 356	0.25
Dialysis	1	2 114	250	8.46	1	1 082	4.33
Endocrinology	1	1 900	2 032	0.94	1	110	0.05
Adolescent medicine	1	1 592	2 489	0.64	1	273	0.11
Emergency	2	1 482	67 580	0.02	7	10 874	0.16
Allergy	1	1 439	3 496	0.41	1	566	0.16
Ophthalmology	1	1 379	15 923	0.09	1	1 045	0.07
Urology	1	1 050	4 143	0.25	1	768	0.19
Dental medicine	2	747	6 177	0.12	1	238	0.04
Neurology	1	653	5 521	0.12	1	284	0.05
Development	1	433	2 576	0.17	1	115	0.04
Diabetes	1	348	2 714	0.13	1	166	0.06
Orthopedics	1	142	16 666	0.01	1	1 422	0.09
Daycare centre	1	88	5 329	0.02	1	778	0.15
Neonatology	2	24	771	0.03	1	10	0.01
Renal transplantation	1	14	5 521	< 0.01	1	1 107	0.20
Total	31	78 955	207 002	NA	29	32 995	NA
Minimum	1	14	250	< 0.01	1	10	0.01
Maximum	5	19 553	67 580	8.46	7	10 874	4.33
Median	1	1 439	5 431	0.25	1	1 045	0.15

NA = not applicable.

*Averages and standard deviations were calculated but are not presented here, as the data did not have a normal distribution.

A total of 159 generic entities and 266 different brands were counted. In decreasing order, by proportion of distribution units of the generic entity, the most important drugs were ibuprofen (15.4% of all distribution units), multivitamins (8.1%), dorzolamide/timolol (4.1%), fluorescein (3.2%), adapalene (2.4%), metronidazole for topical administration (2.4%), hydroquinone (2.0%), cetirizine (1.9%), tretinoin (1.9%), and calcium–vitamin D (1.9%). In monetary terms, the total value of the sample distribution units, including expired units, was Can\$48 783, based on the unit prices in effect in October 2007. In comparison, the value of authorized drugs in the clinics' stock was Can\$21 813.

Of the identified stock, the inventory showed that 732 (8.3%) of the distribution units were expired; the most common expired drugs were anti-infective agents, enzymes, gastro-intestinal medications and sera, antitoxins, and vaccines. Furthermore, 5226 (59%) of the drug sample distribution units identified during the inventory were not on the hospital's

local formulary, as approved by the Pharmacology and Therapeutics Committee.

DISCUSSION

In this study, important quantities of drug samples (78 955 doses worth Can\$48 783) were found in a 500-bed university health centre. To the authors' knowledge, no previous in-house study of this type has been reported. The variety of drugs, the amount of samples inventoried, and the very low level of compliance with local policy and procedures were surprising.

Other descriptive studies have evaluated the value of drug sample inventories in private practice, based on average wholesale prices. In a 1992 study, 5546 drug samples worth a total of US\$19 273 were inventoried by a group of family physicians.¹⁷ Over a 14-month period in 1992–1993, drug samples worth a total of US\$240 782 were recorded in a

Table 2. Comparative Profiles of Drug Samples and Drug Floor Stock by Therapeutic Class*

Therapeutic Class (AHFS no.)	Drug Samples						Drug Floor Stock		
	No. of Companies	No. of Products	No. of Doses	% Expired Doses	Total Cost (Can\$)	% of Doses Not on Formulary	No. of Products	No. of Doses	Total Cost (Can\$)
Hormones and synthetic substitutes (68:00)	15	45	25 043	2	11 831	37	5	790	87
Autonomic drugs (12:00)	5	12	14 913	6	10 614	43	41	1 573	1 776
Skin and mucous membrane agents (84:00)	25	73	9 294	12	7 830	70	24	3 931	1 372
Vitamins (88:00)	3	8	7 344	<1	1 409	52	5	142	285
Central nervous system agents (28:00)	9	23	5 162	9	1 891	60	22	663	1 599
Eye, ear, nose, and throat preparations (52:00)	14	32	4 912	7	4 563	81	40	5 778	1 435
Gastrointestinal drugs (56:00)	14	25	3 142	22	3 213	57	0	0	0
Electrolytic, caloric, and water balance agents (40:00)	5	10	2 178	0	486	76	3	13	114
Blood formation, coagulation, and thrombosis agents (20:00)	3	4	2 038	0	594	100	13	589	474
Respiratory tract agents (48:00)	5	11	1 658	2	1 913	70	0	0	0
Smooth muscle relaxants (86:00)	5	5	862	17	1 126	83	1	5	45
Antihistamine drugs (4:00)	2	5	757	0	446	18	41	5 273	1 867
Miscellaneous therapeutic agents (92:00)	1	1	588	0	545	100	23	4 782	545
Anti-infective agents (8:00)	4	6	535	30	858	38	2	3	310
Diagnostic agents (36:00)	1	1	280	0	57	0	33	1 187	1 928
Enzymes (44:00)	1	1	200	100	21	100	7	135	265
Cardiovascular drugs (24:00)	1	1	21	0	25	0	1	10	6
Serums, toxoids, and vaccines (80:00)	2	2	19	100	145	0	7	63	4 854
Contraceptives (foams, devices) (32:00)	1	1	9	0	1 217	100	24	4 146	2 095

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Table 2. Comparative Profiles of Drug Samples and Drug Floor Stock by Therapeutic Class (continued)*

Therapeutic Class (AHFS no.)	Drug Samples					Drug Floor Stock			
	No. of Companies	No. of Products	No. of Doses	% Expired Doses	Total Cost (Can\$)	% of Doses Not on Formulary	No. of Products	No. of Doses	Total Cost (Can\$)
Heavy metal antagonists (64:00)	0	0	0	0	0	0	1	3	16
Local anesthetics (72:00)	0	0	0	0	0	0	7	581	156
Oxytocics (76:00)	0	0	0	0	0	0	12	89	1 576
Others (99:00)	0	0	0	0	0	0	27	3 239	1 009
Total	62†	266	78 955	8	48 783	59	339	32 995	21 813
Minimum	0	0	0	0	0	0	0	0	0
Maximum	25	73	25 043	100	11 831	100	41	5 778	4 854
Median	3	5	757	14	594	51.46	7	581	474

AHFS = American Hospital Formulary Service.

*Numbers are rounded to the nearest whole unit. Averages and standard deviations were calculated but are not presented here, as the data did not have a normal distribution.

†The total number of companies is less than the sum of values in this column, because some companies had drugs in more than one category.

university-affiliated family medicine residence program.²⁴ In 1998, a physician's private practice inventory of drug samples was worth US\$262 661.³¹ In 2002, drug samples in a rural private practice area were valued at US\$60 620, whereas the value of the samples received during the observation period was US\$22 029.³² In 2004, an inventory was obtained of drug samples in 6 general practice offices in a metropolitan and a rural area of Australia; the samples had a value of A\$31 364.³³ Campbell and others⁵ found that pediatricians were less likely than general practitioners to receive drug samples (odds ratio 0.56, 95% confidence interval 0.33-0.94). Although the value of the Sainte-Justine samples inventoried in this study was lower than that in several US studies, it was 2.4 times the maximum value of the authorized medications (excluding samples) available as floor stock in the hospital, an astonishing ratio. These results indicate that the quantity of drug samples available in hospitals is underestimated, and we therefore recommend that the use of samples in hospitals be regulated to a greater extent. If a hospital pharmacy department is unable to regulate the acquisition, storage, dispensing, and documentation of samples, the use of samples could constitute a parallel pharmacy practice by the industry.

Most previous studies have focused on the number of distribution units of drug samples (e.g., blister packs, bottles), rather than the number of doses. However, we believe that it is more relevant to record the number of doses, because most doses can be dispensed individually, and each dose represents an individual risk for misuse. Moreover, to judge the relative importance of drug samples and authorized floor stock dispensed by the pharmacy department to the clinics, the dose represents the smallest unit that would allow volume and cost

comparisons. Also, the number of doses can be used to estimate the proportion of a treatment that has been given to a patient through drug samples. Nevertheless, reporting the number of doses increases the absolute number calculated for drug samples with multidose formats, such as inhalers used in the treatment of pulmonary ailments.

In this study, certain therapeutic classes were more likely to be available as samples: hormones and their substitutes (American Hospital Formulary System class 68:00; 32%), autonomic nervous system medications (class 12:00; 19%), skin and mucous membrane medications (class 84:00; 12%), and vitamins (class 88:00; 9%). Backer and others⁸ identified 4 categories for the most popular medications (representing 63% of all medications distributed): asthma and allergy agents, anti-infective agents, analgesic and anti-inflammatory medications, and anti-hypertensive agents. In Wolf's observational study,³¹ the drug samples fell into 6 categories: anti-inflammatories (nasal, valued at US\$84 690; lung, valued at US\$70 436), antihistamines (US\$52 146), antibiotics (US\$25 820), bronchodilators (US\$19 149), and miscellaneous (US\$10 420). In 2007, Mabins and others¹⁰ conducted an observational study with 123 patients who had received drug samples. The main conditions treated with samples were hypertension (15.4% of patients), pain (11.4%), dyslipidemia (9.8%), coughs and colds (8.9%), and depression (8.1%). The distribution of therapeutic classes of drug samples in the current study differed from those of other published studies, a difference that can probably be explained by the target patient population at Sainte-Justine (mothers and children).

In this study, 59% of the drug sample distribution units inventoried were not on Sainte-Justine local formulary. In the

study by Haxby and others,²⁴ 29% of drug samples given to patients were not on the hospital's official list. A hospital's drug formulary is established to ensure optimal drug use and patient safety. In the authors' hospital, the drug list includes about 3000 products out of the approximately 26 000 available on the Canadian market. Drugs are listed on the formulary if they have good intrinsic efficacy and safety data, are adequately labelled, and fulfill local patient needs. It is clear that a manufacturer's decision to offer drug samples is dictated by the emergence of new drugs and the search for a market share, rather than the needs of patients or health care professionals.

Given that the industry does not provide samples for drugs that have been on the market many years, we believe that the presence of samples is related to the pharmaceutical industry's marketing activities, aimed at creating a "need" for new medications and influencing physicians to try recently marketed drugs. New drugs are often more expensive than older drugs, and hospital costs represent a small proportion of societal drug costs for any drug that may be used on a long-term, ambulatory basis. Beyond the fact that a majority of the samples identified were not on the hospital's formulary, this study did not allow for an accounting of the additional societal costs related to use of the drugs on an ambulatory basis. Further studies are required to evaluate the factors that bring nonformulary drug samples into hospitals and the potential societal costs associated with the use of drug samples.

Although stocks of drug samples were more common in certain areas of the institution, most outpatient clinics seemed to be targeted and visited by pharmaceutical representatives, who came with the intention of handing out drug samples. In 2004 the institution adopted a strict policy governing the use of drug samples in health care units but still allowing their distribution to outpatient clinics. Despite this policy, only 3.5% of the stock inventoried in this study had been declared to the pharmacy department according to existing procedures. Although less-than-perfect compliance with administrative policies would not be surprising, this very low level of compliance illustrates how difficult it is to monitor the activity of pharmaceutical sale representatives in a large institution. Not only are many sales representatives present in hospitals every day, but the representatives for each company change regularly because of reorganizations and shifts in activities. With no single policy in place throughout the health care system to manage (or proscribe) the distribution of drug samples, such changes in personnel contribute to the confusion and lack of compliance with hospital-based policies for pharmaceutical sale representatives. Also, outpatient clinics are similar to private clinics in that physicians, nurses, and clerks may function according to a local standard, rather than an institutional policy. Some nurses and physicians contacted during the inventory rounds for this study admitted that they thought the

hospital should not regulate the use of drug samples in clinics.

In this study, 8.3% of the drug sample distribution units had expired, similar to the proportion reported by Hall and others³³ (6.3%). The presence of expired medications reflects a lack of structure in the management of drug samples in institutions. Almost 50% of the clinics in this study did not manage drug samples in a structured way. For example, there was no designated individual to take care of samples according to an established procedure. More often than not, pharmaceutical representatives dropped off the samples themselves, and the nurses or physicians simply checked expiration dates before handing out the samples. Several other studies have highlighted the few resources that have been invested in this area, as well as the lack of effective drug sample management.^{8,9,34}

The design of this study did not allow verification of the proportion of drug samples used by staff members of the institution. Nevertheless, a number of elements, such as the presence of products intended only for adults (e.g. vitamins for geriatric patients), suggested that this proportion was significant. Previous studies have noted that the proportion of samples taken for personal use by staff or their associates or by pharmaceutical representatives themselves ranges from one-third to more than half.^{8,19}

This study had certain limitations. The number of drug samples might have been underestimated, given that the research team had to obtain consent from health care staff to access the locations where samples were stored. Some staff members might have been warned about the inventory process the day before, and some people postponed the inventory by booking an appointment with the research assistant at a later date. The lack of longitudinal analysis limits the ability to extrapolate the results over time. It is clear that most stock was periodically replaced by pharmaceutical representatives, but this cross-sectional study did not allow estimation of the annual quantity of samples received, handed out, returned, or discarded. Similarly, it is possible that the actual proportion of expired stock was higher, as certain individuals let it be known that they had done some cleaning up of the storage areas before the "unannounced" visit.

Conclusions

This study reports the inventory of drug samples in a health care institution and compliance levels with existing policies and procedures. Drug samples were found only in outpatient clinics, where they represented 2.4 times the amount of drug floor stock. Most drug sample doses inventoried were not listed on the hospital's formulary. These results indicate that the use of drug samples is underestimated in hospital settings. Further studies should be conducted to evaluate the importance of drug samples in patient care and the risks associated with their use.

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