

Drug sample management in University of Montreal family medicine teaching units

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Abstract

Objective To describe the management and distribution of drug samples in family medicine teaching units (FMUs).

Design Cross-sectional descriptive study.

Setting All 16 FMUs affiliated with the Department of Family Medicine and Emergency Medicine at the University of Montreal in Quebec.

Participants Health care professionals (physicians, residents, pharmacists, and nurses) who manage (n=22) and dispense (n=294) drug samples in the FMUs.

Methods Data were collected between February and March 2013 using 2 self-administered questionnaires completed by health care professionals who manage or dispense drug samples. The data were subjected to descriptive and bivariate analyses.

Results The participation rate was 100.0% for staff who manage drug samples and 72.5% for those who dispense them. Of the 16 participating FMUs, 12 have drug sample cabinets. Eight of the FMUs have a written institutional policy governing the management of drug samples. Of the 76.2% of respondents who said they distributed samples, more than half did not know whether their institution had a policy. In 7 of 12 FMUs with drug sample cabinets, access to samples is not restricted to those authorized to prescribe medications. Cabinets are most often managed by nurses (9 of 12 FMUs). Only 4 of 12 FMUs take regular inventory of cabinet contents. The main reasons cited for dispensing samples were to help a patient financially and to test for tolerance and efficacy when initiating or modifying a treatment for a patient. Three-quarters (78.2%) of dispensers reported that sometimes they were unable to find the drug they wanted in the cabinet; half of those consequently gave patients drugs that were not their first choice. More than half the dispensers reported they never or only occasionally referred patients to their community pharmacists.

Conclusion A portrait of drug sample management and dispensation in the academic FMUs emerged from this study. This study provides insight into current practice and lays the groundwork for the development of guidelines for safe and ethical handling of drug samples.

EDITOR'S KEY POINTS

- While all 16 of the University of Montreal's family medicine teaching units adhered to the general ethical principles governing relationships between the pharmaceutical industry and clinics, 12 reported they had a cabinet containing industry-provided samples.
- Three-quarters of sample dispensers reported that sometimes they were unable to find the medications they sought; half of those said they ended up giving the patient another drug. Most of the personnel who dispensed samples had no knowledge of a framework in their institutions governing the procurement, distribution, and disposal of samples.
- Safe medication use requires that the medication chosen is appropriate for the diagnosis; the prescription is properly recorded in the patient chart; and measures are taken so that the patient uses it optimally. Pharmacists should evaluate the treatment plan and provide counseling to the patient. The use of samples often circumvents important steps such as these and influences the prescriber's product selection.

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Gestion des échantillons de médicaments dans les unités d'enseignement de médecine familiale à l'Université de Montréal

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Résumé

Objectif Décrire les modes de gestion et de distribution des échantillons de médicaments dans des unités d'enseignement en médecine familiale (UMF).

Type d'étude Étude descriptive transversale.

Contexte L'ensemble des 16 UMF affiliées au département de médecine familiale et de médecine d'urgence de l'Université de Montréal.

Participants Les membres du personnel soignant (médecins, résidents, pharmaciens et infirmiers\ères) qui gèrent (n = 22) et distribuent (n = 294) des échantillons de médicaments dans les UMF.

Méthodes On a recueilli les données entre février et mars 2013 à partir de 2 questionnaires auto-administrés auxquels ont répondu les professionnels de la santé qui gèrent ou distribuent les échantillons de médicaments. Ces données ont ensuite été analysées par des analyses descriptives et bidimensionnelles.

Résultats Le taux de participation était de 100 % pour le personnel qui gère les échantillons de médicaments et de 72,5 % pour ceux qui les distribuent. Sur les 16 UMF participantes, 12 avaient des armoires de rangement pour les échantillons. Huit d'entre elles avaient une politique institutionnelle écrite régissant la gestion de ces échantillons. Sur les 72,5 % des répondants qui disaient distribuer des échantillons, plus de la moitié ignoraient que leur institution avait une politique à cet égard. Dans 7 des 12 UMF qui avaient des armoires pour les échantillons, l'accès à ces médicaments n'était pas réservé à ceux qui étaient autorisés à prescrire. Les armoires étaient le plus souvent gérées par des infirmiers\ères (9 UMF sur 12). Seulement 4 UMF sur 12 effectuaient un inventaire régulier du contenu de ces armoires. La principale raison mentionnée pour donner des échantillons était pour aider financièrement le patient et pour vérifier l'efficacité et la tolérance du médicament au moment d'initier ou de modifier un traitement. Les trois-quarts des distributeurs (78,8 %) indiquaient qu'ils étaient parfois incapables de trouver le médicament qu'ils voulaient dans l'armoire; la plupart d'entre eux donnaient alors au patient un médicament qui n'était pas leur choix initial. Plus de la moitié des distributeurs avouaient que jamais ou seulement à l'occasion ils ne dirigeaient les patients à leur pharmacien communautaire.

Conclusion Cette étude trace un portrait du mode de gestion et de distribution des échantillons de médicaments dans les UMF universitaires. Elle donne un aperçu des pratiques actuelles et peut servir de base pour le développement de directives visant une gestion sécuritaire et éthique des échantillons de médicaments.

POINTS DE REPÈRE DU RÉDACTEUR

- Alors que les 16 unités d'enseignement en médecine familiale à l'Université de Montréal ont toutes adopté les principes généraux d'éthique qui régissent les relations entre l'industrie pharmaceutique et les cliniques, 12 ont rapporté qu'elles disposaient d'une armoire de rangement pour les échantillons provenant de l'industrie.
- Les trois-quarts de ceux qui distribuent les échantillons ont mentionné qu'ils étaient parfois incapables de retrouver les médicaments qu'ils cherchaient; la moitié d'entre eux ont dit qu'ils finissaient par administrer un autre médicament au patient. La majeure partie des membres du personnel qui distribuaient les échantillons ignoraient que leur institution avait des règles régissant leur acquisition, leur distribution et la façon d'en disposer.
- L'utilisation sécuritaire d'un médicament exige que son choix soit conforme au diagnostic; que sa prescription soit correctement consignée dans le dossier du patient; et qu'on s'assure que le patient l'utilise de façon optimale. Les pharmaciens devraient aussi évaluer le plan de traitement du patient et lui donner des conseils. Souvent, l'utilisation d'échantillons ne respecte pas des étapes aussi importantes; de plus, la disponibilité des échantillons risque d'influencer le choix du produit prescrit.

Cet article fait l'objet d'une révision par des pairs.

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Pharmaceutical companies use drug samples as a promotional tool.¹ Physicians and health care professionals in public health care institutions are usually given samples directly, without the pharmacy department's involvement.^{2,3} As a result, family physicians in training are potentially exposed to suboptimal medication management practices.

Although the distribution of drug samples has some benefits, it also poses potential health risks.⁴⁻⁶ Potential problems resulting from suboptimal sample management and distribution are discontinuity of treatments initiated with samples, exclusion of community pharmacists, inadequate monitoring of expiry dates, lack of documentation in patients' charts, and lack of provision of appropriate drug information to patients. Providing patients with samples might also result in higher costs to the health care system, as it can cultivate the habit of prescribing more expensive, patented drugs.⁷ A recent meta-analysis showed that when physicians dispense samples to initiate a treatment, they tend to prescribe the patented drugs to continue it.⁸

The availability of drug samples in family medicine teaching units (FMUs), where health care professionals are trained and where they develop their clinical competencies, raises a number of important issues.

The objective of this article is to describe how drug samples are managed and dispensed in the FMUs of the Department of Family Medicine and Emergency Medicine at the University of Montreal in Quebec.

METHODS

A review of the literature revealed no theoretical framework describing the trajectory of drug samples in FMUs (how they enter, how they are stored, and how they exit). Therefore, the first phase of the present study involved mapping the process, from the drug samples' arrival at the clinic to their distribution to patients (**Figure 1**). For each step, the elements, issues, and people involved were identified.

Study design and population

A cross-sectional descriptive study was conducted in all 16 FMUs affiliated with the Réseau de recherche en soins primaires de l'Université de Montréal, the Department of Family Medicine and Emergency Medicine practice-based research network.

The study population comprised all personnel who managed or dispensed drug samples in the participating FMUs. Health care professionals who had been with the FMU for less than 1 month were excluded from the study.

Instruments

Two self-administered, multiple-choice questionnaires were developed for this study. The first was intended for

personnel responsible for managing samples (*managers*) and dealt with sample management policy: the selection, procurement, and storage of samples, and procedures for taking inventory, checking expiry dates, and disposing of expired samples. The second questionnaire was intended for those who dispensed samples (*dispensers*) and surveyed their knowledge about sample management policy and addressed various aspects pertaining to sample distribution, as well as relationships with pharmaceutical representatives.

A group comprising physicians, pharmacists, sample managers, and family medicine residents pretested both questionnaires. The questionnaires took an average of 15 minutes to complete. A few minor problems with the questionnaires were detected during their validation and they were subsequently revised.

Data collection procedures

Data collection was conducted between February and March 2013. A designated person from each participating FMU drew up the list of eligible personnel, presented the research project and solicited participants, distributed the questionnaires, and followed up with the participants in accordance with a procedure preestablished by the researchers. The questionnaires were completed anonymously, picked up by the designated person, and returned to the project coordinator. In the FMUs where no samples were stored or distributed ($n=4$), only the questionnaire for sample managers was distributed and completed.

Data analysis

Descriptive, bivariate statistical analyses were performed using SPSS software. The study was approved by the research ethics boards of the University of Montreal (Comité d'éthique de la recherche en santé) and the Centre de santé et de services sociaux de Laval (Comité scientifique et d'éthique de la recherche).

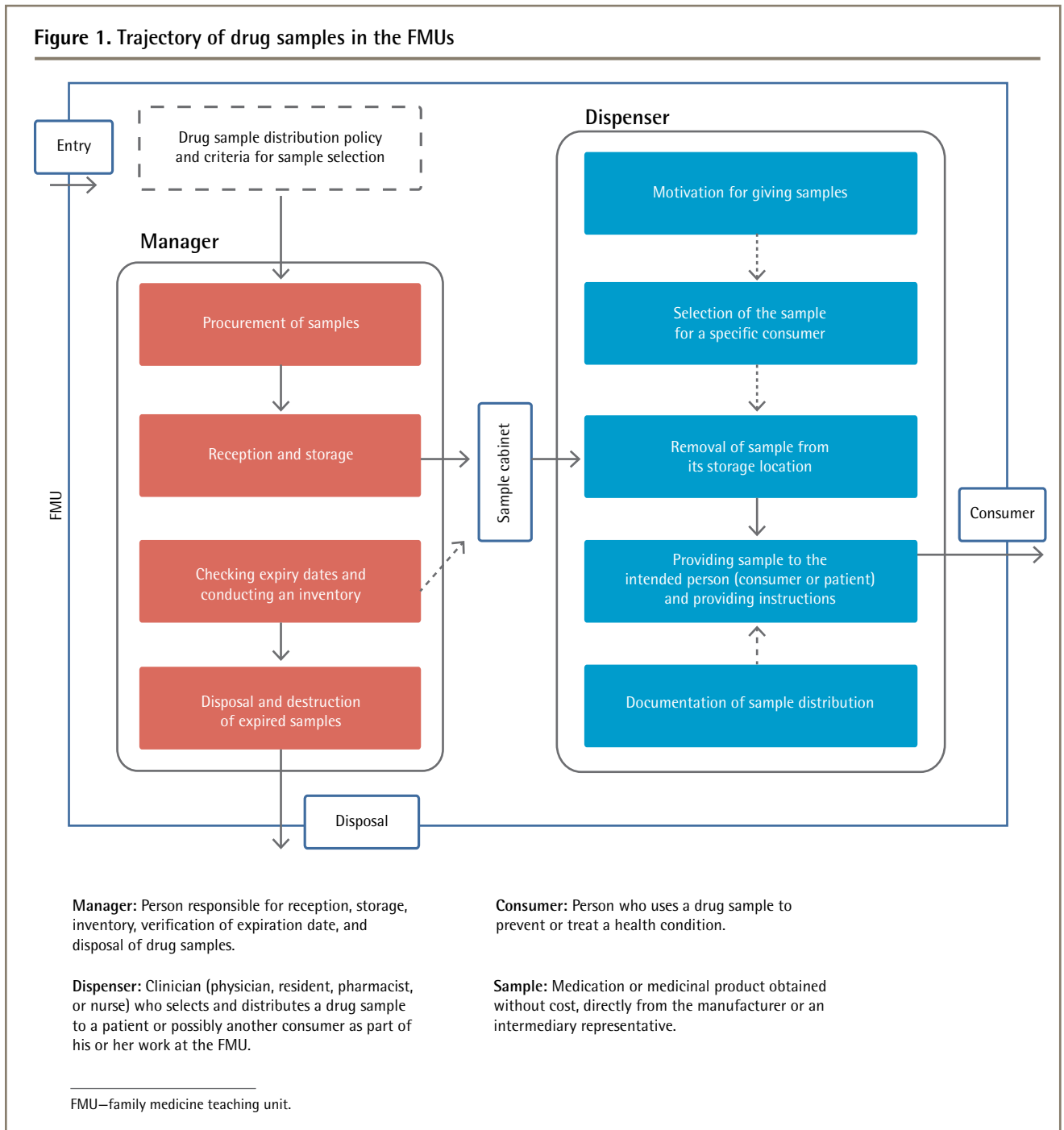
RESULTS

In all, 22 sample managers and 294 dispensers participated in the study. The response rates were 100.0% and 72.5%, respectively. The respondents' occupations are summarized in **Table 1**.

Drug sample management in the FMUs

Sample management policy. According to the drug sample managers, 8 of the 16 FMUs have written institutional policies governing the management of drug samples. In addition, 6 of 16 FMUs reported that their FMUs had general criteria for sample selection. However, no written formal documentation of these criteria exists. Most sample dispensers (178 of 224) did not know if

Figure 1. Trajectory of drug samples in the FMUs



their institutions had written sample management policies, or if their FMUs had selection guidelines (115) or a list of accepted samples (107). Almost half of respondents were not aware if a policy governing contact between residents and pharmaceutical representatives existed at their FMUs (Table 2).

Storage. Four FMUs do not receive or dispense any drug samples. Drug samples are stored in shared cabinets in the other 12 FMUs. Samples are also kept in

individual physicians' offices in 4 of these 12 FMUs (Figure 2). Samples in the shared cabinets are organized by health issue (pain, contraception, etc) or system (gastroenterology, cardiology, psychiatry, etc) in half of the FMUs with shared cabinets (n=6).

Access and inventory management. In 5 of 12 FMUs, the samples are kept behind a locked door. In the others, access is unrestricted and open to all FMU personnel, including clerical and cleaning staff.

Table 1. Respondents' occupations according to their roles in drug sample management and dispensing

OCCUPATION	DISPENSERS, N (%)	MANAGERS, N (%)
Supervising physicians	118 (40.1)	9 (40.9)
Family medicine residents		
• First year	71 (24.1)	0 (0.0)
• Second year	40 (13.6)	0 (0.0)
Nurses	30 (10.2)	8 (36.4)
Pharmacists	4 (1.4)	4 (18.2)
Research assistants	0 (0.0)	1 (4.5)
Not specified by the respondent	31 (10.5)	0 (0.0)
Total	294 (100.0)	22 (100.0)

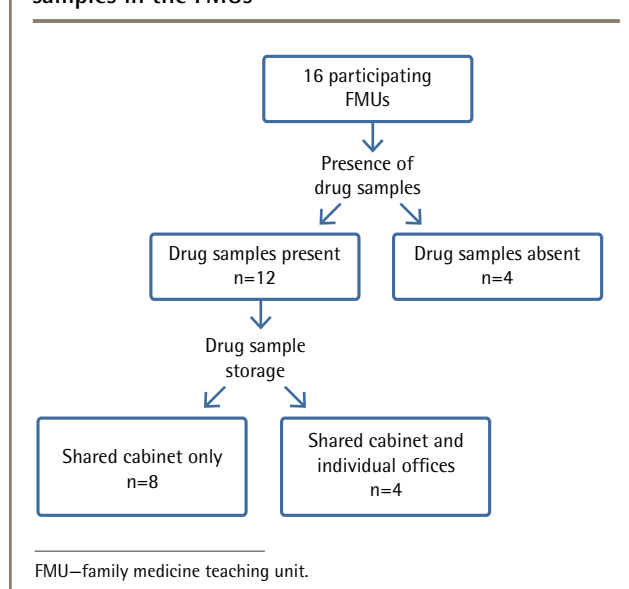
Table 2. Drug sample dispensers' knowledge about sample management policies: N = 224 dispensers (who distributed drug samples in the previous 6 months) in FMUs with drug sample cabinets.

KNOWLEDGE OF DRUG SAMPLE MANAGEMENT POLICY	YES, N (%)	NO, N (%)	DOES NOT KNOW, N (%)
Existence of a written drug sample management policy at the FMU	25 (11.2)	84 (37.5)	115 (51.3)
Existence of a written drug sample management policy at the health care institution	24 (10.7)	22 (9.8)	178 (79.5)
Existence of sample selection criteria at the FMU	38 (17.0)	71 (31.7)	115 (51.3)
Existence of a list of drug samples accepted at the FMU	32 (14.3)	85 (37.9)	107 (47.8)
Existence of a written policy governing contact between residents and pharmaceutical representatives at the FMU	63 (28.1)	55 (24.6)	106 (47.3)

FMU—family medicine teaching unit.

A team, most often led by a nurse (9 of 12), devotes an average of 3 hours a month to sample management. Inventory of the contents of the shared cabinet is conducted at regular intervals in 4 of 12 FMUs; in 3 of these, inventory is performed by visual inspection only.

Expired samples are disposed of using 1 of 4 protocols: expired samples are sent to the hospital pharmacy (6 FMUs), returned to the issuing pharmaceutical company (4 FMUs), disposed of with biomedical waste (1 FMU), or thrown into the trash (1 FMU).

Figure 2. Presence and storage of drug samples in the FMUs

Distribution of drug samples

Overall, a large proportion of respondents (224 of 294, 76.2%) said they had provided patients with samples at least once in the previous 6 months. Within each FMU this ranged from 35.0% to 92.3%. Nearly half the sample dispensers (44.9%) reported issuing samples at a frequency of at least once a month. Oral contraceptives, analgesics (including nonsteroidal anti-inflammatory drugs), intranasal corticosteroids, antacids (including proton pump inhibitors), and ointments were the products most commonly distributed (**Figure 3**).

The primary reasons cited for giving samples to patients were to help them financially, to test for tolerance and efficacy when initiating or modifying a treatment for patients, and to provide patients with relief from pain or other important symptoms (**Figure 4**). Other frequent reasons for using samples included facilitating adherence to treatment and initiating a treatment without delay (ie, the pharmacy was inaccessible at the time). Kindness was identified as a motivation to give samples by a few dispensers.

Three-quarters of dispensers (78.2%) reported that sometimes they were unable to find the drug sample they wanted; 49.3% of those said that as a result they gave their patients a different medication than the one they looked for in the cabinet. They selected an alternative from the same pharmacologic class.

The percentage of dispensers wishing for access to a medication class is consistently higher than the percentage of individuals having dispensed that class during the period assessed by the study (**Table 3**). The difference between use and want is largest for antihistamines, antimigraine medications, and inhaled medications.

Figure 3. Classes of medications distributed to patients over the previous 6 months

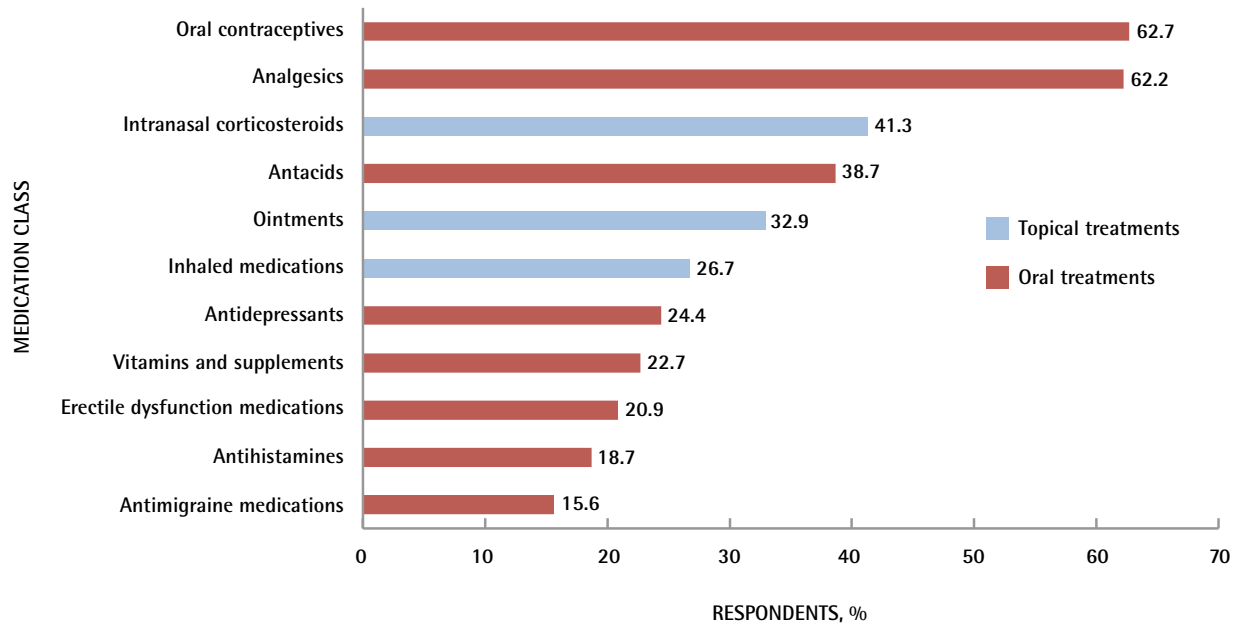
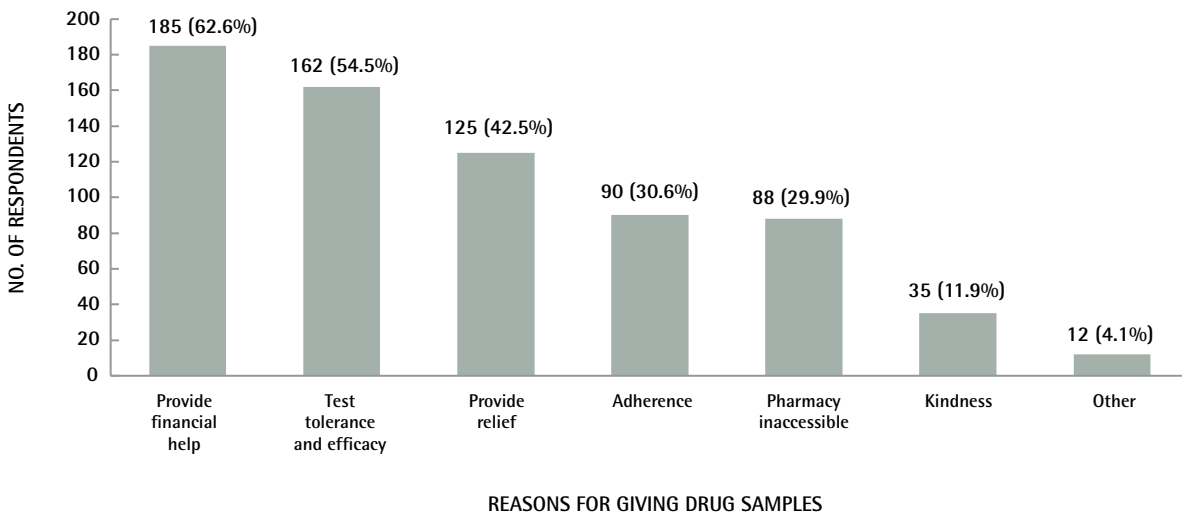


Figure 4. Primary reasons cited by respondents for dispensing drug samples to patients



While a substantial proportion of supervising physicians (67.2%) declared they documented their distribution of samples in patients' charts, only 32.8% of residents reported they did. **Figure 5** shows what information is recorded in the chart when a sample is given. More than 70% of dispensers said they documented the name, dosage, and quantity. Lot numbers were seldom recorded. More than half the respondents (57.9%) said they never or only occasionally referred patients to their community phar-

macists for additional information. A higher proportion of supervising physicians (59.4%) than residents (36.0%) said they met with pharmaceutical representatives.

DISCUSSION

To our knowledge, this is the first Quebec study of its type conducted in settings where future family

Table 3. Distribution of and desire for samples by medication class: N = 224 dispensers (who distributed drug samples in the previous 6 months) in FMUs with drug sample cabinets.

DRUG CLASSES	DISPENSERS WHO DISTRIBUTE THIS CLASS OF SAMPLE, %	DISPENSERS WHO WANT ACCESS TO THIS CLASS OF SAMPLE, %
Oral contraceptives	62.9	91.9
Analgesics	62.5	87.0
Ointments	33.0	65.5
Antacids	38.7	64.6
Inhaled medications	26.8	61.4
Intranasal corticosteroids	41.5	59.2
Antihistamines	18.8	57.0
Antimigraine medications	15.6	55.6
Antidepressants	24.6	52.5
Vitamins and supplements	22.3	40.4
Erectile dysfunction medications	21.0	33.6

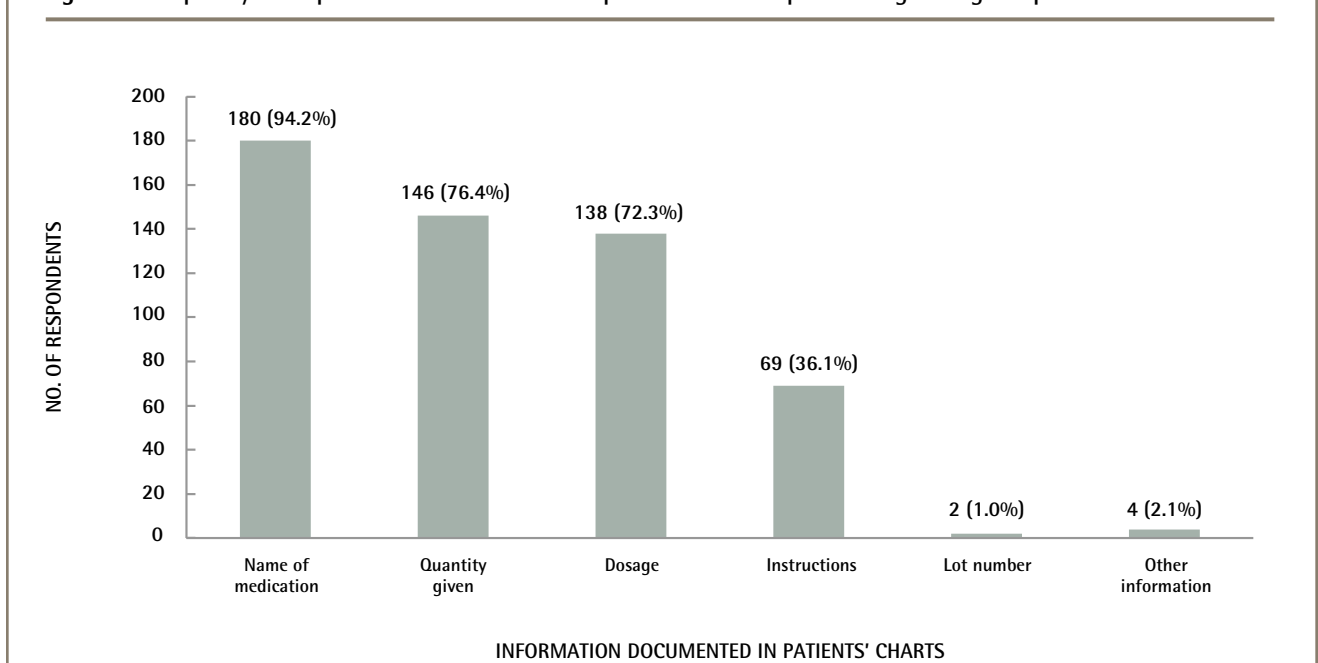
physicians are trained. Most studies deal with ethical aspects of the relationships between physicians and pharmaceutical industry representatives. Surprisingly, although drug samples are one of the industry's top strategies for influencing physicians' prescribing behaviour, none of the literature deals with the practical aspects

of sample management and distribution in clinics. Notably, our investigation found that while all 16 FMUs adhered to the general ethical principles governing relationships between the industry and clinics, 12 reported they had a cabinet containing industry-provided samples.

Most of the FMUs studied had drug sample cabinets. However, most of the personnel who dispensed samples had no knowledge of a framework governing their procurement, distribution, and disposal. This is concerning, as a number of studies have shown that the availability of samples influences physicians' judgment and prescribing behaviour.⁷ Access to drugs as samples is associated with a higher frequency of prescribing those drugs that were provided as samples.⁹ In addition, health care professionals' decisions about prescriptions are often made using information provided by pharmaceutical representatives.^{10,11}

Although the proportion of those who dispense samples is rather high, the frequency with which they do so is relatively low. The primary reasons our respondents cited for dispensing samples are clinically relevant (ie, to reduce costs for the patient, to test tolerability and efficacy, to provide immediate relief, and to foster treatment adherence). Three-quarters of sample dispensers reported that sometimes they were unable to find the medications they sought; half of those said they ended up giving their patient another drug. This supports claims about the influence of pharmaceutical companies on modifying physicians' prescribing behaviour. Other investigators have reported similar findings.^{3,12} With no framework to regulate the samples stored in the

Figure 5. Frequency of dispensers' documentation in patients' charts upon issuing a drug sample: N = 191.



clinics' cabinets, the available samples, largely provided by pharmaceutical representatives, do not meet clinicians' needs.¹²

With regard to the safe management of medications, our study reveals that in many of the FMUs, access to prescription drugs is not limited to personnel authorized to prescribe or dispense them. Samples are not always under lock and key, and in many cases no one is responsible for monitoring who accesses them. In addition, the hospital pharmacy department plays little or no role in managing the contents of the cabinets. While expired samples are generally disposed of safely, few of the FMUs conduct a systematic inventory (ie, with medication counts as in hospital pharmacies) of the cabinet contents at regular intervals.

The distribution of samples is not always documented in patients' charts, and when it is, the entries lack important information. Additionally, more than half of the time a patient is provided a drug sample, the community pharmacist is not informed. As a result, the patient's medication record is not up-to-date and the patient does not benefit from the community pharmacists' expertise. This break in continuity can be especially unsafe for patients with multiple chronic conditions.

Limitations

One of the principal limitations of this study is that we did not consult patient charts to validate the data we collected. We are thus unable to confirm the rates at which samples were dispensed or what information was entered in the charts. Social desirability bias on the part of the respondents is also a possibility, although likely mitigated by the anonymity of the data collection process.

Conclusion

Our research highlights issues to take into consideration for the development of best practice guidelines for safe and ethical drug sample management and distribution. Safe medication use requires that the medication chosen is appropriate to the diagnosis, the prescription is properly recorded in the patient chart, and measures are taken so that the patient uses it optimally. Pharmacists should evaluate the treatment plan and provide counseling to the patient. The use of samples often circumvents important steps such as these and influences the prescriber's product selection. The same standards that apply to drugs obtained through the pharmacy should apply to samples to ensure they are used appropriately, safely, and responsibly.

These results will inform the development of best practice recommendations by the Collège des médecins du Québec for drug sample use in medical practice. 🌿

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Competing interests

None declared.

Contributors

Dr Lussier was primary investigator and supervised the project. All authors conceived and designed the study instruments, and contributed to the initial survey dissemination. **Dr Binta Diallo** oversaw and coordinated the field work (distribution of the surveys, retrieval of the surveys, and data entry) and analyzed the data. **Dr Binta Diallo** and **Mr Gagnon** contributed to the presentation of the data. **Dr Binta Diallo** drafted the manuscript and all authors contributed to the revision of the manuscript.

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