Editor's key points

- This cross-sectional survey in Quebec found that several family medicine teaching units (FMTUs) and pharmaceutical companies did not follow Canadian medical and pharmaceutical guidelines regarding drug sample management. Although pharmaceutical companies are obliged to distribute drug samples only to authorized health care professionals (ie, physicians and pharmacists), these professionals were involved in the procurement and reception of samples in only 79% and 56% of the FMTUs, respectively.
- A mere 15% of FMTUs recorded the samples they dispensed, 82% ensured that samples had not expired, and 85% ensured proper disposal of expired samples as per Canadian medical guidelines, with 6% disposing of expired samples in the regular trash. Almost one-third of FMTUs allowed uncontrolled access to their drug sample cabinet, and non-authorized individuals had access to sample cabinets in most FMTUs.
- According to drug sample managers, no FMTUs have written selection criteria to guide sample choice, raising new questions about the influence of the pharmaceutical industry on physician prescribing habits.

Drug samples in family medicine teaching units: a cross-sectional descriptive study

Part 2: portrait of drug sample management in Quebec

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Abstract

Objective To draw a portrait of drug sample management in academic primary health care settings and assess conformity to existing Canadian guidelines.

Design Descriptive cross-sectional survey.

Setting All 33 family medicine teaching units (FMTUs) in Quebec that kept drug samples.

Participants Health care professionals or FMTU staff who managed drug samples (ie, *managers*).

Main outcome measures Drug sample managers completed a self-administered questionnaire between February and December 2013. Questionnaires inquired about sample selection, procurement, reception, storage, inventory, and disposal. Results were compared with the Canada's Research-Based Pharmaceutical Companies *Code of Ethical Practices* (2012) and the Canadian Medical Association *Guidelines for Physicians in Interactions with Industry* (2007).

Results All 33 FMTUs responded to the questionnaire. According to managers, no FMTUs had written selection criteria to guide sample choice. Almost one-third (30%) of FMTUs had uncontrolled access to drug sample cabinets. Even though pharmaceutical companies must distribute drug samples to authorized professionals only, these professionals were involved in the procurement and the reception of samples in 79% and 56% of FMTUs, respectively. Only 15% of FMTUs kept track of samples distributed, 82% checked expiration dates, and 85% ensured proper disposal as recommended.

Conclusion The management of drug samples in the FMTUs in Quebec is heterogeneous, with many FMTUs and pharmaceutical companies not following Canadian guidelines.

Les échantillons de médicaments dans les unités d'enseignement de médecine familiale : une étude descriptive transversale

Deuxième partie : Aperçu de la gestion des échantillons de médicaments au Québec

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Résumé

Objectif Tracer un portrait de la gestion des échantillons de médicaments dans des établissements universitaires de soins primaires et vérifier si cette gestion respecte les directives canadiennes.

Type d'étude Une enquête transversale descriptive.

Contexte Les 33 unités d'enseignement de médecine familiale (UEMF) du Québec qui conservent des échantillons de médicaments.

Participants Des professionnels de la santé (PS) ou des membres du personnel de l'UEMF qui sont responsables de la gestion des échantillons (p. ex. les *gestionnaires*).

Principaux paramètres à l'étude Les gestionnaires des échantillons ont répondu à un questionnaire auto-administré entre février et décembre 2013. Les questions portaient sur la façon de choisir les échantillons, d'en faire l'acquisition, de les recevoir, de les entreposer, d'en tenir l'inventaire et d'en disposer. Les résultats ont été comparés avec les normes du *Code of Ethical Practices (2012) des Canada's Research-Based Pharmaceutical Companies* et avec *Les interactions avec l'industrie pharmaceutique : Lignes directrices pour les médecins* (2007) de l'Association médicale canadienne.

Résultats Les 33 UEMF ont répondu au questionnaire. D'après les gestionnaires, aucune UEMF n'avait des critères écrits pour orienter le choix des échantillons. Près du tiers des UEMF (30 %) n'avaient aucun contrôle sur l'accès aux armoires d'entreposage des échantillons. Même si les compagnies pharmaceutiques ne doivent fournir leurs échantillons qu'à des professionnels autorisés, ces derniers participaient à l'acquisition et à la réception des échantillons respectivement dans 79 % et 56 % des UEMF. Seulement 15 % des UEMF effectuaient un suivi des échantillons reçus, 82 % vérifiaient les dates de péremption et 85 % s'assuraient d'en disposer conformément aux recommandations.

Conclusion La gestion des échantillons de médicaments dans les UEMF du Québec est très inégale, plusieurs UEMF et compagnies pharmaceutiques ne respectant pas les lignes directrices canadiennes.

Points de repère du rédacteur

- Cette enquête transversale effectuée au Québec a trouvé que plusieurs unités d'enseignement de médecine familiale (UEMF) ainsi que certaines compagnies pharmaceutiques ne respectaient pas les directives médicales et pharmaceutiques du Canada sur la gestion des échantillons de médicaments. Même si les compagnies pharmaceutiques doivent nécessairement dispenser leurs échantillons de médicaments uniquement à des professionnels de la santé (PS) (médecins ou pharmaciens), ces derniers ne participaient à l'obtention et à la réception des échantillons que dans seulement 79 % et 56 % des UEMF, respectivement.
- À peine 15 % des UEMF utilisaient un registre pour les échantillons qu'ils distribuaient, 82 % vérifiaient que leur date de péremption n'était pas échue et 85 % s'assuraient de disposer des échantillons expirés conformément aux directives médicales canadiennes, dont 6 % disposaient des échantillons expirés dans les poubelles ordinaires. Près du tiers des UEMF permettaient un accès sans contrôle à leur armoire d'entreposage pour échantillons, et des personnes non autorisées avaient accès aux armoires pour échantillons dans la plupart des UEMF.
- D'après les personnes qui géraient les échantillons, aucune des UEMF n'avait critères de sélection écrits pour orienter le choix d'échantillon, ce qui soulève certaines questions quant à l'influence de l'industrie pharmaceutique sur les habitudes de prescription des médecins.

The distribution of drug samples in Quebec primary health care settings, including family medicine teaching units (FMTUs), is a widespread practice. These limited packages of drugs sponsored by the pharmaceutical industry are intended for patients, free of charge, to test clinical response.[1] They are distributed to the clinics through authorized health care professionals (HCPs), who can distribute them to patients. The management of these samples before they are distributed is a shared responsibility between the pharmaceutical industry and HCPs working in the clinics, who must follow a number of rules.[1,2]

Canada's Research-Based Pharmaceutical Companies *Code of Ethical Practices,* last reviewed in 2012, defines the obligations of pharmaceutical companies toward samples.[1] Briefly, samples must only be distributed to authorized HCPs (physicians, dentists, veterinarians, or pharmacists) who have signed an order. Pharmaceutical companies have no obligation concerning sample storage after they distribute them but are responsible for ensuring proper disposal of their own products. In 2007, the Canadian Medical Association (CMA) adopted guidelines for physician interactions with industry.[2] These guidelines stipulate that physicians who accept samples should record the type and amount of product dispensed. They are also responsible for checking expiration dates, maintaining security of samples, and properly disposing of samples. While expiration dates should be verified, neither the steps to fulfil this nor their frequency are specified. No clear policy exists to define selection criteria to choose samples and to regulate their storage. Even though some Quebec FMTUs have adopted their own policies, their application seems suboptimal.[3]

Mismanagement of drug samples once they reach clinics might have negative effects on patients, physicians, and the health care system. In fact, the types of samples kept might influence physician prescription habits.[4-8] It might also increase medication costs by promoting drugs that are not first-line treatment or by allowing unused products to expire.[9] Mismanagement of samples might also put the safety of patients and non–authorized prescriber staff at risk.[10]

In 2015, Lussier et al developed a theoretical framework describing the trajectory of drug samples in FMTUs.[11] They also demonstrated that the management of drug samples was suboptimal in the practice-based research network (PBRN) of the University of Montreal in Quebec.[11] However, little is known about drug sample management on a larger scale. In this second of a series of 3 articles on drug sample use and management in the FMTUs in Quebec, our objectives were to draw a portrait of drug sample management in the FMTUs, and to assess conformity to existing Canadian medical and pharmaceutical guidelines in terms of procurement, reception, inventory, expiration date–related quality, security, and proper disposal of drug samples.

Methods

The general method of this 3-part series is described in part 1 (**page e531**).[3] In brief, we conducted a descriptive cross-sectional study in all 42 FMTUs affiliated with the 4 Quebec university PBRNs that had existed for at least 1 year at the time of the study. Data collection was performed between February and December 2013.

In the FMTUs that had drug samples, we invited all HCPs authorized to hand out samples (practising physicians, residents, pharmacists, and nurses) to complete an anonymous self-administered questionnaire on the use and management of drug samples. In addition, HCPs or staff members who were in charge of drug sample management in these FMTUs (ie, *managers*) completed a self-administered manager questionnaire and an inventory log sheet. The study was approved by all research ethics boards of the involved institutions.

Methodology specific to part 2

This article reports on the answers given to questions on the manager questionnaires from the 33 FMTUs that kept drug samples. When an FMTU was split across geographically separate sites, more than 1 manager completed the questionnaire (1 per site). In these cases, we compared answers for each question. In FMTUs with similar sample management at each site, we analyzed 1 questionnaire per FMTU. Discrepancies between questionnaires were validated with the FMTU directors. In FMTUs with distinct sample management between sites, we analyzed each questionnaire separately. To reduce response variation in the questionnaires, we reviewed each FMTU questionnaire looking for contradictory responses. When this occurred, we sought further clarification from the FMTU directors and corrected the response if needed.

Data analysis

We conducted descriptive analyses with SPSS software, version 20.

Results

Among the 33 FMTUs keeping drug samples, 5 had more than 1 geographic site. Three of the FMTUs had 2 sites, each with an on-site drug sample manager (n=6 managers), and 2 of the FMTUs had 3 separate geographic sites (n=6 managers). This resulted in 40 managers completing the manager questionnaire for the 33 FMTUs. The response rate to the questionnaire was 100%.

Table 1 presents the professional status of respondents. Four of the 5 FMTUs with more than 1 respondent (1 per location) managed their drug samples similarly so we analyzed 1 questionnaire per FMTU. One of the FMTUs managed drug samples differently in its 2 locations. As we analyzed the 2 questionnaires separately,

we obtained a total of 34 FMTU locations with different drug sample management strategies.

Even if they were designated as drug sample managers, 27% of respondents stated that no one was officially responsible for drug sample management in their FMTUs.

Table 2 presents the conformity to the CMA and Canada's Research-Based Pharmaceutical Companies guidelines regarding drug sample management in the 34 sites of the 33 FMTUs.[1,2]

Table 1. Professional status of drug sample managers in the 40 FMTU locations that kept drug samples

PROFESSIONAL STATUS	N (%)*
Practising physician	8 (20)
Nurse	17 (43)
Pharmacist	9 (23)
Pharmacy technician	1 (3)
Resident	2 (5)
Administrative or support staff	3 (8)
Total	40 (100)

FMTU—family medicine teaching unit.
*Overall, 33 FMTUs kept drug samples but 5 were located in 2 (n = 3) or 3 (n = 2) different geographic locations. One respondent per location completed the questionnaire. Percentages do not add to 100% owing to rounding.

Selection criteria

Eleven FMTU sites (32%) had criteria to guide sample choice. According to the managers, none of these criteria were recorded in a written document. Criteria were not reviewed on a regular basis in 9 of the 11 sites (82%). Six sites (18%) had a predetermined list of accepted drug samples developed by physicians or pharmacists. There was no established frequency of review of the list in 5 of the 6 sites (83%).

Procurement

Eight FMTU sites (24%) reported obtaining samples only through pharmaceutical sales representatives at scheduled visits or on request. Two sites (6%) obtained samples only by ordering them. The 24 remaining sites (71%) obtained samples both through pharmaceutical representatives and by ordering. Among the 32 sites obtaining samples through pharmaceutical representatives, physicians or pharmacists met the representatives at 23 sites (72%); nurses met with them at 8 of the remaining 9 sites (89%).

At the 26 sites that ordered samples, orders could be placed by fax (59%), telephone (47%), or Internet (35%). Physicians or pharmacists ordered samples at 13 sites (50%). Nurses were in charge of ordering samples at 10 of the other 13 sites (77%).

Table 2. Conformity to the CMA guidelines and Rx&D *Code of Ethical Practices* for the management of drug samples within FMTUs keeping drug samples: *Overall, 33 FMTUs kept drug samples; 5 of them were situated in more than 1 location but only 1 managed their samples differently in the 2 locations. Thus, we used 34 FMTU locations in our analysis.*

DRUG SAMPLE MANAGEMENT ELEMENTS	CMA AND RX&D GUIDELINES	CONFORMITY ACCORDING TO MANAGERS
Selection criteria	Not regulated	None of the FMTUs had written drug selection criteria
Procurement	Authorized HCPs* must sign an order for the product[1]	Physicians or pharmacists involved† in 27 FMTUs (79%)
Reception	Distribution only to authorized HCPs[1]	Physicians or pharmacists involved in 19 FMTUs (56%)
Storage	Not regulated	Controlled access‡ in 24 FMTUs (71%) Uncontrolled access in 10 FMTUs (29%)
Inventory	Type and amount of medication or product dispensed is recorded[2]	Regular inventory performed in 13 FMTUs (38%) Register kept of samples removed from cabinet in 5 FMTUs (15%)
Verification of expiration dates	Expiration dates and security of drug samples are checked[2]	Regular checking§ in 28 FMTUs (82%) Irregular or unknown frequency of checking in 5 FMTUs (15%) No checking in 1 FMTU (3%)
Disposal	Proper disposal of expired drug samples is ensured[1,2]	Proper disposal‖ in 29 FMTUs (85%) Improper or unknown disposal in 5 FMTUs (15%)

CMA—Canadian Medical Association, FMTU—family medicine teaching unit, HCP—health care professional, Rx&D—Canada's Research-Based Pharmaceutical Companies.
*Authorized HCPs include physicians, dentists, veterinarians, or pharmacists.
†FMTU locations where physicians or pharmacists were involved in ordering samples or in meeting pharmaceutical sales representatives to obtain samples, or both.
‡*Controlled access* is defined as a locked cabinet, limited access to the storage location, or both. *Uncontrolled access* is defined as no locked cabinet combined with no limited access to the storage location.
§*Regular checking* is defined as a frequency of once every 6 mo or more often.
‖Proper disposal included samples returned to the pharmacy, returned to the pharmaceutical companies, or brought to the incinerator directly or through medical waste disposal facilities.

Reception

Physicians or pharmacists (ie, authorized HCPs) received the samples at 19 FMTU sites (56%). In the 15 sites where neither physicians nor pharmacists were involved in receiving samples, nurses (11 sites; 73%), administrative staff (2 sites; 13%), and pharmacy technicians (2 sites; 13%) received the samples.

Storage

Sample storage was controlled by both a locked cabinet and limited access to the storage location at 14 FMTU sites (41%). Ten sites (29%) had limited access to the storage location without a locked cabinet. Ten (29%) had neither limited access to the storage location nor a locked sample cabinet. In addition to practising physicians and pharmacists, nurses could access sample storage in 97% of the sites, residents in 88%, administrative staff in 41%, and pharmaceutical sales representatives in 29%.

Cabinet inventory

Thirteen FMTU sites (38%) performed a regular inventory of samples in their cabinets, mainly at a frequency of once per month (10 of 13 sites; 77%). Five sites (15%) kept a register of samples removed from the cabinet.

Checking expiry dates

Thirty-three FMTU sites (97%) checked expiry dates. Checking was done once per month at 21 sites (62%), once every 3 months at 3 sites (9%), and once every 6 months at 4 sites (12%). Frequency was longer or undetermined at 5 sites (15%) and no checking was done at 1 site.

Disposal of expired samples

Expired samples were returned to the hospital or community pharmacy in 21 FMTU sites (62%). They were given back to the pharmaceutical sales representatives or companies at 3 sites (9%). They were brought to the incinerator directly or to the hospital medical waste facility at 5 sites (15%). One site (3%) sent them to community disposal facilities and 2 sites (6%) threw them out in the regular trash. The method of disposal of expired samples was unclear at the 2 other sites (6%).

Discussion

To our knowledge, this is the first study to provide a complete portrait of drug sample management in primary care teaching settings in North America. A large proportion of Quebec FMTUs kept drug samples (79%).[3] However, the way they were managed differed from one FMTU to another. We found that several FMTUs and pharmaceutical companies did not follow Canadian medical and pharmaceutical guidelines regarding drug sample management. Pharmaceutical companies are obliged to distribute drug samples only to authorized HCPs; however, authorized HCPs were involved in the procurement and reception of samples in only 79% and 56% of the FMTUs, respectively. A mere 15% of FMTUs recorded the samples they dispensed, 82% ensured that samples had not expired, and 85% ensured proper disposal of expired samples as per Canadian medical guidelines. These results highlight the need for better management of drug samples in this clinical context.

No recommendations exist to guide the choice of samples to keep in primary health care settings or how to store them in a safe manner. According to managers, no FMTUs have written selection criteria to guide sample choice, raising new questions about the influence of the pharmaceutical industry on physician prescribing habits. However, the difficulty of establishing and respecting such criteria in the face of pharmaceutical marketing practices[12] might explain the absence of established criteria in FMTUs and in current published policies.

Almost one-third of FMTUs had uncontrolled access to their drug sample cabinet. In contrast to the CMA, which does not recommend any specific regulations for storing samples in medical clinics,[2] the American Medical Association endorses storage of prescription drug samples in a secure manner.[13] Despite this recommendation, the safe storage of samples does not appear to be more prevalent in American primary care offices. Galt et al led a field study in 31 primary care offices in Nebraska regarding best practices in medication safety.[10] They found that 52% of samples were stored in a locked cabinet or room, which is comparable to our results. The lack of rigour regarding the storage of drug samples that can be obtained only by medical prescription in most cases raises concerns about patient safety and unauthorized use by staff. In fact, we found that nonauthorized individuals had access to sample cabinets in most FMTUs. The lack of guidance on this matter from the current Canadian guidelines should be addressed.

Limitations

The absence of standard procedures to manage drug samples made it difficult for managers to answer certain questions, even though they should be the most informed with respect to drug sample management in their FMTUs. This difficulty was reflected by contradictory responses in some questionnaires and by different answers among managers working for the same FMTU in different locations. However, frequent contacts with the FMTU to verify answers allowed us to draw a reasonably accurate portrait of sample management in all Quebec PBRNs. Social desirability bias might also have influenced answers.

Conclusion

The management of drug samples throughout FMTUs in Quebec is heterogeneous, fails to respect established standards in terms of procurement, reception, inventory, expiration date–related quality, security, and proper

disposal, and lacks rigour regarding sample selection and storage. Actions to optimize drug sample management in the FMTUs are required. Prohibiting their use across FMTUs should be considered.

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Contributors

Dr Lessard conceptualized and designed the study, provided input for statistical analyses, wrote the first draft of the manuscript, provided critical review and revision of the manuscript, and wrote the final manuscript. **Dr Lussier** was the principal investigator of the larger study on which this paper reports. **Drs Lussier** and **Diallo** contributed to conceptualizing this study, prepared the data set for analysis, provided input for statistical analyses, and supplied critical review and revision of the manuscript. **Drs Labrecque, Rhéaume, Pluye,** and **Grad** supplied critical review and revision of the manuscript, and made substantial contributions to the acquisition, analysis, and interpretation of data. All authors approved the final manuscript as submitted and agree to act as guarantors of the work.

Competing interests

None declared

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