Strong action is required to encourage federal legislative changes and to reverse this negative trend in the Canadian pharmaceutical market. Meanwhile, we will continue to monitor the situation.

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Availability of Drug Samples in Hospitals: Opportunity or Threat?

In Canada, the *Food and Drug Act* allows the distribution of drug samples to physicians, dentists, and pharmacists.[1] Most provincial regulatory authorities do not prohibit the distribution of such samples in health care settings.[2] However, drug samples are perceived differently by different health care stakeholders.[2] In particular, the use of drug samples may bypass the optimal drug-use process in hospitals and retail pharmacies.[3-5]

The objective of this cross-sectional observational study was to compare the number of drug samples available in outpatient clinics in a mother–child university hospital centre in the province of Quebec in 2007, 2009, and 2012. In the study hospital, drug samples were not allowed in patient wards but were tolerated in outpatient clinics. Drug samples were monitored every 6 months by pharmacy staff, who made unannounced visits to the clinics. In addition to biannual monitoring, extensive audits were conducted periodically over 1- to 2-week periods. During the first extensive audit, in 2007, the

Table 1. Profile of Drug Samples in a Mother–Child Teaching Hospital in 2007, 2009, and 2012

Outpatient Clinic*	2007		2009		2012	
	No. of Samples	Doses per Patient Visit	No. of Samples	Doses per Patient Visit	No. of Samples	Doses per Patient Visit
Pulmonology	564	5.16	484	0.88	189	0.73
Obstetrics and gynecology (*n* = 5)	1 157	0.52	308	0.12	239	0.17
Pediatrics (*n* = 2)	961	1.26	867	0.67	785	0.57
Dermatology (*n* = 3)	2 398	1.49	3 525	5.53	3 563	6.06
Otolaryngology	6 056	0.64	1 316	0.79	989	0.52
Gastroenterology	251	0.45	480	0.23	249	0.66
Dialysis	202	1.61	0	0.00	0	0.00
Endocrinology	19	0.94	33	0.04	2	0.08
Adolescent medicine	179	0.64	36	0.06	116	1.02
Emergency (*n* = 2)	311	0.02	44	0.01	0	0.00
Allergy	200	0.41	0	0.00	245	2.10
Ophthalmology	858	0.09	212	0.26	268	0.05
Urology	78	0.25	23	0.03	46	0.09
Neurology	170	0.12	33	0.03	30	0.04
Dentistry (*n* = 2)	329	0.12	63	0.03	268	0.17
Growth and development	152	0.17	273	0.45	0	0.00
Diabetes	214	0.13	205	0.35	0	0.00
Orthopedics	71	0.01	28	0.01	0	0.00
Daycare	33	0.02	19	0.02	0	0.00
Neonatology (*n* = 2)	4	0.03	0	0.00	0	0.00
Renal transplantation	14	0.02	131	0.71	0	0.00
Total (*n* = 31)	14 221	0.40	8 080	0.38	6 989	0.41

*Data were collected from one location within each outpatient clinic, except where indicated otherwise.

number of units (e.g. tablets, vials) of drug samples in all outpatient clinics was counted. The audit was repeated in November 2009 and July 2012. For each audit period, the total numbers of both units and doses of drug samples were calculated, and the average number of doses was estimated for liquids (0.5 mL/dose) and topical agents (0.5 g/dose). The number of doses of drug samples per patient visit was also calculated, to indicate potential exposure of patients to samples.

In total, 31 locations (i.e., health care units) were identified in 21 outpatient clinics. A total of 14 221 units of drug samples were counted in 2007, 8080 units in 2009, and 6989 units in 2012 (see details in Table 1). Although the number of units decreased over time, the number of doses increased, from 78 955 in 2007 to 75 487 in 2009 and 91 000 in 2012 (breakdown by clinic not shown), mostly because of a higher proportion of topical drugs in the dermatology clinic. The number of doses of drug samples per patient visit remained stable: 0.40 in 2007, 0.38 in 2009, and 0.41 in 2012.

In 2012, only 19% of doses documented during the audit were listed on the official hospital drug formulary; in addition, 4% of the doses were expired. Despite implementation of a Web-based intranet form to declare drug samples received from industry sales representatives, most doses of drug samples had not been declared to the pharmacy by hospital staff.

The availability of drug samples in outpatient clinics at the study hospital has remained stable for the past 5 years. It may seem feasible to prohibit the distribution of samples locally in outpatient clinics, but in fact, it is difficult to do so when such distribution is not prohibited by the pertinent regulatory authorities. For instance, physicians and medical residents often work in multiple hospitals, and their regulations regarding drug samples may vary. We believe that drug samples do not contribute to better patient care and should only be dispensed by retail pharmacies through a structured approach, with documentation of doses dispensed in the patient's record.

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Appropriateness of Triple Therapy after COPD Exacerbation

Dault and others[1] retrospectively examined discharge medications for patients who had been admitted to hospital for acute exacerbation of chronic obstructive pulmonary disease (COPD). Their primary objective was to determine the proportion of admissions for which the combination of long-acting ß$_2$ agonist, tiotropium, and an inhaled corticosteroid was prescribed. This so-called triple therapy is recommended in the Canadian COPD guidelines for patients with moderate to severe COPD and a history of recurrent exacerbations (one or more exacerbations per year, on average, for 2 consecutive years).[2] Presumably, however, some of the patients in the chart review published by Dault and others[1] were presenting with their first exacerbation of COPD. Thus, for a significant number of study participants, the prescription of triple therapy might not have been appropriate.

In the Canadian COPD guidelines,[2] the use of triple therapy in patients with moderate to severe COPD and a history of recurrent exacerbations is designated as having level 1A evidence. As alluded to by Dault and others,[1] the basis for this 1A level of evidence was the Canadian Optimal Therapy of COPD Trial,[3] which showed no significant reduction in the proportion of patients experiencing an exacerbation with triple therapy relative to tiotropium monotherapy (the primary end point). As pointed out by Suissa and others,[4] the results of the Optimal trial may have been influenced by the withdrawal of inhaled corticosteroids. In other words, patients who were receiving inhaled corticosteroids at the time of randomization and who were assigned to receive placebo would have experienced withdrawal from the regimen of inhaled steroids, with the possibility of a deleterious outcome, as has been demonstrated previously.[5,6]

Triple therapy is expensive, a factor that should be taken into account during selection of a therapeutic regimen for these patients. It has been my experience that maximal COPD therapy is often routinely prescribed during admission for an acute exacerbation, with little attention paid to the appropriateness of