

Full Length Research Paper

Effect of drug sample availability on physician prescribing behavior: A systematic review

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The purpose of this investigation was to systematically review and assess the influence of the pharmaceutical industry on physician prescribing. MEDLINE, PubMed and WebSPIRS were searched using the following terms: sample closet, drug samples, sample medications, sample medication utilization, sample dispensing, drug sample availability, drug industry, legislation drug samples, drug promotion, prescribing behavior and advertising. Two researchers independently evaluated and abstracted each article and compiled descriptive data. Of the 334 potentially relevant articles screened using the key words, 96 studies were considered for evaluation by reviewers. Of these, 40 studies addressed effects of sample availability on physician prescribing behavior. Access to drug samples influenced prescribing decisions in most of the studies. Physicians were more likely to prescribe heavily advertised drugs when they had access to samples. At the same time, there was a decrease in the prescribing of over-the-counter, generic, and inexpensive drugs. Availability of samples promoted prescribing habits inconsistent with practice guidelines and in conflict with teaching and formulary policies. The reliance on samples tended to prompt the question, "What samples do we have?" rather than, "Which drug is best for the patient?"

Key words: Drug samples, pharmaceutical industry, prescribing behavior, systematic review.

INTRODUCTION

Drug companies currently use a multifaceted approach to drug promotion, including the distribution of free drug samples. The World Health Organization (WHO) defines pharmaceutical promotion as "all information and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/ or use of medicinal drugs" (Norris et al., 2005). Provision of drug samples has accounted for 50 - 64% of the total marketing expenditures by the pharmaceutical industry in the U.S.

According to Paul H. Rubin (2008), Professor of Law and Economics at Emory University, "there is nothing wrong with letting drug representatives schmooze with

the doctors" because it promotes marketing and research. Patients also like going home with free samples because it saves them a trip to the pharmacy and the amount of the co-pay; moreover, everyone likes "freebies" (Rabin, 2007). The clinical use of samples is common in many ambulatory care settings. A drug sample is defined as "a package containing a limited quantity of a pharmaceutical product sufficient to evaluate clinical response, distributed to authorized health care practitioners free of charge, for patient treatment" (Rx and D, 1999).

However, sample use is under scrutiny by various agencies, including the Food and Drug Administration in the United States. Drug samples may benefit patients by allowing physicians to initiate treatment immediately (Shaughnessy and Bucci, 1997), evaluate effectiveness and adverse effects, demonstrate proper use (as in dermatological medications or inhalers), and decrease cost for patients who are in difficult financial situations.

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On the other hand, use of drug samples may promote poor prescribing habits, deprive patients of the benefit of pharmacy counseling, undermine the use of evidence-based prescribing guidelines, and complicate checking for drug interactions (Chew et al., 2000).

Distribution of drug samples continues to be a controversial, highly debated topic. There have been various studies describing pharmaceutical industry influence on physician prescribing habits. In this systematic review, we focus on studies limited to prescription drug samples and assess how the availability of samples affects physician prescribing behavior.

DATA SOURCES

MEDLINE, PubMed and WebSPIRS were searched by using combinations of the following search terms: sample closet, drug samples, sample medications, sample medication utilization, sample dispensing, drug sample availability, drug industry, legislation drug samples, drug promotion, prescribing behavior and advertising. All bibliographies of included articles were cross-referenced for other relevant studies, which were then included, as were the recent articles brought to our attention.

REVIEW METHODS

Inclusion and exclusion criteria

To be included in the review, papers had to address the effect of drug samples on physician prescribing behavior. No restrictions were placed on the study design. Position papers, review articles and letters to the editor were included if they presented data from small studies. Our exclusion criteria were non-English language articles, non-human studies, studies conducted with pediatric patient populations, and studies that addressed drug promotion/advertising without including data on drug sample availability.

Study selection

Our search extended back to 1986, though some references identified even earlier work. However, given that the 1987 U.S. Prescription Drug Marketing Act (PDMA) (Greenberg, 1988) was made law in 1988, we reviewed only studies published after 1988. All original research papers were randomly distributed among the four authors and then evaluated independently. Each paper was critically appraised using data extraction sheets to assess the study design, methods, inclusion and exclusion criteria, results and conclusion. Two reviewers evaluated each article for the above data and resolved any discrepancies by consensus. We obtained the full text of all potentially appropriate articles.

RESULTS

Of the 334 potentially relevant articles screened using the key words, 96 studies were considered for evaluation by reviewers. Of these, 40 studies addressed the effect

sample availability had on physician prescribing behavior. Study designs included randomized control trial (1), cohort with comparison group (8), cohort without comparison group (5), case control study (1), and cross-sectional descriptive study (25). Publication dates of the studies reviewed ranged from 1988 - 2006 and countries in which the studies were conducted included the United States (31), Canada (3), Australia (2), Africa (2), New Zealand (1), and the United Kingdom (1). Table 1 summarizes key studies, including study population, study design, results and conclusions.

The systematic review identified numerous issues regarding prescription medication sampling. Sample use is high in primary care clinics, with >\$100,000 per year worth of samples distributed in some clinics (Haxby et al., 1995; Wolf, 1998). Medication sample use is prevalent among clinic staff (Westfall et al., 1997). Approximately 30% of sample medications are non-formulary (Haxby et al., 1995). There is little structure in organization and distribution of samples in most of the clinics surveyed. (Backer et al., 2000) Military programs are less likely to use samples and are more aware of guidelines on accepting gifts (Lichstein et al., 1992; Gibbons et al., 1998).

Those using samples were younger, more likely to be residents, more likely to be practicing internal medicine rather than family medicine and of female gender. (Chew et al., 2000) Ferguson et al. (1999) indicated a relationship between workload and sample use: busy internists tended to have a greater chance of meeting with pharmaceutical representatives and accepting samples. Morelli and Koenigsberg (1992) found that faculty in a family physician office labeled samples with the practice's contact information and patient information, as well as dosage instructions, more often than trainees. Faculty was also more likely to give written education materials to the patients.

Alexander et al. (2005) demonstrated that there was no difference in sample use between primary care versus specialty physicians (e.g., cardiology). There was generally poor compliance in labeling and recording of samples; Christie et al. (1998) showed that 25% of all medications prescribed and 42% of physician self-prescribed medications were from sample cabinets.

Per Lichstein et al. (1992) and Hodges (1995), pharmaceutical sales representatives (PSRs) provided samples for resident clinics in 69% of all Accreditation Council for Graduate Medical Education-approved residencies. Junior residents tended to receive more drug samples. Spiller and Wymer (2001) conducted a study on physicians attending a continuing medical education conference, surveying them on the usefulness of various pharmaceutical information sources. The response rate was 67%; only 5% of those respondents reported never using samples, and 44% considered free samples an extremely useful source of pharmaceutical information. Several studies have shown that provision of free drug samples is considered to be an important service provided by PSRs (Peay and Peay, 1988; Thomson et

Table 1. Summary of key studies, including study population, study design, results and conclusions.

References	Population	Study design*	Results/Summary
Adair and Holmgren (2005) Am. J. Med.	Internal medicine (IM) residents	RCT	Access to samples influenced prescribing decisions; residents were more likely to prescribe heavily advertised drugs when access to samples available; there was a trend to use less OTC, generic drugs, and less inexpensive drugs.
Agarwal et al. (2004). Acad. Med.	Family medicine (FM) residents in a Canadian program	Cohort study with comparison group	Short-term attitudes towards drug marketing of residents change with educational intervention (became less favorable - attitudes, value/usefulness, future plan to use drug samples reduced.
Alexander et al. (2005). Arch. Int. Med.	Random sample of internists / cardiologists	Cross sectional descriptive study	IM/Cardiologists not different; sample use was considered a strategy to decrease out-of-pocket prescription costs.
Backer et al. (2000). J. Fam. Pract.	Primary care clinicians and Family Practitioners	Cohort study without comparison group	Samples were used in 20% of encounters; multiple drugs were dispensed in 14.6% of encounters. There was little structure in organization and distribution of samples. Detailed patient education on samples was rare. Clinics with specific policies about interaction have more satisfaction from encounters with pharmaceutical industry.
Banks and Mainous (1992). Acad. Med.	Full-time medical school faculty	Cross sectional descriptive study	42% of MDs and 63% of Ph.D.s believed that free samples influence prescribing patterns.
Boltri et al. (2002). Fam. Med.	Family medicine residents/attendings in a primary care clinic	Cohort study with comparison group	Prescription of first-line drugs for the treatment of hypertension increased after drug sample distribution was prohibited. Overall, faculty were less likely than residents to prescribe first-line medication.
Brett et al. (2003) Arch. Int. Med.	All residents and faculty at a US medical school	Cross sectional descriptive study	31/39 residents and 20/37 faculty stated that presence of drug samples as "very influential."
Brewer D (1998). Fam. Med.	Family practice residents	Cohort study with comparison group	Higher percent of generics written in more controlled environment - that is in programs that eliminated / limited samples, but no decrease in the "cost per prescription."
Chew et al. (2000). JGIM	Physicians (general medicine and family practice)	Cross sectional descriptive study	Sample users - younger, more likely to be residents, IM > FM, female > male. Main reason for sample use was to avoid patient cost. Availability of samples led physicians to dispense and subsequently prescribe drugs that differ from their preferred drug choice.
Christie et al. (1998). JAMA	4 US categorical internal medicine program's residents	Cross sectional descriptive study	Most common source of all medications was sample closet; 25% of all prescribed and 42% of self-prescribed drugs were from sample cabinet.

Table 1. Cont'd

Dill and Generali (2001). Hosp. Pharm.	Drug sample inventory in a university teaching hospital family practice clinic	Cohort study with comparison group	\$11,860 worth samples were dispensed, only 11.4% were documented. Post educational intervention documentation increased to 19.7%.
Ferguson et al. (1999). Am. J. Med.	Active staff in an internal medicine department of a medical school hospital and two affiliated community hospitals	Cross sectional descriptive study	More busy practitioners have more chance of meeting with pharmaceutical sales representatives (PSRs) and accepting samples. There was no difference in likelihood of accepting samples based on whether physicians were trained in a program with policy restriction or not.
Gaedeke et al. (1999). Health Mark. Quar.	Physicians and PSRs who attended medical meeting	Cross sectional descriptive study	Providing free drug samples were considered to be the single most important service provided by PSRs; 65% of physicians thought it was very important.
Garrison and Levin (2000). Ann. Pharmacother.	NY State licensed prescribers	Cross sectional descriptive study	Sample availability - low priority when choosing antidepressants.
Gibbons et al. (1998). JGIM.	Physicians and their patients	Cross sectional descriptive study	Patients considered gifts more influential and less appropriate than did MDs; <10% of physicians thought gifts might influence prescribing behavior, except samples (59%). Staff and military physicians were more aware of guidelines on accepting gifts. Residents find gifts more appropriate and more influential.
Hall et al. (2006) Medical Care	Family physicians	Cross sectional descriptive study	Majority of family physicians did not think they were influenced in their prescribing by presence of drug samples; there was poor compliance in labeling and recording of samples; many interviewed used samples to begin treatment and then wrote a continuing brand name prescription.
Haxby et al. (1995). Am Soc of Health-Sys. Pharm.,	All drug samples distributed within study period to a university affiliated family medicine residency program	Cohort study without comparison group and Cross sectional descriptive study	>\$240,000 worth samples were delivered to the clinic over 14 months; 29% of samples were nonformulary. Physicians were not well informed about delivered samples; only 49% of samples were stocked by pharmacy department.
Hodges (1995). Can. Med. Assoc. J.,	Physicians in training in psychiatry at 7 teaching hospitals in Canada	Cross sectional descriptive study	Junior residents received more drug samples; 34% felt discussion with PSRs have no impact on prescribing; 57% felt accepting promotional items had no impact on prescribing.
Keim et al. (2004). Acad. Emerg. Med.	Emergency medicine program directors	Cross sectional descriptive study	52% of program directors never or very rarely allow PSRs to give residents free samples at work; program directors seeking guidelines were less likely to allow unrestricted interaction of residents with PSRs; 90% thought pharmaceutical promotional activities can affect prescribing practices.

Table 1. Cont'd.

Lichstein et al. (1992). Arch Int. Med.	Internal medicine residency program directors	Cross sectional descriptive study	PSRs provided samples for resident clinic in 69% of programs; 32% of program directors felt residents depended on samples. Military programs are less likely to use samples.
Miller et al. (2002)	Prescription copies at a university affiliated community internal medicine outpatient practice	Cohort study with comparison group	When samples were not available, physicians were more likely to prescribe generic medications to self-pay patients, no change for medicaid patients.
Morelli and Koenigsberg (1992). J. Fam. Pract.	Sample medication collection in a family practice clinic	Cohort study without comparison group	Faculty dispensed more samples than residents; faculty labeled samples more often; when a prescription was written at the time that a sample was dispensed, it was almost always for the same brand name.
Mukamal et al. (2002). J. Am. Board Fam. Pract.	10 affiliated primary care practices	Cohort study with comparison group	Intervention of removing nonformulary samples did not influence prescribing when compared to control group.
Poirier et al. (1996). Am. J. Hosp. Pharm.	P and T Committee	Cross sectional descriptive study	Doctors more likely than pharmacists to be OK with marketing. Higher percentage of pharmacists than physicians found it unethical to provide no cost medications to patients.
Randall et al. (2005). Acad. Psych.	Residents - psychiatry training	Cohort study with comparison group	Majority thought that they were not influenced by PSRs. Most acceptable gifts from PSRs as per residents were drug samples; educational seminar intervention decrease acceptance of office supplies by 35%, gifts with no educational value by 20%, but no change in drug samples.
Reeder et al. (1993). Ann. Emer. Med.	Chief residents in different emergency medicine residency programs	Cross sectional descriptive study	20% believed that accepting gifts from PSRs could affect prescribing habits; 66% of chief residents reported sample medications were distributed by PSRs. Believed samples are useful for indigent and self-pay patients.
Roughhead et al. (1998). Aust. NZ J. Med.	15 general medical practitioner encounters with PSRs	Cohort study without comparison group	Reciprocation was used by PSRs as most commonly observed method of influence. Use of product samples appeared to have a direct influence on prescribing practices with practitioners admitting their choice of drug was related to which sample they had on hand at the time of prescribing.
Schumock et al. (2004). Ann. Pharmacother.	Physicians, pharmacists, formulary committee members	Cross sectional descriptive study	Physicians rated the availability of drug samples and personal experience more influential on prescribing than clinical pharmacists and formulary committee members.
Seidel (1999). SAMJ	3 physicians in a private general practice in South Africa	Cohort study without comparison group	Definite presence of sample; 90% considered to be of value

Table 1. Cont'd

Shaughnessey et al. (1997). <i>Ann. Pharmacother.</i> ,	Family practice residency program directors and sample of residents from these programs	Cross sectional descriptive study	55% thought samples influenced their prescribing; residents were unaware of the rules governing the labeling of samples; residents in programs with a sample policy were more likely to affirm that samples should be given to the financially needy.
Spiller and Wymer (2001). <i>Health Mark Quart.</i>	Physicians attending a CME conference	Cross sectional descriptive study	Only 5% of MDs report never using samples, 44% considered free samples as useful pharmaceutical information source. Sample supply, patient finances, and insurance affirmed as factors in dispensing samples. 42% considered samples to have strong influence on prescribing behavior.
Strang et al. (1996). <i>Annals CRMCC</i>	Random sample of Canadian physicians	Cross sectional descriptive study	86% thought PSRs should be allowed to offer free samples; 70% considered that drug detailing affected prescribing habits; 74% thought that PSRs should be required to use guidelines for drug detailing.
Thomson et al. (1996). <i>Br J. Gen. Pract.</i>	General Practitioners in New Zealand, a random sample	Cross sectional descriptive study	Provision of practical prescribing advice by PSRs and gifts relevant to medicine were seen as desirable activities; 10 of 67 reported samples as important to seeing PSRs.
Westfall et al. (1997). <i>JAMA</i>	Physicians, residents, nursing staff, office staff in a family practice residency	Cross sectional descriptive study	230 separate drug samples used for personal/family use; factors influencing prescribing behavior not discussed.
Wolf BL (1998). <i>JAMA</i>	Inventory of drug closet in an allergy practice	Cross sectional descriptive study	Sample use was high in that clinic worth > \$250,000 dollars (7 in a yr) Says it was given to people in need. 10% was wasted, due to too many samples.

*Type of study: 1. RCT 2. Cohort study with comparison group 3. Cohort study without comparison group 4. Case Control design 5. Cross sectional descriptive study.

al., 1994). Gaedeke et al. (1999) reported that 65% of physicians considered samples the most important service PSRs provide.

Access to drug samples influenced prescribing decisions in nine studies (Morelli and Koenigsberg, 1992; Brewer, 1998; Roughead et al., 1998; Chew et al., 2000; Boltri et al., 2002; Miller et al., 2003; Adair and Holmgren, 2005; Hall et al., 2006; Symm et al., 2006). Adair and Holmgren (2005) showed that resident physicians were more likely to prescribe heavily advertised drugs when they had access to samples, and that they wrote fewer prescriptions for less expensive OTC and generic drugs. Chew et al. (2000) demonstrated that availability of drug samples led physicians to dispense and subsequently prescribe drugs that differ from their reported preferred drug choice.

In Hall et al. (2006) interview study, physicians reported using samples to commence medicines and then wrote a

continuing brand name prescription. Conversely, Miller et al (2003) showed that physicians were more likely to prescribe generic medications to self-pay patients when samples were not available. Chew et al. (2000) found that the main reason for sample use was "to avoid cost to patients."

Perhaps the important point from these studies is that less than half of practitioners believed that presence of drug samples could affect their prescribing behavior. Further, most practitioners stated that accepting drug samples was not unethical (Halperin et al., 2004; Randall et al., 2005; Hall et al., 2006; Morgan et al., 2006).

Backer et al. (2000) found that clinics with specific policies about industry interaction reported more satisfaction from encounters with pharmaceutical industry representatives. In the study by Shaughnessey and Bucci (1997), residents in programs with a sample policy were more likely to affirm that samples should be given to the

financially disadvantaged. Agrawal et al. (2004) indicated that education about sample use was shown to influence short-term attitudes toward pharmaceutical marketing; after participating in an educational session, residents reported less favorable attitudes toward the value/usefulness of samples and planned to use such samples less in the future.

In a survey of emergency medicine program directors, Keim et al. (2004) found that 52% of these directors never or very rarely allow pharmaceutical representatives to give residents free samples at work, and that 90% of them thought that pharmaceutical promotional activities can affect prescribing practices. In Brewer's (1998) survey of family medicine residents, programs that eliminated or limited sample use reported a higher percentage of generic prescriptions being written but found no decrease in the "cost per prescription." A study by Hodges (1995) showed that the more money and promotional items a physician-in-training received, the more likely he or she was to believe that discussion with representatives did not affect prescribing ($p < 0.05$). This was demonstrated through examining attitudes regarding interactions with PSRs, number of personal meetings with PSRs, number of drug samples and promotional items received, and the estimated value of gifts received by each resident during a 1-year period.

DISCUSSION

Studies have shown that physician-industry relationships are common and complex. A responsibility of the pharmaceutical industry is drug discovery, development, and production that contribute to improved health care. Although pharmaceutical industry efforts have promoted the welfare of patients through research and product development, biopharmaceutical firms need to commit their responsibility to their shareholders, who expect reasonable returns on their investments. Since physicians write the prescriptions that yield sales of new products, the industry naturally focuses substantial marketing efforts on physicians to influence their prescribing behaviors. Much of this physician marketing is carried out through PSRs who visit physicians and provide information about their products while promoting the use of their products by offering gifts, meals and free drug samples. The studies reviewed herein suggest that physicians tend to underestimate their personal response to these marketing efforts.

Sample use may fall into two general categories: those dispensed for the treatment of acute illness (e.g., urinary tract infection or muscle sprain) and those dispensed for the treatment of chronic illness (e.g., hypertension or diabetes). It is in the latter category that the issue becomes more complicated: in the treatment of chronic illnesses, the short-term financial gains of free samples can be quickly offset by higher prices when patients

begin to purchase the medicine for long-term use.

Access to free drug samples was prevalent in most of the physicians' clinics surveyed. Again, while most physicians deny that availability of samples has any effect on their prescribing practices, numerous studies that we reviewed show otherwise. Sample availability in clinics has not been shown to help the financially needy. In fact, interaction with PSRs and use of their information may be associated with increased primary care physician prescribing costs (Caudill et al., 1996).

Availability of drug samples led physicians to dispense and subsequently prescribe drugs that differ from their self-described preferred choice. Many physicians interviewed gave samples to patients to start them on a drug, then wrote a prescription for a name brand drug. Any short-term financial gains realized by dispensing free samples are quickly offset by the higher prices patients pay after the name brand drugs are prescribed. The availability of samples promotes prescribing habits not recommended in guidelines that may also conflict with teaching and formulary policies. The reliance on samples tends to prompt the question, "What samples do we have?" rather than, "Which drug is best for the patient?"

To improve patient compliance with taking medications, thereby ensuring that they gain the intended therapeutic effect, physicians need to consider ways to reduce costs for patients, especially the uninsured and financially disadvantaged. Possible steps to take include identifying patients in need, increasing physician awareness about the cost of drugs, minimizing the number of medications prescribed, increasing the prescribing of generic drugs, considering drug alternatives that are available for \$4 through retailers like Wal-Mart, and even suggesting pill splitting when possible. Educational interventions specifically aimed at doctors-in-training may be effective in changing attitudes or behaviors towards physician-industry interactions. Residents should be educated about prescribing drugs based on efficacy and safety, and about cost as well.

Conclusion

Based on our review, we believe that the popular view that accepting drug samples is appropriate and benefits patients should be reconsidered. An ethical and productive physician-industry relationship is critical to improving drug discovery and public health. Many national organizations have made recommendations to reduce conflict of interest, legal exposure, and dissemination of biased information. In 1987, Congress passed the PDMA to increase control over the distribution of drug product samples by manufacturers and to prevent and detect diversion. PDMA requires that samples be distributed only with a written prescription, and that recipients execute a written receipt for samples delivered.

This review of relevant literature highlights many issues

about doctors receiving free drug samples. As academic medical centers examine and revise their policies on physician interaction with PSRs, and as they are graded on their pharmacy curricula, they must focus on what the relationship between physicians and pharmaceutical companies should become in the future.

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