Restocking the Sample Closet: Results of a Trial to Alter Medication Prescribing

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Background: Although medication costs make up a large and growing portion of health care costs, few interventions have successfully encouraged physicians to alter prescribing patterns.

Methods: To promote the use of an open formulary, we altered the contents of the sample closets of five primary care practices in eastern Massachusetts. In these practices, we removed all nonformulary drugs in five drug classes and restocked with purchased generic samples. We performed a time series analysis of formulary compliance, before and during an 8-month intervention, with five concurrent control practices for comparison.

Results: Although providers in both the intervention and control practices complied well with the formulary, we found no incremental effect of the sample closet intervention on absolute formulary compliance (P = .46) or on the secular trend in formulary compliance (P = .60). We also found no effect on these measures in any of the individual drug classes studied.

Conclusions: This sample closet intervention did not appear to improve further the good formulary compliance in these practices. In such settings, better ways are needed to guide prescribing behavior. (J Am Board Fam Pract 2002;15:285–9.)

Medication costs make up a large and growing share of US health care costs. Annual pharmaceutical sales in the US now approximate \$90 billion, with 15% yearly growth. To sustain this growth, the pharmaceutical industry spent nearly \$14 billion in detailing, sampling, and advertising in $1999.^{2}$

To ensure appropriate medication use amid this growth in pharmaceutical spending, researchers have sought ways to improve physician prescribing patterns, including counterdetailing, physician education, and restrictive formularies.3-5 Because more than 60% of office visits to physicians result in a medication prescription,6 interventions aimed at the point of patient contact are particularly valued, if not always successful.^{7,8}

One potential site for intervention is with pharmaceutical sampling. The pharmaceutical industry distributed approximately \$8 billion in pharmaceutical samples in 2000, highlighting the importance

of samples to the industry.9 An Australian survey has confirmed that sampling encourages more rapid adoption of new drugs, 10 but little else is known about the role of sampling in physicianprescribing behavior.11

In 1998, CareGroup, an integrated network of hospitals and practices in eastern Massachusetts, established an open pharmaceutical formulary for affiliated physicians, in which specific medication choices were recommended but not mandated. We sought to determine whether nonformulary medications in sample closets affected compliance with this formulary. We studied 10 affiliated primary care practices, five of which received a multifaceted intervention to restock their sample closets. This intervention included removing nonformulary medications and providing generic samples.

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Methods

Study Population

The Affiliated Physicians Group of Beth Israel Deaconess Medical Center is an association of 29 office practices located throughout the greater Boston area. Because of funding limitations, we selected five primary care practices for intervention. We chose five control primary care practices, matched approximately for the number of provid-

Table 1. Characteristics of the Sample Closet Intervention.

- 1. Introductory educational lecture for providers
- 2. Installation of organizing containers
- Removal of nonformulary medications: nonsteroidal antiinflammatories, antihypertensives, antihyperlipidemics, antibiotics, and histamine₂ receptor antagonists
- 4. Purchase of generic samples: amoxicillin, penicillin, cephalexin, doxycycline, trimethoprim-sulfamethoxazole, enteric-coated erythromycin, atenolol, hydrochlorothiazide, sustained-release verapamil, cimetidine, ranitidine, gemfibrozil, ibuprofen, naproxen, and piroxicam
- Ongoing maintenance of sample closets: purchase of additional generic samples, solicitation and monitoring of industry-supplied samples, and removal of excluded medications

ers, to assess the effect of secular trends and concurrent interventions.

All 10 practices actively used sample closets; a preintervention survey of participating physicians (with a 60% response rate) found that nearly all respondents reported providing samples at least weekly. In this study, the sample closet was defined as that part of the office in which were stored samples of prescription medications received from pharmaceutical representatives. In practice, these so-called closets ranged from small supply closets to multiple examination rooms.

Pharmaceutical Formulary

In 1998, CareGroup established a suggested formulary. The CareGroup Pharmacy and Therapeutics Committee recommended specific agents, chiefly based on effectiveness and average wholesale price, for approximately 10 classes of medications (oral contraceptives, nonsteroidal anti-inflammatory agents, etc). Copies of the formulary were distributed to all CareGroup physicians, practice leaders received periodic status reports on formulary compliance, and clinical pharmacists conducted academic detailing. No specific penalties for nonformulary medication use existed.

Sample Closet Intervention

The sample closet intervention consisted of multiple steps (Table 1). We intervened during January 1999, making February 1999 the initial month of study. First, we provided brief educational lectures about the CareGroup formulary and the proposed intervention. Second, we reorganized the closet, placing all medications into clearly labeled, orga-

nized compartments. Third, we removed all nonformulary medications. Fourth, only formulary medications were allowed into the sample closet on an ongoing basis. Finally, we ordered generic samples of specific medications to be dispensed exactly as branded medications were.

Data Collection and Analysis

We received information from individual managed care organizations on all prescriptions filled by patients in these practices who were enrolled in capitated managed care contracts. We included only new prescriptions written by providers in the 10 study practices, defined as the first prescription of a medication not filled during the preceding 3-month period. Each month, we calculated the number of prescriptions for formulary medications divided by the total number of medications prescribed in the classes of medication under study. As a further control, we studied antidepressants, which were not included in the sample closet intervention. We studied the 6 months preceding the intervention and an 8-month intervention period. Because we excluded nonformulary medications from intervention sample closets, we excluded actual samples from analysis and studied only filled prescriptions.

We used segmented linear-regression analysis¹² to estimate changes in levels or trends in the time series of medication use (the formulary compliance for each drug class in each month). Regression models included a constant term, a term for the concurrent control trend, and terms to estimate changes in the level or trend of service use that coincided with the sample closet intervention, excluding data from January 1999.¹³ We controlled for autocorrelation by assuming a first-order autoregressive process, and we used residual analysis to test model adequacy.

Results

Table 2 shows the characteristics of the study and control practices. The practices were well matched in size, prescription volume, and baseline formulary compliance.

We found no effect of our intervention on overall formulary compliance for the classes of drugs we studied (Figure 1). In a time-series regression analysis, the sample closet intervention was associated with no change in either absolute formulary com-

Table 2. Characteristics of the Study and Control Practices.

Site Characteristic	Intervention	Control
Number of practices	5	5
Total number of physicians	23	21
Total number of nurse practitioners	4	1
Range of providers in each practice	3–8	3–6
Total number of prescriptions, January through June 1998	12,203	14,831
Formulary compliance at onset of study, 1 July 1998	89%	88%
Mean number of new prescriptions for study drugs per month during study (range)	432 (294–822)	509 (355–1055)

pliance (P = .46) or the trend in formulary compliance with time (P = .60). Likewise, we found no effect of the intervention on absolute compliance or the trend in compliance among any single drug class: nonsteroidal anti-inflammatory agents (P =.89 and .81), antihyperlipidemic agents (P = .59and .81), antihypertensive agents (P = .63 and .49), histamine, receptor antagonists (P = .44 and .28), and antibiotics (P = .08 and .75). The effect of the intervention among these drug classes was similar to the effect among antidepressants (P = .50 and .99), which were not targeted for intervention.

Discussion

In this study of patients in 10 primary care practices, we found that restricting the contents of sample closets had no effect on the proportion of prescriptions that complied with an open formulary. This finding was true for all classes of drugs we studied. At least in settings where other interventions to improve physician prescribing are underway, the sample closet does not appear to be a promising target for additional intervention.

Several factors that might explain the failure of this intervention to improve formulary compliance include the targeted patient population, high baseline compliance (a ceiling effect), and limitations of the drugs studied.

We studied patients enrolled in capitated managed care plans and for whom we had complete information about prescription medication use. These patients were essentially all employed, younger than 65 years of age, and insured for prescription medications, which might have limited their likelihood of profiting from a sample closet intervention. Instead, patients with no medication

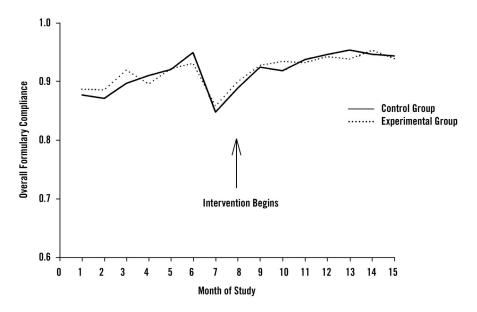


Figure 1. Overall formulary compliance for all new prescriptions in five selected classes of medications, according to intervention or control status. Dotted line indicates intervention group.

coverage might be more likely to receive samples (at no immediate cost to the patient) than the patients we studied.

Formulary compliance among both groups was high during our study. Thus, a ceiling effect might have occurred in which no further improvement could reasonably be expected, although formulary compliance remained less than ideal. Whereas a sample closet intervention might be effective for guidelines that are less widely adhered to than our formulary, it clearly resulted in little incremental value relative to the other interventions already in place in these offices and in many other similar practices throughout the United States.

We studied medications that are frequently prescribed and sampled, making them good candidates for intervention. The preintervention survey of participating physicians found that the drugs most widely distributed were antibiotics, antihistamines, antihypertensives, antidepressants, and asthma medications. Other classes of drugs might be better choices, however, if the decision to choose a particular agent of that class is strongly influenced by availability in a sample closet.

Despite the null findings of this study, other measures that were in place to encourage formulary compliance appeared effective. These measures included academic detailing by pharmacists, regular reporting to practice leaders and physicians, and periodic newsletters. In other settings, academic detailing and involvement of practice leaders improved physician-prescribing patterns^{14,15} and should guide future efforts to change prescribing behavior.

Our formulary did not restrict entire drug classes; rather, it excluded specific agents within a class. For example, the formulary included cimetidine and ranitidine and excluded famotidine and nizatidine. This type of within-class switching has proved feasible and cost-effective in similar populations. Within-class switching, however, does not address such problems as prescribing too many medications, prescribing for too long a time, and prescribing inappropriate classes of drugs (eg, calcium-channel blockers for initial treatment of hypertension). Restocking sample closets might be an approach worthy of study for the latter problem.

Another aspect of our intervention bears mention. Massachusetts Department of Public Health regulations require that samples dispensed from physicians' offices be individually labeled and re-

corded, a stipulation also required elsewhere. None of the 10 practices involved in this study fully complied with this regulation at the onset of our study. By limiting the range of branded samples in each sample closet and purchasing prepackaged generic samples, we enabled intervention sites to track dispensed samples and comply with the sampling regulation, an accomplishment that none of the control sites achieved.

In conclusion, we found that restocking sample closets in primary care practices with preferred and generic medications did not materially alter compliance with an open formulary. Other interventions already in place, however, including academic detailing and involvement of practice leaders, appeared to sustain high formulary compliance with time. Where such interventions are in place, additional attention to restocking sample closets might be unnecessary.

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