

## “Trial” Prescriptions to Reduce Drug Wastage: Results From Canadian Programs and a Community Demonstration Project

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**Objective:** To determine the acceptability of a program to avoid drug wastage through “trial” prescriptions.

**Study Design:** Cross-sectional survey, followed by a 9-month demonstration project.

**Methods:** Consultants to trial prescription programs operated by 2 public- and 3 private-sector drug plans in Canada were surveyed. All of the trial prescription programs were voluntary. The demonstration project involved 215 English-speaking adults who filled a “new” prescription for an angiotensin-converting enzyme inhibitor,  $\beta$ -blocker, or calcium channel blocker (CCB) in 1 of 16 Peterborough, Ontario pharmacies. Patients received a 7-day supply of medication and a reminder card on which the dispensing pharmacist recorded the mutually agreed date and time the patient would be contacted to assess the results of the “trial.” Patients who tolerated the medication received the balance of their original prescription.

**Results:** Most patients (86%) who were offered trials in the demonstration project accepted them, and most (82%) who accepted them found them helpful. The proportion of patients who received the balance varied by program, ranging from 47.1% to 86.6%. The dollar value of the wastage avoided through trial prescriptions varied by drug class. This was driven largely by differences in the unit cost of the medications, but also to a lesser extent by larger prescriptions for CCBs.

**Conclusions:** Trial prescriptions were acceptable to patients and, if focused on specific medications, could reduce the direct cost of drug wastage. More work is needed to define the conditions under which trial prescription programs are feasible for pharmacists and drug plans.

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cies<sup>2</sup> totaled more than Can \$120,000 in just 4 and 8 weeks, respectively. Reasons cited for the returns in the latter study included product expiration (25%), patient- (19%) and physician-initiated (12%) discontinuation, and drug intolerance (8%),<sup>2</sup> some of which suggest opportunities for intervention.

One way to reduce drug wastage caused by an early change or discontinuation of treatment is to systematically limit the quantity of medication that is initially dispensed. In Canada, this idea has been tested by several public and private-sector drug plans by permitting pharmacists to fill “new” prescriptions for prespecified, long-term medications in 2 parts—an initial or “trial” quantity and, if the drug is tolerated, the balance. Although these programs have operated for some time in Canada, little is known about their effectiveness. Are community-based pharmacists willing to participate in a formal trial prescription program? Are trial prescriptions acceptable to consumers? What is the dollar value of the wastage avoided through trial prescriptions? To begin to explore these questions, we undertook a survey of established trial prescription programs in Canada and, where information was lacking, conducted a 9-month demonstration project.

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In many jurisdictions, state pharmacy laws or regulations exist that prohibit the resale of previously dispensed prescription medication. Although designed to protect the public, such laws also produce thousands of dollars’ worth of medication wasted each year. In 2 recent Canadian surveys, medication returns to 29 Sudbury, Ontario, pharmacies<sup>1</sup> and a random sample of 58 Alberta pharma-

...METHODS ...

**Survey of Trial Prescription Programs in Canada**

By May 1997, 4 provincial and at least 3 private-sector drug plans had operated formal trial prescription programs in Canada. Consultants to these programs were contacted by telephone on 3 occasions to request a program description and a copy of the most recent evaluative data that were available at the time. **Table 1** lists the program features and **Table 2** lists outcomes for which we sought information. Based on results from this survey, we designed a

demonstration project that would provide further information about the number of trial opportunities taken by pharmacists and patients; obstacles to using trial prescriptions; patients' opinions of trial prescriptions; why prescriptions are discontinued during the trial period; and the dollar value of drug wastage avoided through trial prescriptions.

**Demonstration Project**

*Setting.* The demonstration project was conducted between May 1997 and June 1998 in Peterborough, Ontario, Canada, a city of roughly

**Table 1.** Features of Trial Prescription Programs in Canada

Feature	Program					
	Peterborough Demonstration Project	British Columbia Trial Prescription Program	Saskatchewan Trial Prescription Program	Alberta Trial Prescription Pilot Project	General Motors Community Pharmacy Intervention Project	Metropolitan Toronto Medication Use Management Program
Location	Peterborough, Ontario	British Columbia	Saskatchewan	Red Deer, Alberta	Oshawa and St. Catharines, Ontario	Toronto, Ontario
Date started	August 1997	February 1995	April 1996	August 1994	August 1996	January 1997
Duration	9 mo	Ongoing	Ongoing	6 mo	6 mo	12 mo
Participants	Adult residents	Seniors and those on social assistance	Provincial drug benefit plan beneficiaries	Seniors with government-sponsored coverage	Salaried employees (roughly 12,000) and dependents	Employees, retirees, and their dependents
Drug classes/therapeutic areas	ACEI, BB, CCB	ACEI, antiulcer, BB, CCB, NSAID, misc.	$\alpha$ blocker, antidepressant, antilipemic, CCB, NSAID, misc.	ACEI, CCB, H <sub>2</sub> -blocker, NSAID	ACEI, antiulcer antilipemic, antiulcer, BB, CCB, NSAID	ACEI, BB, CCB, NSAID
Trial duration	7 d	7–14 d	7 or 10 d	7 d	7 d	7 d
Eligible patients identified by drug claims adjudicator?	< 1%	No	No	No	Yes	Yes
Professional fee/Copayment on trial quantity?	Yes/If applicable	Yes/No	Yes/Yes	Yes/Yes	Yes/Yes	Yes/No
Professional fee/Copayment on balance of prescription?	No/No	Yes/Yes	No/Yes	Yes/Yes	Yes/No	Yes/No
Fee paid to document outcome of trial?	Yes	No	Yes	No	No	No

All programs were voluntary.

ACEI = angiotensin-converting enzyme inhibitor; BB =  $\beta$ -blocker; CCB = calcium channel blocker; NSAID = nonsteroidal anti-inflammatory drug.

70,000 residents that houses several medium-sized industries, 2 postsecondary institutions, 1 general hospital, and well-organized and active medical and pharmacy associations.

*Recruiting Pharmacies and Developing the Program.* Peterborough pharmacists were introduced to the project through a series of meetings organized by the local pharmacists' association. Thirty-three pharmacy managers were invited to attend the first meeting. The purpose of that meeting was

to describe the objectives of the project, to obtain feedback on its design and implementation, to identify prospective participants, and to organize a working group to finalize the details of the protocol (including the entry criteria, procedures for processing the trial prescriptions, the contents of the consent and data collection forms, and the data collection fees). Subsequently, 2 workshops were held to share the project protocol with the local pharmacy community. At the conclusion of these workshops,

**Table 2.** Findings From Trial Prescription Programs in Canada

Measure	Program					
	Peterborough Demonstration Project	British Columbia Trial Prescription Program	Saskatchewan Trial Prescription Program	Metropolitan Toronto Medication Use Management Program	General Motors Community Pharmacy Intervention Project	Alberta Trial Prescription Pilot Project
Evaluation period	9 mo (August 1997 — April 1998)	12 mo (January 1997 — January 1998)	12 mo (April 1996 — April 1997)	12 mo (January 1997 — January 1998)	6 mo (August 1996 — January 1997)	6 mo (August 1994 — January 1995)
No. of eligible pharmacies	25	Approx. 700 (province-wide)	Approx. 350 (province-wide)	Approx. 2500 (province-wide)	165	36
No. of trial opportunities	> 5500	—	—	—	2226	1748
No. of pharmacies initiating trials (% of eligible)	15 (60.0)	308 (44.0)	—	700 (28.0)	—	20 (55.6)
No. of trials initiated (% of opportunities)	234 (< 5.0)	4480	2619	3095	247 (11.1)	82 (4.7)
No. of prescriptions discontinued (% of trials initiated)	32/234 (13.7)*	1665/4480 (37.2) <sup>†</sup>	1140/2619 (43.5) <sup>†</sup>	1636/3095 (52.9) <sup>†</sup>	113/247 (45.7) <sup>†</sup>	11/82 (13.4) <sup>†</sup>
Discontinuation rate for common drug classes/therapeutic areas (% of trials initiated)	ACEI: 12/90 (13.3) CCB: 10/71 (14.4) BB: 10/73 (13.7)	—	CCB: 125/367 (34.0) NSAID: 571/1057 (54.0)	CVD: 218/681 (32.0) NSAID: 888/1455 (61.0)	—	ACEI: 2/11 (18.2) CCB: 4/35 (11.4) NSAID: 4/30 (13.3)
Dollar value of drug wastage avoided per trial initiated (Can \$)	Without professional fee on balance: Overall: 5.52 ACEI: 4.78 CCB: 10.12 BB: 1.98	—	—	—	With professional fee on balance: Hypotensive: -1.66 NSAID: 3.88 Anti-ulcer: 7.07	With professional fee on balance: -1.28 Without professional fee on balance: 5.72

ACEI = angiotensin-converting enzyme inhibitor; BB =  $\beta$ -blocker; Can \$ = Canadian dollars; CCB = calcium channel blocker; CVD = cardiovascular disease; NSAID = nonsteroidal anti-inflammatory drug.

\*As documented by pharmacists.

<sup>†</sup>Based on electronic drug claims data.

<sup>‡</sup>Based on drug claims data and written documentation submitted by pharmacists.

**Table 3.** Characteristics of Patients Who Participated in the Peterborough Demonstration Project

Characteristic	Number (%)
Age (< 65 y; n = 211)	98 (46.4)
Sex (female; n = 211)	101 (47.9)
Drug plan coverage (n = 202)	
Ontario Drug Benefit Plan	113 (55.9)
Private drug plan	53 (26.2)
None (cash paying)	36 (17.8)

pharmacy managers were asked to confirm whether or not they would be participating in the study; 25 (75.8%) agreed.

*The Intervention.* Trial prescriptions were dispensed in 2 parts: a 7-day supply of medication and, if the drug was tolerated, the balance of the original prescription. Three classes of drugs were eligible: angiotensin-converting enzyme inhibitors,  $\beta$ -blockers, and calcium-channel blockers (CCBs). These medications were selected for 3 reasons: they are long-term therapies prescribed in large quantities; all 3 classes had been included in previous trial prescription programs; and, according to “cabinet clean-out” campaigns, they represented an important opportunity for waste prevention.<sup>1,2</sup>

Patients were eligible for a trial prescription if they were older than 18 years of age; were able to read and understand English; had been prescribed at least a 21-day supply of an eligible medication;

**Table 4.** Patients’ Reasons for Nonparticipation in the Peterborough Demonstration Project

Reason	Number (%)
Unavailable when balance to be dispensed	11 (32.4)
Inconvenience/too far to return for balance	7 (20.6)
None given	5 (14.7)
MD appointment just beyond trial period	4 (11.8)
Too busy	3 (8.8)
Discomfort with reduced quantity	2 (5.9)
Unable to obtain informed consent	2 (5.9)
Total number (% of those eligible and approached) who declined participation	34 (13.7)

and had not taken the medication at the same or a higher strength in the previous 12 months. Coverage by a drug plan was not an entry criterion. Pharmacy staff were responsible for confirming patients’ eligibility using pharmacy records and information provided by the patient.

Those who accepted trial prescriptions received the 7-day supply of their medication (applying the usual fees and copayments), a pamphlet describing the program, and a reminder card on which the dispensing pharmacist recorded the mutually agreed date and time the patient would be called to assess the results of the trial. Patients who tolerated their medication received the balance and were charged for the drug cost plus markup. All but 2 participating pharmacies provided delivery service. In lieu of a professional fee that normally would have been charged on dispensing the balance of the prescription, participating pharmacists agreed to be compensated from the study budget through a series of “data collection fees” that, together, were roughly equivalent to the average professional fee charged at the time of study. These fees were paid on receipt of each completed data collection form.

Various supports and services were available to pharmacists throughout the course of the project, including flowcharts detailing the program procedures, posters and cue cards for the dispensary, pamphlets for patients, and forms to help pharmacists track and document follow-up calls. Monthly newsletters and telephone calls from the project coordinator (JMP) provided updates on patient enrollment and answered pharmacists’ questions.

**Data Sources and Analysis Plan**

Information about established trial prescription programs was taken from internal study reports provided by the program consultants.

Three data sources were used to evaluate the demonstration project. Pharmacists were paid a data collection fee to obtain patients’ written informed consent, record the details and outcomes of each trial prescription, note the time required to perform and document the services, and question patients about the helpfulness of the program at the time of their last contact with patients. This information was captured on a standardized data collection form. To calculate the dollar value of the wastage avoided through trial prescriptions, the quantity and cost (plus markup) of the medications were taken from patients’ original prescription

receipts. For prescriptions that were discontinued (stopped or changed), the value of the wastage was calculated as the product of the unit cost of the medication and the difference between the trial quantity and what was originally prescribed. Data for claims to the Ontario Drug Benefit Plan (which provides drug benefits for all Ontario residents aged 65 years or older) were used to approximate the number of patients who were eligible for trial prescriptions during the study period. This estimate was based on claims that met the study entry criteria for persons 65 years of age or older. Finally, at the conclusion of the study, one of us (JMP) conducted semistructured telephone interviews with pharmacy managers to obtain descriptive information about the pharmacies and to identify obstacles to using trial prescriptions.

A goal of the demonstration project was to determine whether trial prescriptions could reduce drug wastage. Based on data from the British Columbia Trial Prescription Program (D. Derosiers, British Columbia Pharmacy Association, personal communication, December 1996), we hypothesized that among patients who would accept a trial, about 75% would receive the balance of their medication. We determined that at least 200 trial prescriptions would be needed to detect this proportion within 5 percentage points and with 90% confidence.<sup>3</sup>

Univariate descriptive statistics (proportions for categorical data and means and standard deviations [SDs] for continuous data) were used to summarize the study results. Responses to open questions to pharmacy managers were grouped into categories and reported as frequency counts and proportions. Tests for interprogram and subgroup differences ( $\chi^2$  tests for proportions and Student *t* test for means) were 2-sided, with type I error ( $\alpha$ ) set at 0.05. Data were managed and analyzed using Microsoft Access (Microsoft, Redmond, WA) and SAS (SAS Institute, Cary, NC) software.

This research protocol was approved by a research ethics board at Sunnybrook and Women's College Health Sciences Centre in Toronto.

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...RESULTS...

### **Characteristics of Trial Prescription Programs in Canada**

Five of the 7 consultants responded to requests for information about their programs. Features of 2 province-wide (British Columbia and Saskatchewan) and 3 private-sector trial prescription programs are summarized in Table 1, along with those of the Peterborough Demonstration Project. Three pro-

grams provided evaluative data for 12 months of operation. The others operated for 6 months. All were voluntary and offered a 7-day supply of cardiovascular drugs and nonsteroidal anti-inflammatory drugs (NSAIDs), although the 2 provincial programs also permitted slightly longer trials. The programs varied considerably in terms of who and exactly what drugs were covered, whether claims adjudicators identified eligible patients at the time a claim was submitted for processing, and whether pharmacists received a professional fee if patients did not obtain the balance of their prescriptions. Rather than pay pharmacists only when prescriptions continued beyond the trial period, the Saskatchewan Trial Prescription Program and the demonstration project paid a fee to document the results of each trial prescription, regardless of the outcome of the trial. Only the demonstration project enrolled patients who did not have a drug plan.

### **Pharmacy Participation in Trial Prescription Programs**

Three programs provided figures for the number of pharmacies that were eligible to offer trial prescriptions, and the number of pharmacies that actually dispensed them. These data are presented in Table 2. Including the demonstration project, the participation rate ranged from 28% to 60% of eligible pharmacies (mean [SD] 46.9% [14.3%]), although the proportion for the Metropolitan Toronto Program may have been unfairly low because all pharmacies in the province were eligible to participate, but eligible consumers resided mainly in Toronto.

### **Opportunities for Trial Prescriptions Taken by Pharmacists and Patients**

Two programs reported the proportion of opportunities that were both offered by pharmacist and accepted by patients (Table 2): 4.7% and 11.1%. These figures provide no information about the proportion of trials that were offered, but declined. For comparison, roughly 5% of opportunities were taken in the demonstration project, 70% of these by 4 (of the 25 eligible) pharmacies. Factors that may have contributed to the relative success of these particular pharmacies were motivation, efforts to involve all pharmacy staff in the program, and a willingness to change the way in which they did business to achieve success.

### **Obstacles to Using Trial Prescriptions**

After 1 year of operation, the Saskatchewan Trial Prescription Program surveyed its 789 community

pharmacists seeking information about barriers to using trial prescriptions. Thirty-one percent responded to the survey. Sixty percent of respondents cited "physician prescribing practices/sampling" as the number-one barrier; followed by "list of eligible drugs" and "low public awareness," each cited by about 25%.<sup>4</sup>

In the demonstration project, pharmacy managers (n = 21) cited lack of time (48%) and absence of a computerized system to identify eligible patients (19%) as their most important obstacles. Data recorded on the documentation forms showed that pharmacists took a mean of 5.6 minutes (SD 2.6; n = 231) to enroll each patient, and a mean of 4.3 minutes (SD 2.4; n = 211) to conduct and document each follow-up call.

**Acceptability to Patients**

Among patients who were eligible and offered trial prescriptions in the demonstration project (n = 249), 215 (86%) accepted 234 trials. Their characteristics are summarized in Table 3. The age and sex distributions of participants and nonparticipants were not different (data not given).

Patients' reasons for nonparticipation are listed in Table 4. The main reasons were that they were going out of town (32%), and that returning for the balance of their medication was either inconvenient or too far (21%). When those who did participate were asked by pharmacists to rate the helpfulness of the program at the time of their follow-up contact, 82% of respondents (n = 105) rated it 4 or better on a 5-point scale (where 1 = "not at all helpful" and 5 = "extremely helpful").

**Proportion of Prescriptions Discontinued (Stopped or Changed) During a Trial**

All 5 programs reported the proportion of prescriptions that were discontinued during the trial period (Table 2). Data for 4 programs were based on drug claims data, and 1 used a combination of claims data and written documentation submitted by the dispensing pharmacists. Whereas the latter reported an overall discontinuation rate similar to the demonstration project (about 14%), the others reported rates ranging from 37.2% to 52.9% (pooled: 43 of 316 [13.6%] vs 4554 of 10,441 [43.6%], *P* < .001). This difference persisted after controlling for drug class. In Saskatchewan, 66% of prescriptions for CCBs continued beyond the trial period versus 86% in the demonstration project (*P* < .01).

Among demonstration project participants, older subjects were more likely to discontinue prescrip-

tions than individuals younger than 65 (22 of 124 [17.7%] vs 10 of 110 [9.1%], respectively, *P* = .05). Drug plan coverage also had a small, statistically nonsignificant effect (drug plan: 25 of 183 [13.7%] vs cash paying: 3 of 38 [7.9%], *P* = .33). The reasons for drug discontinuation are presented in Table 5. More than half of the discontinuations were because of drug adverse events or allergies.

**Dollar Value of Drug Wastage Avoided Through Trial Prescriptions**

Two programs provided information about the direct cost of the medication wastage avoided through trial prescriptions: one incorporated a professional fee that was paid when the balance of the prescription was dispensed, and the other reported costs including and excluding the professional fee (Table 2). Results from the demonstration project were similar to those from the Alberta Pilot Project: overall, trial prescriptions avoided roughly Can \$5.50 in drug wastage per trial initiated (exclusive of data collection fees). This savings varied by drug class, ranging from Can \$1.98 for β-blockers to Can \$10.12 for CCBs (*P* < .01).

...DISCUSSION...

Our findings suggest that trial prescriptions are acceptable to patients and, if focused on specific medications, could be used to reduce the direct cost of drug wastage. More work is needed, however, to define the conditions under which trial prescription

**Table 5.** Reasons for Prescription Discontinuation in the Peterborough Demonstration Project

Reason	Number (%)
Adverse drug reaction or drug allergy (as assessed by physician or patient)	18 (56.2)
Other physician-initiated	
Dosage too high or too low	5 (15.6)
Concurrent illness or hospitalization	3 (9.4)
No explanation given	1 (3.1)
Other patient-initiated	
Failure to return for balance or could not be contacted	4 (12.5)
Unconvinced of need for, efficacy of medication	1 (3.1)

programs are feasible for pharmacists and drug plans.

Most patients approached in the demonstration project understood and supported the idea of trial prescriptions. Among the 14% who declined trials, most did so because they were unavailable or resided too far from the pharmacy to obtain the balance of their medication. For patients who lived in rural areas outside the normal boundaries for delivery service or who traveled frequently, inconvenience was an important barrier to accepting trials. Such findings reinforce the need for trial prescriptions to remain voluntary, and perhaps argue for greater freedom on the part of the pharmacist to vary, within limits, the duration of the trial.

Although community pharmacists were also interested in the notion of trial prescriptions, few used them consistently when given the opportunity. In Saskatchewan, pharmacists identified "physicians' prescribing patterns/distribution of medication samples," "list of eligible drugs," and "low public awareness" as key obstacles to using trial prescriptions. In the demonstration project, lack of time and an easy way to identify eligible patients were cited as key barriers. Because the distribution of medication samples by physicians makes patients ineligible for pharmacy-based trial prescription programs, some have argued for more coordinated "sampling" programs that involve pharmacists or at least inform them that samples have been given, allowing the pharmacist to contact the patient to provide advice and to document the results of the trial.<sup>4</sup> However, such programs would require important changes to the way in which pharmacists work and have traditionally been paid, placing greater emphasis on "cognitive services" rather than dispensing.<sup>5</sup> As evidenced by pharmacists' use of trial prescriptions in Saskatchewan and the demonstration project, such changes in approach to reimbursement for a small proportion of patients may not affect pharmacist participation unless accompanied by remedies for other important obstacles.

Several factors affect the dollar value of the wastage avoided through trial prescriptions. These include the likelihood that the balance of a prescription will be dispensed, the unit cost of the medication, and the quantity of medication that is prescribed. Factors associated with drug continuation are drug related, patient related, and system related. Drug-related factors include the purpose of the medication and the risk of an adverse event that would lead to discontinuation. Patient factors include, among others, age, severity of illness, pres-

ence of other diseases or drugs, and the patient's experience with similar medications. Finally, we define system factors as features of a trial prescription program that might affect a patient's willingness to seek the balance of the prescription. Examples include access to delivery service and whether the dispensing pharmacist provides telephone follow-up. One issue worth exploring is whether the institution of large-scale trial prescription programs affects physicians' prescribing habits, because the widespread writing of smaller initial prescriptions for long-term therapies would ultimately reduce the number of patients eligible for such programs.<sup>6</sup>

The proportion of prescriptions stopped or changed in the demonstration project was similar to that documented in the Alberta Pilot Project, but considerably lower than the rates of 40% to 50% reported by the other programs. Reasons for this discrepancy are unclear. One possibility is different data collection methods. Whereas results from the demonstration project and the Alberta Pilot Project were based on written documentation provided by the dispensing pharmacists, results for the others were based on drug claims data. A second possibility is that different levels of selection bias were active across the programs. If pharmacists involved in the "high-rate" programs enrolled patients on a less selective basis, as might be the case if eligible patients were identified by a claims adjudicator at the time prescriptions were processed, higher discontinuation rates might be expected. A third possibility is that the study populations differed in other ways. Of note, the 14% discontinuation rate observed in the demonstration project is in line with what might be expected based on population-based studies of newly prescribed antihypertensive agents.<sup>7,8</sup> Other factors that make direct comparisons difficult include differences in who compensated pharmacists and how they were paid.

The finding that some medications produced more costly waste than others was not surprising, and has implications for program design. In the demonstration project, this gap was driven largely by differences in the unit cost of the medications, but also to a lesser extent by larger prescriptions for CCBs. These results highlight the importance of drug selection when weighing what could be saved against the costs to operate a large-scale trial prescription program. For example, data recorded on our documentation forms showed that pharmacists took an average of 5.6 minutes to enroll each of 231 patients, and a further 4.3 minutes on average to conduct and document each of 211 follow-up calls: an estimated

36.7 hours of pharmacist time overall. If we assume that pharmacists were paid according to recently published Ontario guidelines (ie, Can \$1.50 per minute),<sup>9</sup> the cost of pharmacist fees alone would have totaled Can \$3300, compared with the roughly Can \$1300 in drug wastage avoided. Limiting our analysis to CCBs or the elderly would substantially narrow this gap, but would still exclude costs for pharmacist training, physician and public education, delivery service to patients, and in the case of pay-direct drug plans, additional data transmission fees.

This study has both strengths and limitations. To our knowledge, it is the first attempt to summarize what is known about the effectiveness of trial prescription programs in Canada. However, we did not survey physicians; and because the demonstration project was conducted in a single community, included only cardiovascular drugs, and enrolled a select group of patients, the generalizability of its findings is limited. Future work should explore what happens to patients who discontinue prescriptions after the trial period, where and how physicians can influence the effectiveness of trial prescription programs, and the conditions under which such programs are feasible for pharmacists and drug plans.

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