

Prescription Duration After Drug Copay Changes in Older People: Methodological Aspects

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OBJECTIVES: Impact assessment of drug benefits policies is a growing field of research that is increasingly relevant to healthcare planning for older people. Some cost-containment policies are thought to increase noncompliance. This paper examines mechanisms that can produce spurious reductions in drug utilization measures after drug policy changes when relying on pharmacy dispensing data. Reference pricing, a copayment for expensive medications above a fixed limit, for angiotensin-converting enzyme (ACE) inhibitors in older British Columbia residents, is used as a case example.

DESIGN: Time series of 36 months of individual claims data. Longitudinal data analysis, adjusting for autoregressive data.

SETTING: Pharmacare, the drug benefits program covering all patients aged 65 and older in the province of British Columbia, Canada.

PARTICIPANTS: All noninstitutionalized Pharmacare beneficiaries aged 65 and older who used ACE inhibitors between 1995 and 1997 (N = 119,074).

INTERVENTION: The introduction of reference drug pricing for ACE inhibitors for patients aged 65 and older.

MEASUREMENTS: Timing and quantity of drug use from a claims database.

RESULTS: We observed a transitional sharp decline of $11\% \pm$ a standard error of 3% ($P = .02$) in the overall

utilization rate of all ACE inhibitors after the policy implementation; five months later, utilization rates had increased, but remained under the predicted prepolicy trend. Coinciding with the sharp decrease, we observed a reduction in prescription duration by 31% in patients switching to no-cost drugs. This reduction may be attributed to increased monitoring for intolerance or treatment failure in switchers, which in turn led to a spurious reduction in total drug utilization. We ruled out the extension of medication use over the prescribed duration through reduced daily doses (prescription stretching) by a quantity-adjusted analysis of prescription duration.

CONCLUSION: The analysis of prescription duration after drug policy interventions may provide alternative explanations to apparent short-term reductions in drug utilization and adds important insights to time trend analyses of drug utilization data in the evaluation of drug benefit policy changes. *J Am Geriatr Soc* 50:521–525, 2002.

Key words: prescription medications; drug benefit policy changes; methods; pharmacoepidemiology; reference pricing; pharmacy claims data

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After decades of cost containment in the United States that focused on payers and healthcare providers, attention is now focused on strategies that involve patients in the process of resource allocation. Increasingly, out-of-pocket contributions, including differential cost sharing (DCS) for prescription medications, are required of the poor and older people in pharmaceutical benefits plans. The different forms of DCS are all based on the assumption that medication classes with interchangeable effectiveness can be identified and that a common reimbursement level can be established. Reference pricing allows selected substances within a class to be reimbursed fully by the drug benefits plan, but patients have to pay the price difference for a higher-priced substance out of pocket.¹ Popular implementations in the United States include “three-tier” copayments, whose level of cost-sharing increases stepwise with the medication price, and proportional cost-sharing, which requires a copayment of up to 20% of the medication price.^{2,3} Health economists are discussing ref-

erence pricing as a possible cost-containment measure for a Medicare drug coverage program.⁴

In addition to the intended effects of reference pricing, including increased use of lower-priced drugs and cost savings in the pharmaceutical benefits plan, there are potential unintended effects, prime among them that patients may reduce the use of effective treatment in critical circumstances. It has been hypothesized that this results in more-frequent physician visits, the necessity for more medical procedures, and more-frequent hospitalization,⁵⁻¹⁰ but evidence is sparse.¹¹

Policy makers and clinicians are concerned about temporary reductions in the utilization of effective medications immediately after a policy change that might suggest reduced compliance through stopping, dose reduction, or stretching—skipping days or delaying prescription renewals by reducing daily doses to postpone copayments. Therefore, it is important to rule out or confirm noncompliance as a reason for reduced utilization. However, it often remains difficult to distinguish inappropriate or appropriate reductions in drug use with reasonable certainty using claims data. Conclusions about potential underutilization of essential drugs are often based only on time series analyses of pharmacy claims data without further examination of the data.¹² This may in some instances lead to misinterpretation, because a change in total drug utilization is a function of many factors, of which the duration between two dispensings is only one.

We investigated how characteristic short-term changes in prescription duration might produce misleading estimates of the reduction of total drug utilization trends. We developed a simple method to test for prescription stretching based on pharmacy claims data. The recent introduction of reference pricing for angiotensin-converting enzyme (ACE) inhibitors in British Columbia serves as an example.

METHODS

Example: Reference Pricing in British Columbia

A large-scale natural experiment began in British Columbia when reference pricing was introduced for ACE inhibitors in January 1, 1997. Costs for the least-expensive captopril, quinapril, and ramipril preparations available in pharmacies were covered under the policy without any cost sharing. For other ACE inhibitors (enalapril, lisinopril, fosinopril, cilazapril, benazepril), patients were required to pay the price difference, ranging from Can \$2 to \$62 per monthly supply, out of pocket.¹³

Population

The population for this study consisted of all enrollees in Pharmacare Plan A, the province-wide pharmaceutical benefits program for all residents aged 65 and older (approximately 479,000 in 1995 and 509,000 in 1998).¹⁴ All patients with at least one dispensing of any ACE inhibitor during the 24 months before the policy change (January 1, 1995–December 31, 1996) or 18 months after the policy change (January 1, 1997–June 31, 1998) were identified. Patients immigrating to British Columbia or becoming age 65 during the observation period were included and contributed information starting the day of immigration or on their 65th birthday.

Typical Changes in Prescription Duration After Drug Policy Changes

Changes in total drug utilization after policy interventions may be partly affected by temporal changes of prescription duration and compliance. We postulate three types of changes of prescription duration after the start of a new reimbursement regulation and illustrate them with extreme numerical examples to clarify our points.

Scenario A: "Testing"

As a consequence of DCS, some patients, with their physicians, will consider switching from a higher-priced medication to the medication preferred by the pharmaceutical benefits plan. Physicians may worry about the tolerance and effectiveness of the new medication. Often patients are older and taking multiple medications, so they should be monitored more intensely to rule out drug interactions. A common medical practice is to supply older patients with a shorter duration of prescription supply and reevaluate the new drug therapy afterwards.¹⁵ After a period of several shorter-term prescriptions, patients return to their usual length of supply. Figure 1a illustrates the effects in a cohort of three patients who reduced their usual prescription duration from a 3-month to a 1-month supply after a new policy begins. This example assumes that there is no temporal increase in utilization and that the new policy is

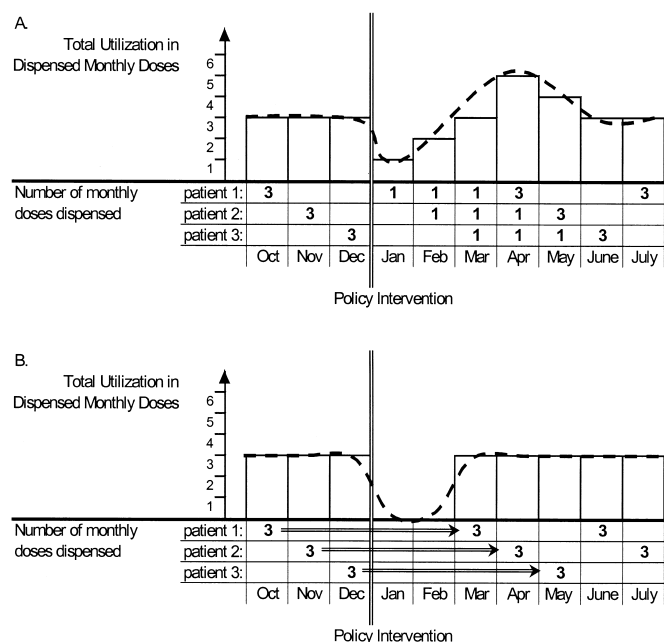


Figure 1. Hypothetical examples of two types of changes in prescription duration (A and B) and their effects on total drug utilization. (A) The effect of a shorter-than-usual prescription duration on total drug utilization. Patients 1, 2, and 3 initially received three monthly doses per prescription. After the copay change, patients received only one monthly dose for the following 3 months. Accordingly, the usual prescription duration during these months is shorter. The total utilization appears to be temporarily reduced. (B) The effect of a temporal prescription stretching on total drug utilization. Patients 1, 2, and 3 initially received three monthly doses per prescription. After the copay change prescriptions were stretched over 5 months (\Rightarrow). The total utilization appears to be temporarily reduced.

not changing the overall utilization measured in dispensed monthly doses. Because of the temporal reduction of the prescription duration, one can observe an apparent decline in total utilization followed by an “excess” utilization. The cumulative decrease is equal to the excess increase above the projected utilization trend (three monthly doses). The number of patients with at least one dispensing per month appears to increase, although in fact the same number of patients is under treatment.

Scenario B: “Stretching”

Patients who decide to stay on a medication with cost sharing might consider stretching their prescription, to wait longer before switching to no-cost medications or obtaining a new cost-sharing prescription. Stretching may lead to insufficient treatment of their medical condition because the average daily dose between two dispensings will be reduced. In Figure 1b, patients stretch a 3-month supply over a period of 5 months. In the case where stretching is a temporary phenomenon, the consequence is a dip in total drug utilization. Note that apparent stretching can be explained not only by noncompliance but also by the availability of alternative sources of drug not captured in the claims data. Frequently, when a restrictive reimbursement policy starts, pharmaceutical manufacturers provide physicians with larger numbers of free samples to allow them and patients more time to consider staying with their products.¹⁶ Use of nonprescription drugs, prescription drugs not covered by the drug plan, purchase of drugs at pharmacies outside the insurance plan, or finishing back-up supplies of the old drug (e.g., the extra container kept at the workplace) before switching to the new one, are other potential contributors to a spurious appearance of medication stretching.

Scenario C: “Splitting of Higher-Dose Tablets”

It is common practice for higher-dose tablets to be priced only slightly higher than lower-dose tablets. As a money-saving strategy, physicians sometimes prescribe higher than necessary doses and ask the patients to split tablets. If a policy causes an increase in splitting of higher-dose tablets, this will produce an initial increase in standard monthly doses (SMDs) dispensed but not the number of tablets. If this is a temporary phenomenon, the increase will be followed by an equal decrease before utilization returns to the usual level.

Prescription Duration and Quantity-Adjusted Duration

Prescription duration was calculated as the number of days between two consecutive ACE inhibitor dispensings less than 200 days apart. The duration is attributed to the month of the second refill. The median duration is plotted for each month. Increases in duration can be intended, in the sense that more monthly doses are dispensed to cover a longer period, or can be unintended, in the sense that duration increases but the dispensed number of monthly doses stays stable (stretching). Adjusting for the quantity that is dispensed will allow us to distinguish those scenarios. Such a quantity-adjusted measure of duration (QAD) is the ratio of the observed duration over the expected duration given the actual quantity dispensed.

$$QAD = \frac{O_{Dur}}{E_{Dur}} = \frac{\text{observed duration[month]}}{\text{dispensed dose[mg]/standard monthly dose}\left[\frac{\text{mg}}{\text{month}}\right]}$$

Monthly doses can be determined by the defined daily dose (DDD) system of the World Health Organization¹⁷ or by calculating SMDs. SMDs were defined as the median monthly doses in milligrams dispensed during the 8-month period from November 1, 1995, to June 30, 1996, in those patients who filled at least one prescription during the 120 days before and the 120 days after the 8-month period. SMDs reflect more accurately the prescribing pattern in the study population.^{9,18} Individual quantity-adjusted durations were calculated at the time of the second dispensing of each dispensing pair but were attributed to the substance of the first dispensing (i.e., cost-sharing or no-cost drugs). Medians of observed over expected ratios were calculated with the corresponding interquartile ranges for each month.

Time Series Analysis

Time trends of ACE inhibitor utilization were plotted as SMDs dispensed per 10,000 British Columbia residents aged 65 and older. Each month was standardized to a 30-day month. We used interrupted linear regression to estimate sudden changes in trends or levels of ACE inhibitor utilization after the introduction of reference pricing.¹⁹ Regression models included a constant term, a term for linear time trend before reference pricing, and binary indicators for a 5-month transition period from December 1, 1996, to April 30, 1997, and for the time afterwards. In addition, we included two linear time trends for those periods to measure changes in slope after the policy change.^{7,20,21} A Durbin-Watson test indicated autocorrelation in some analyses.²² Therefore, we assumed autocorrelated covariance structures in the regression models. We determined the statistical significance of regression coefficients using two-sided *t* tests, and present slope estimates and percentage changes between predicted and observed medication utilization trends. Two-sided *P*-values of changes in level are only reported at the time of the interruption of the trend line.

RESULTS

The characteristics of the study population with ACE inhibitor use (N = 119,074 patients) were stable during the 42-month observation period. Throughout the study, women represented 57% of the population, with little month-to-month variation (standard deviation (SD) = 0.28%). The mean age ± SD was 73.3 ± 0.45, with a decreasing trend of 0.5 years of age per calendar year.

Changes in the Utilization of ACE Inhibitors

In January 1995, 1,500 SMDs of all ACE inhibitors were dispensed per 10,000 residents, increasing to 1,930 over 23 months (see Figure 2). The level of utilization of all ACE inhibitors dropped from 1,930 SMDs per 10,000 in November 1996 to an average of 1,710 SMDs during the first 3 months after the policy change, corresponding to an

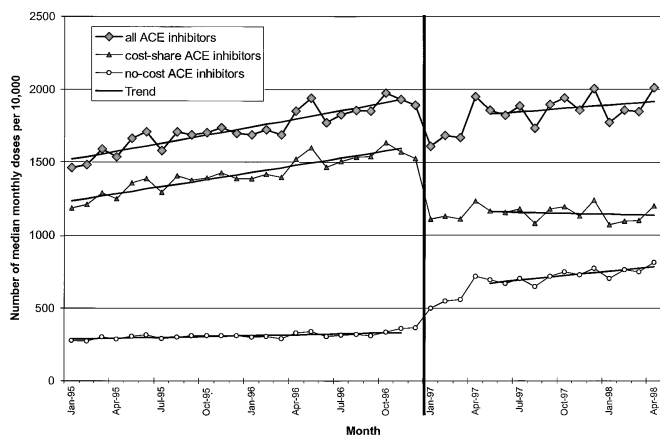


Figure 2. Changes in angiotensin-converting enzyme (ACE) inhibitor utilization rate in British Columbia residents aged 65 and older in dispensed median monthly doses per 10,000 residents aged 65 and older. The thick vertical line marks the introduction of reference pricing. Utilization rates are adjusted for the length of months.

11% decrease (standard error (SE) = 3%, $P = .02$). After this transition period, the postpolicy level was 1,825 SMDs in June 1997, or 11% below the projected prepolicy trend. The postpolicy slope was slightly but not significantly lower (8 SMDs per month, $P = .14$) than the prepolicy trend.

The temporal decrease immediately after the policy change was brought about by a rapid decline in the use of cost-sharing ACE inhibitors (-29% , SE = 2.7%, $P < .0001$) combined with a slow increase in no-cost ACE inhibitors.

Changes in the Prescription Duration and Quantity-Adjusted Duration

The median prescription duration in no-cost ACE inhibitors was stable around 71 days until November 1996 (P for slope = 0.88, see Figure 3). From December 1996 (after the policy announcement) to March 1997, the prescription duration declined to a low of 51 days, a 31% reduction, and climbed steadily to a median of 74 days by October 1997. The temporary decline in duration was due mainly to those patients who switched from cost-sharing (median duration before December 1996 = 82 days) to no-cost medications after the policy implementation (median duration in April 1997 = 50 days, a 39% reduction in duration).

Patients who decide to stay on cost-sharing ACE inhibitors despite the new policy should be the most susceptible to stretching their medications in an effort to reduce out-of-pocket costs. Remaining on cost-sharing medication was defined as receiving such medication before and after the policy implementation and not receiving no-cost medications. The quantity-adjusted prescription duration remained at the prepolicy level of an observed-to-expected ratio of 1.0 with wide interquartile ranges.

DISCUSSION

Total drug utilization rates based on pharmacy dispensings after the implementation of reference pricing or other

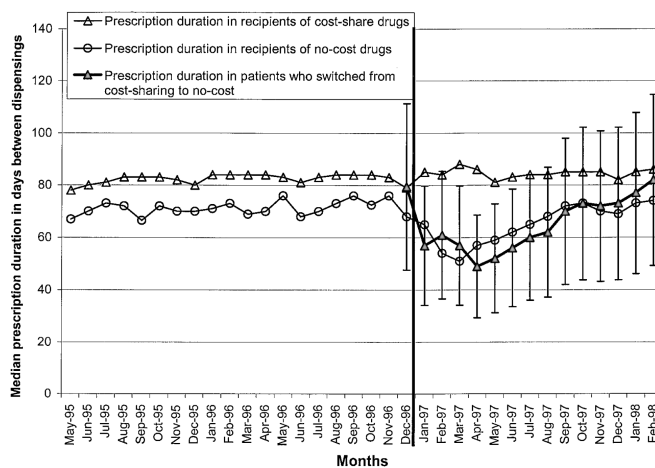


Figure 3. Median prescription duration for cost-sharing and no-cost ACE inhibitor recipients in British Columbia before and after reference pricing. The duration for drug switchers from cost sharing to no-cost is shown starting after the announcement of reference pricing in November 1996. The interquartile ranges are plotted. The thick vertical line marks the implementation of reference pricing. Numbers are adjusted for the lengths of months.

cost-sharing policies often reflect a combination of distinct reactions to the new policy—primarily medication switching but also changes in prescription duration or, possibly, prescription stretching that can contribute to changes in total drug utilization trends.

With the introduction of reference pricing of ACE inhibitors in British Columbia, we observed a 29% decrease in utilization of cost-sharing medications.^{18,23} Many of these patients switched to low-price no-cost ACE inhibitors. However, utilization time trends suggest a delayed increase in no-cost utilization that causes a temporary reduction in total ACE inhibitor utilization. From earlier analyses, it was known that substitution of high-price cost-sharing ACE inhibitors with other antihypertensives or stopping of antihypertensives explains only a small proportion of the reduced utilization.²⁴ An unexplained reduction would concern physicians and policy makers alike.

We demonstrated that the seeming reduction in ACE inhibitor utilization was the consequence of a temporary reduction in prescription duration; a large proportion of patients stopped taking cost-sharing medications after the policy, leading to a 28% reduction in their utilization. Patients who switched to no-cost medications reduced their prescription duration by 39%, which is most likely related to increased monitoring for intolerance or treatment failure after medication switching.²⁵ Thus, the prescription duration in the combined group of chronic and new no-cost ACE inhibitor recipients was reduced by 31%. According to Figure 1a, we would expect a reduced utilization of no-cost ACE inhibitors, but we observed a slow increase (Figure 2). The slow net increase in no-cost ACE inhibitors was caused by the influx of former cost-sharing recipients into the group of no-cost recipients, combined with a temporary reduction due to shorter prescription duration.

Thus, we observed a spurious reduction in total ACE inhibitor utilization, which is most likely due to good clin-

ical practice (increased monitoring for tolerance and interaction after switching medications in older patients).

The described effects on drug utilization increase with longer average duration between two dispensings. If medications are dispensed every 30 days (such as in Medicaid) and the unit of analysis is a month, then the spurious decline in utilization should be almost unobservable.

Stretching of prescriptions, which is in most cases clinically not favorable because it is associated with a reduction in daily doses, could be ruled out by demonstrating a stable ratio of observed-to-expected prescription duration during and beyond the policy implementation.

Changes in prescribing behavior for reasons other than the drug benefit policy change, such as new information about the indications for ACE inhibitors in heart failure or the management of hypertension in diabetes mellitus, also influence drug utilization trends. However, it is unlikely that other causes of changes in prescribing act as suddenly as a policy change and also coincide with the policy. This is an important strength of using longitudinal data with analyses of interruptions in utilization trends in the evaluation of health policy changes.^{19,21}

The analysis of prescription duration adds important insight to the time trend analysis of overall utilization data in the evaluation of policy changes. After the introduction of reference pricing in British Columbia, we observed a spurious reduction in the use of cost-sharing ACE inhibitors and a temporary, transitional phase of shorter prescription duration, most likely attributable to increased monitoring of patients who switched medications. These methods allowed us to rule out unintended stretching of prescriptions in those who continued to receive cost-sharing medications.

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