The Effect of User Fees on the Use of Prescription Drugs: Variation in Magnitude and Distribution of Effects by Neighborhood Income and Level of Drug Use

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Expenditures on prescription drugs have been increasing rapidly. For example, between 1976 and 2001, total Canadian drug expenditures increased at an average rate of 14.8% per year and the share of provincial health expenditures devoted to drugs has more than quadrupled, from 1.6% in 1976 to 6.9% in 2000.

Cost sharing policies are being widely implemented to control drug program costs. They take a variety of forms, such as premiums and deductibles, which are paid by all enrolees in a program, or copayments and coinsurance (i.e. user fees) that require the patient to bear some portion of the cost of the prescriptions that they fill. Usually, the term "copayment" refers to a payment of a fixed amount per prescription, while "coinsurance" refers to a percentage of the prescription cost. To simplify, we will generally refer to both as "copayments". Delisting of products from provincial formularies, and policies such as reference-based pricing and maximum allowable cost policies can also be seen as cost-sharing policies since they shift prescription drug costs to the consumer. Copayment policies aim to reduce program costs by shifting some of the costs to the consumer.

Proponents of copayment policies argue that they create price sensitivity on the part of patients, thus encouraging more appropriate drug use, use of less expensive alternatives, and discouraging inappropriate practices such as drug hoarding. The evidence is clear that copayment policies reduce program costs and drug utilisation, although the reported price elasticities are generally not large.

Critics argue that copayment policies may lead patients to make irrational decisions about medication use, particularly since it is primarily the physician, and not the patient who is most knowledgeable. This critique is backed by substantial evidence that copayment polices reduce the use of essential as well as less essential drugs. For example, antihypertensive drugs are more affected than analgesics, and even copayments as low as US$0.50 per prescription are associated with reduced prescription drug use. Moreover, there is some evidence that copayment polices are associated with negative health outcomes. For example, a recent study by Tamblyn et al (2001) found that the introduction of a copayment policy in Quebec resulted in reductions in the use of essential medications, and that the reductions were associated with increased rates of adverse events. It would be premature to say that evidence of adverse events is conclusive, but it does provide a clear basis for caution.

Critics also argue that copayment policies are inequitable. Persons with chronic and multiple health conditions will have the highest out-of-pocket expenses. This, compounded with the well-established association between low income and poor health, means that co-payment policies, unless income-based, will place a larger financial burden on persons with low income.

Given the fiscal realities of drug programs, eliminating patient cost sharing is not a viable option for drug plan managers. In the absence of effective, alternative measures to control the growth in prescription drug use and overall costs, cost sharing polices are seen as fundamental to program sustainability. However, there are many different types of cost-sharing policies, and different forms of copayment policies, and they may impact patients differently. For example, if patients are charged a fixed amount per prescription, they are encouraged to reduce the number of prescriptions they fill in a year. This may be accomplished by obtaining prescriptions with a larger number of days supply, reducing the amount of medication they consume, or reducing the number of

different types of medication taken. On the other hand, a copayment based on a percentage of the drug cost encourages the use of lower cost alternatives, creates a stronger incentive to reduce the quantity of medication consumed, and will only encourage fewer refills if the copayment is on the dispensing fee as well as the drug cost. Different types of policies also distribute cost sharing in different ways. Both fixed copayments and coinsurance impose higher cost sharing for program participants with multiple health conditions. Relative to fixed copayments, coinsurance shifts the cost-sharing burden to patients using more expensive medications and those requiring higher daily doses.

Interestingly, the effects of different types of copayment policies on patient drug use have not been systematically compared. Are some types of copayment policies potentially more harmful than others? How do different types of programs distribute costs? For drug program managers, this is a critical question.

Nova Scotia, a Canadian Province of about 1 million people, has a provincial program that has provided universal and comprehensive drug coverage for seniors since the 1970s. The Nova Scotia Senior's Pharmacare Program (NSSPP) provides a unique opportunity to compare the effects of different types of copayment policies on prescription drug use, and examine how those effects varied by patient's income and level of drug use. The NSSPP provided medications free of charge to seniors until June, 1990 when a fixed $3 copayment per prescription up to a maximum of $150 per year was implemented. Several modifications of the policy have since been implemented, including a change from a fixed fee per prescription to copayments based on a percentage of the total cost (drug cost plus dispensing fee), changes in the annual maximum of copayments to be paid by program enrolles, and the introduction of annual premiums. The Nova Scotia Pharmacare Program thus provides a "natural experiment" for studying the impact of different types of copayment policies.

Objectives:

This study examined the effects of different types of co-payment policies in the Nova Scotia Senior's Pharmacare Program (NSSPP) on patient's use of prescription drugs. The study focused on the first two copayment policies introduced to the program. The first policy, introduced in June 1990, was a $3 per prescription charge up to an annual accumulated maximum of $150. Once the $150 ceiling was reached, there were no additional user charges. Then, in July 1991 a 20% (minimum $3) coinsurance was introduced.

In considering the distributional effects by income and level of drug use, we focused on the role of the annual maximum copayment. We hypothesized that the annual maximum copayment would result in different policy effects depending on the level of a senior's drug use. Seniors expecting to exceed the annual maximum copayment of $150 (typically patients with chronic disease requiring multiple or expensive medications) would have no incentive to reduce their medication use. For them, the $150 acts like a premium. It is something they expect to pay. However, patients who don't expect to exceed the annual maximum reduce their out-of-pocket costs if they reduce their drug use.

Neighbourhood income was expected to interact with policy effects in two ways. First, income would indirectly interact with policy changes through its effect on the level

of drug use. Since lower income groups have lower health status and higher prevalence of chronic disease, they were expected to have higher use of prescription drug use, thus increasing the likelihood of reaching the annual maximum. Second, it was expected that the price effect of the policy would be larger for residents of low-income neighbourhoods.

Methods

Data and subjects:

Subjects for the study were all persons enrolled in the Nova Scotia Senior's Pharmacare program at any time between April 1989 and March 31, 1997, and who resided in an urban area (about 62,000 persons at any given month). For the time period that is the focus of this study, the Program provided prescription drug coverage to nearly all persons age 65 in the province. Indians living on reserve, veterans, and former members of the Royal Canadian Mounted Police are covered under Federal programs, and thus were not included in the study.

The primary source of data for this study was claims data from the NSSPP. The claims data consists of records for all prescriptions filled. Each record includes a patient identifier, the data the prescription was filled, the specific medication filled (ATC code and DIN), the quantity, and the days supply. To identify periods of program eligibility, as well as place of residence, a program registry was also used. For each enrolee, the registry identified eligibility dates, a date of death (if occurred), and the six-digit postal code for the place of residence.

Census data on mean household income by enumeration area was also employed. Using the Geocode Postal Code Conversion Algorithims developed by Statistics Canada, this data was linked to the other data sources using postal code of residence.

Outcomes and Measurement

This study examined the effect of the copayment policies on the use of two specific classes of drugs. By focusing on specific drug classes, it is easier to account for events such as new product releases and key publications that might confound estimates of policy effects. The drug classes examined were:

(1) H_2Blockers: A commonly used gastrointestinal drug for the treatment of peptic ulcer disease (PUD), gastroesophogeal Ruflux (GURD), and dyspepsia. H2Blockers are one of the drugs most commonly used by seniors. For many patients, H_2Blockers are not an essential drug. However, because similar benefits can be achieved by inexpensive over-the-counter antacids.

(2) Oral Antihyperglycemics (OHGs): OHGs are the primary medications used to treat type II diabetes mellitus, the type of diabetes that is common in seniors. When lifestyle changes (diet and exercise) are not effective at lowering blood sugar levels, OHGs are used. With progression of the disease, daily doses are increased, and multiple types of OHGs may be used simultaneously. Some patients will eventually be treated in combination or exclusively with insulin. OHGs are clearly essential drugs for diabetics. Poor compliance can lead to many diabetic complications such as kidney disease, blindness, and heart disease.

Our study outcomes were (1) the use versus non-use of a study drug, and among users, (2) a change in the average quantity of medication used. Pharmacare claims data were used to estimate enrolees' use of study medications by month. An algorithm that we developed was used for this purpose. The algorithm uses the periods between sequential prescriptions and the quantity dispensed to estimate periods of time over which a subject was using a medication, and the average daily dose used between prescriptions. This use history was divided into 30-day increments ("months") to develop person-month records for each subject. In each month, we estimated whether or not each type of medication was being used, and if used, how much of it was used. Quantity of use was measured as the average standardized daily doses used (SDD). The SDD can be thought of as the average number of "typical" doses of a drug used, and standardizes quantity across drugs that have different strengths and dosing.

We wanted to determine if policy effects differed by income and region of residence. Since data on seniors' incomes were not available, seniors were assigned to income groups based on the mean household income of their neighborhood (<$30,000, $30,000 - $50,000, $50,000 and over). Neighborhood income is only moderately correlated with household income, but for seniors may have the advantage of reflecting assets. Region of residence was defined as Halifax versus other urban. Halifax is the largest metropolitan area in the province and includes the majority of specialists and the acute care hospitals. We only examined seniors in urban areas because of concerns about the validity of neighborhood income data for in rural areas.

To test hypotheses about how the annual maximum interacts with the changes in copayments, we computed an "expectation-to-exceed" variable for each senior in each month. Medication use in the previous three months, and the copayments accumulated up to that month, were used to project the likelihood that a patient would exceed the annual maximum. This variable was scaled as a probability using a logistic function, and ranges between zero and 1.0, where a score of 1.0 indicates that the annual maximum has or certainly will be exceeded, and 0.0 indicates that the annual maximum will not be exceeded.

Consultations with clinicians, literature reviews, and a detailed review of drug programs changes were used to identify factors other than the copayment policies that might have affected patterns of use in the study drugs during the study period. These were included as additional covariates in multivariate models to avoid confounding.

Study Design and Analysis

An interrupted time-series design was employed using person-month data on drug use. The study design measured policy effects as a change in trend in the rate and average quantity of use associated with the policy. We compared the effects of policy changes by region and neighbourhood income group.

We used two analytic approaches. First, aggregate time-series analysis was used. We examined policy effects on the age-sex adjusted rates of drug use of the study drugs by month. Separate adjusted rates were computed for each income group and region. Thus, six monthly time series were generated (2 regions X 3 income groups). Changes in trends associated with policy changes were assessed graphically and with multivariate time-series regression models. A segmented regression approach, focusing on a change

in slope, was used to estimate the policy effects. The models were seasonally adjusted, and estimated with feasible generalized least squares. The models specified separate first order auto-regressive serial correlation of errors by panel (income group X region) and contemporaneous correlated errors across panels. Interactions terms were estimated to assess whether policy effects differed by income group.

The second analytical approach used individual-level data to examine the effect of the policy on both use and quantity of use. This enabled us to test hypotheses about the effect of the annual maximum copayment, and to adjust for individual-level variables that could confound results. Models were estimated to determine whether, on average, individuals' drug use was affected by the policies and whether the effect differed by expectation-to-exceed.

For use vs non-use, logistic regression models on person-month data were estimated with generalized estimating equations (GEE). Models were adjusted for age, sex, season, Halifax/other and income group, and other events that might confound policy effects. Six-month lagged values of use were included in the models to adjust for bias that could result from the effect of study drug use on the expectation to exceed. As with the aggregate analysis, we estimated policy effects as a change in slope. Interactions between the change in slope and expectation-to-exceed variable were examined to test study hypotheses. Interactions between income group and the policy changes were used to estimate adjusted differences in policy effects by income.

The quantity-of-use analysis was conditioned on the use of the study drug. Policy effects on quantity of use were estimated with fixed-effect regression models on the log of the average SDDs used in each month. Policy effects were estimated as a change in level. The models were adjusted for age, season, and other events that might confound policy effects. The use of fixed-effects models helped to adjust for unmeasured variables, such as underlying propensity to use medications that could bias results.

Results

Aggregate analyses

The first analytical approach used aggregate time series analysis to examine trends in the rates of use and quantity of use for each of the study drugs, and how the trends were affected by various copayment policies. Figures 1 and 2 show trends in the rate of use of H_2Blockers in Halifax and other urban areas in Nova Scotia. Figures 3 and 4 show the trends for OHGs.

The first three periods provide an interesting and clear set of contrasting policies: no copayment, a fixed copayment, and coinsurance. Only the use of H_2Blockers is affected substantially by the policies. The trend lines (and time series models – not shown) show that, prior to the introduction of a copayment policy, the rate of use of H_2Blockers was increasing, but this trend was reversed with the introduction of a $3/Rx copayment policy ($p<.01$). Following the policy, the rate of use of the medication decreased. A similar, but much smaller change in trend is was observed for the OHGs ($p=.044$). While statistically significant, the change in slope for OHGs is very small in magnitude, and inconsequential from a policy perspective.

Surprisingly, the introduction of a 20% coinsurance policy was associated with a shift in trend back to increasing rates of use. This is counter intuitive, as the increased

marginal cost to patients would be expected to further decrease rates of use. This shift in trend was substantial for the H_2Blockers ($p<.001$), and much smaller but significant for the OHGs ($p<.001$).

The rates of drug use varied considerably by income. Persons living in the lowest neighborhood income group used H_2Blockers at the highest rate, while those in the highest income group used H_2Blockers at the lowest rate. Rates of use were also lower in Halifax than in other urban areas for all three income groups. An income gradient was also evident for OHGs.

While the levels of drug use varied by income group, the effects of the first two copayment policies did not. In the time series models, interactions between income group and the changes in slope associated with the policy were, with one exception, not significant. The exception was for H_2Blockers with the introduction of the 20% coinsurance policy. The shift in trend towards an increasing rates of use was larger for the lowest income group than for the middle ($p=.002$) and the highest ($p=.019$). However, the size of the difference in effect was small, and not large enough to be meaningful from a policy perspective.

We did not investigate effects of the fourth and fifth policy periods, aside from graphically. In the fourth policy period, the 20% coinsurance policy remained, but the annual maximum was increased to $400 for seniors who were not on guaranteed income supplements. This was associated with another shift in trend back to decreasing rates of use for the H_2Blockers. However, in the middle of this period, the Senior's Pharmacare program became the insurer of last resort, and thus changes in rates may result from the selection as large numbers of persons were dropped from coverage (i.e. the drug use patterns of those remaining in the program are different than the drug use patterns of those leaving). A similar problem in understanding changes in trends results with the last policy period, were a premium policy was introduced. Because of the difficulty in isolating the effects of copayments in the fourth and fifth policy period, we decided to focus the analysis on the first three policy periods.

Micro-level analyses on use versus non-use

Table 1 shows results from the micro-level model of the effects of policy changes and expectation to exceed on the use versus non-use of H_2Blockers. Model 1 mirrors the aggregate analyses. In particular, there is the counter intuitive increase in trend associated with the introduction of the 20% coinsurance policy. However, when the policy effect is interacted with the expectation to exceed variable (model 2), this anomalous effect disappears. For persons with a low expectation to exceed, the introduction of the 20% coinsurance policy resulted in an additional reduction in the trend in rates of use. As was hypothesized, the interaction effects show that the effect of both polices were diminished as the expectation to exceed the maximum copayment increases. However, the very small effect sizes should be noted. The relative slope estimated for the 20% coinsurance policy when expectation to exceed is zero is only slightly less than 1.0. We tested for nonlinear interactions with the expectation to exceed the maximum copayment, and found that they did not improve the fit of the model

Table 2 shows the corresponding models for OHGs. As with the H_2Blocker results, model 1 mirrors the results of the aggregate analysis. But unlike the H_2Blocker

results, the anomalous effects did not disappear in model 2. However, all of the effect sizes in this model are very small, and certainly not significant from a policy perspective.

No significant three-way interactions were observed between income group, expectation to exceed, and either of the policies. Counter to what we hypothesized, changes in the rate of medication use associated with the policies did not vary by income.

Micro-level analyses of the quantity of medication used among users

For the micro-level analyses on the quantity of medication use, fixed effects models were estimated that were similar in specification to the models on the probability of use. The models included interactions between the relative slopes, corresponding to the policy periods, and the expectation to exceed variable. Nonlinear interactions were explored by including polynomials of the expectation to exceed variable in the model. A model with a squared and cubic term was found to significantly improve the fit of the model. Because the confidence intervals of the parameter estimates are small, and interpretation of the parameters is difficult, the results of the analysis are displayed graphically.

Figure 5 shows the results for the H_2Blockers. The graph shows the proportionate change in the average number of standardized daily doses per user associated with each of the two copayment policies. Differences are both expressed relative to the no copayment policy period. At low levels of expectation to exceed, both policies were associated with significant decreases in the quantity of medication used. The $3 per prescription policy was associated with about a 5% decrease in the quantity used, while the 20% coinsurance policy was associated with about a 15% decrease in the quantity used (10% relative to the $3 copayment policy period). This is a much larger effect than was observed for the use versus non-use analysis. As the expectation to exceed increases, the effects of both policies diminish. This is consistent with our hypothesis that there will not be a reduction in use for persons who expect to exceed the annual maximum copayment. Three way interactions with income group were added and found not to be significant. Thus, it appears that policy effects do not differ by income.

Very similar results were observed for OHGs (Figure 6). For persons with a low expectation to exceed, reductions in the quantity of medication used were associated with both policies; although the incremental reduction in the quantity used when the 20% coinsurance policy was introduced (versus the $3 per prescription policy) was much smaller than the incremental change observed for H_2Blockers. As with the H_2Blocker, interactions with income were not found to be significant.

Offsetting effects of the $3 per prescription copayment policy and the 20% co-insurance policy

How can the aggregate results be reconciled with the micro-level results? In the aggregate analyses, and in the micro-analyses that did not include interactions terms with the expectation to exceed variable, the introduction of the 20% coinsurance policy was associated with an increase in medication use (use and quantity for H_2Blockers, and quantity only for OHGs). Figure 7 shows the proportion of seniors that exceeded the maximum copayment by month. The graph shows that the introduction of the 20% coinsurance policy increased the percentage of persons exceeding the maximum copayment. So, the 20% coinsurance policy had countervailing effects. On one hand, it

resulted in additional declines in the rate of use for persons with a low expectation to exceed. However, it also increased dramatically the percentage of persons who would expect to exceed the maximum, thus reducing the percentage of persons that are affected by the policy. For example, among the OHG users, about 65% would have been expected to reduce their levels of use under the $3 copayment policy, but only about 33% would be exp3ected to reduce their level of use under the 20% coinsurance policy.

This graph also shows that income was indirectly associated with the policy effects. While we did not observe larger reductions in use for the low-income group, adjusted for expectation to exceed (i.e. a direct effect), neighborhood income was associated with the likelihood of exceeding the annual maximum copayment. A higher percentage of persons in low-income neighbourhoods reached the maximum than persons in higher income neighbourhoods.

Discussion

Policy makers should be concerned about the potential for negative health outcomes from copayment policies. The results of this study, in combination with the litrature, provide sufficient evidence to conclude that copayments and user fees do not generally promote more appropriate drug use. Consistent with previous studies, this study found that copayments reduce the use of both essential and less essential drugs. Moreover, we found that copayment policies were found to have a bigger effect on the quantity of medication used by patients than on whether they use a drug or not. This is likely because the decision as to whether a medication is prescribed, and thus used, rests largely with the physician. The amount of medication actually consumed, however, is under the control of the patient.

This study did not examine whether changes in drug use resulting from policy changes affected health outcomes. Few studies have examined whether reductions in the use of essential medications associated with co-payments result in negative health outcomes, but there is some evidence suggesting that co-payments are associated with negative health outcomes. This is backed by plausibility. Given that that copayments reduce the use of essential medications, there is a risk of negative health outcomes. So, while it would be premature to conclusively state that prescription co-payments result in negative health outcomes, there is clearly a basis for concern. Until more studies are completed, prudence suggests that policy makers should proceed on the basis that copayments and coinsurance can result in negative health outcomes.

The fiscal realities of drug programs make the elimination of cost sharing policies unviable. But, policy makers should try to implement cost sharing policies that are equitable and minimize the potential for negative health outcomes. The results of this study provide valuable and practical evidence to do so. This study shows that different types of copayment policies have different effects on patient drug use, and different distributional consequences (i.e. how cost sharing is distributed). Different combinations of copayments per prescription, annual maximum copayments and premiums will affect patient drug use in different ways. Thus, policy makers should be able to design alternative cost sharing policies that are cost-neutral to drug plan budgets while potentially generating cost savings elsewhere by reducing negative health outcomes.

Based on the results of this study, and others, we recommend that cost sharing based on a copayments (a fixed fee per prescription), or coinsurance (a percentage of the

prescription cost) should be avoided. If copayments per prescription are used, less-essential drug classes that provide symptomatic relief should be targeted (e.g. Non-steroidal anti-inflammatory medications). Also, copayments should be combined with annual maximums, and a combination of the two should be selected that maximize the percentage of patients that reach the annual maximum. This eliminates the effects of the policy on medication use for those most vulnerable; namely; patients with chronic and multiple health problems, or requiring multiple or more expensive medications. Low income seniors will be more highly represented in this group. To encourage the use of cheaper alternatives, maximum allowable cost or reference-based pricing policies may be preferable to copayments.

Methods of cost sharing that can equitably distribute the financial burden should be preferred. While politically unpopular, income taxes are probably the fairest and most efficient approach to financing drug programs. However, premiums are a viable alternative. They can be income-based, provide risk-pooling, and avoid the potentially negative impacts of copayments.

Surprisingly, we did not find evidence that the effect of copayment policies differed by income group for either of the two drug classes studied. However, we did not have actual measures of seniors' incomes. Instead, seniors were grouped into three income groups based on the mean household income of people living in their neighborhood. This is known to be a relatively weak substitute for data on household income and assets. Moreover, there may be tendency for seniors, whose income is often fixed, to be financially disadvantaged if they live in wealthy neighbourhoods. Accordingly, this result should be interpreted with caution. We did, however, find evidence that income indirectly affects policy effects via its effect on the level of drug use. Persons in lower income neighbourhoods were more likely to reach the annual maximum, and thus were less likely to reduce their level of drug use in response to the policy.

Table 1. Time-Series Analysis of H2 Blocker Use Rates: Policy Effects by Expectation to Exceed

	Model 1			Model 2		
	O.R.	95% C. I.		O.R.	95% C.I.	
Slope when expectation=0						
No copay	1.020	(1.014,	1.027)	1.02	(1.013,	1.027)
$3 per Rx (vs no)	0.972	(0.963,	0.982)	0.969	(0.960,	0.978)
20% per Rx (vs $3)	1.010	(1.002,	1.017)	0.994	(0.985,	1.003)
Slope X Expectation to Exceed						
$3 per Rx (vs no)				1.013	(1.006,	1.020)
20% per Rx (vs $3)				1.023	(1.006,	1.040)

Note: adjusted for age, sex, season, Halifax/other, income group and 6 month lagged value of use. Model estimated by GEE on person-month data using an AR1 correlation structure. Slope effects are incremental (i.e. change in slope versus the previous period).

Table 2. Time-Series Analysis of Oral Antihyperglycemic Use Rates: Policy Effects by Expecation to Exceed

	Model 1			Model 2		
	O.R.	95% C.I.		O.R.	95% C.I.	
Slope when expectation=0						
no copay	1.019	(1.014,	1.023)	1.018	(1.014,	1.023)
$3 per Rx (vs no)	0.991	(0.985,	0.997)	0.99	(0.984,	0.996)
20% per Rx (vs $3)	1.012	(1.007,	1.018)	1.011	(1.005,	1.017)
Slope X Expectation to Exceed						
$3 per Rx (vs no)				1.007	(1.004,	1.009)
20% per Rx (vs $3)				0.995	(0.987,	1.002)

Note: Adjusted for age, sex, season, Halifax/other urban, income group, and 6 month lagged values of use. Model estimated by GEE on person-month data using an AR1 correlation structure. Slope effects are incremental (i.e.change in slope versus the slope of the previous period).

Figure 1. Standardized Rates of Use of H2 Blockers: Halifax

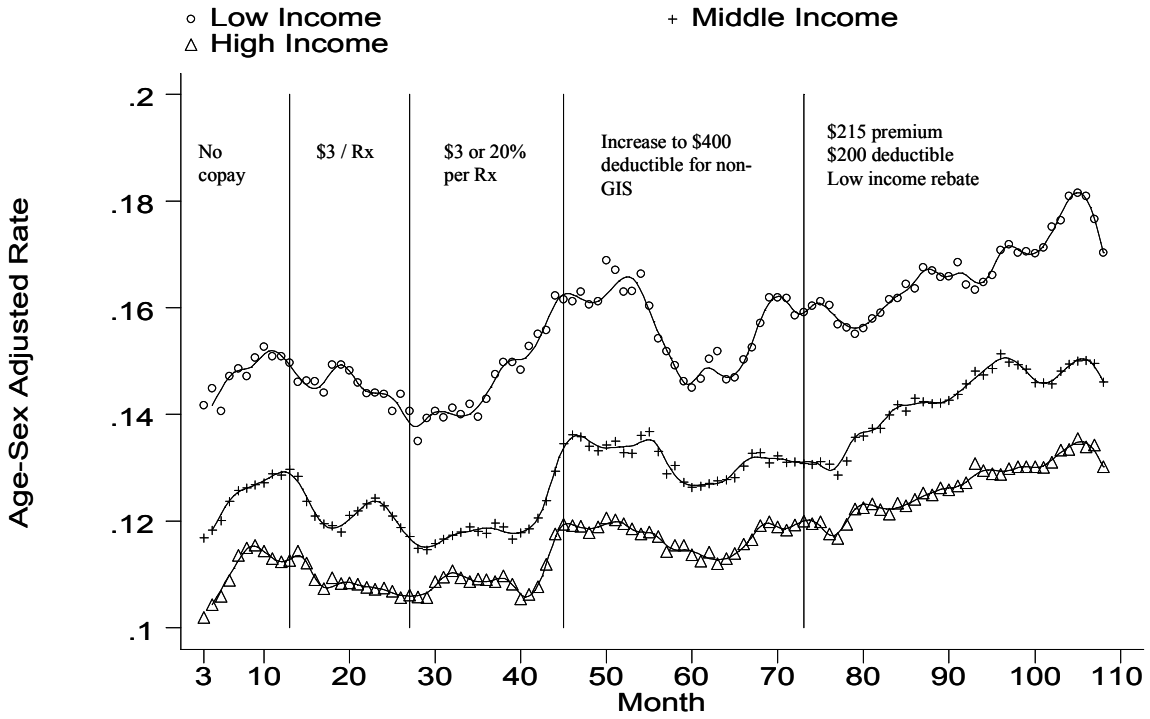

Figure 2. Trends in Rates of H2 Blocker Use: Other Urban

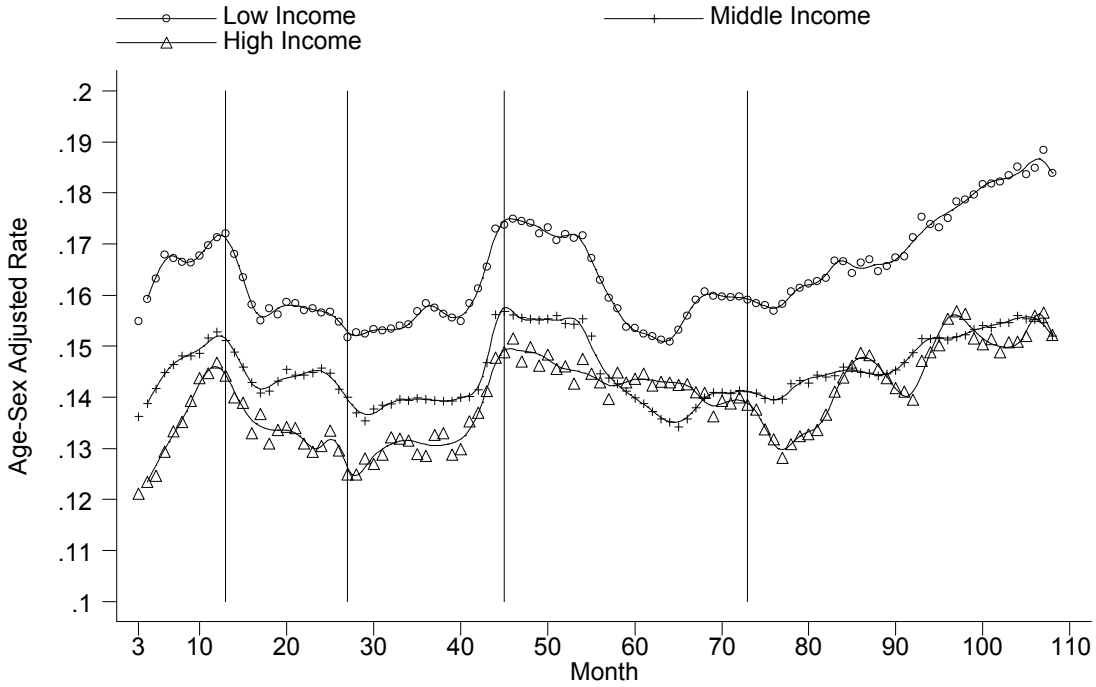

Figure 3. Trends in Rates of Oral Antihyperglycemic Use by Income: Halifax

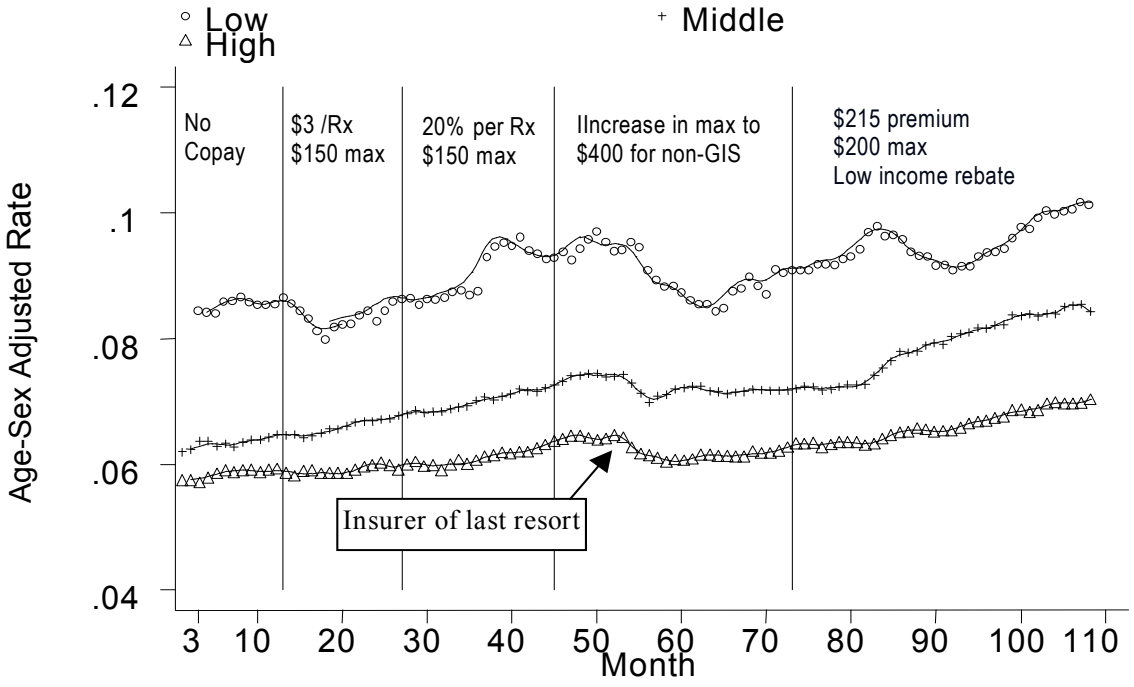

Figure 4. Trends in Rates of Oral Antihyperglycemic Use by Income: Other Urban Areas

Figure 5. Estimated Policy Effect by Expectation to Exceed: H2 Blockers

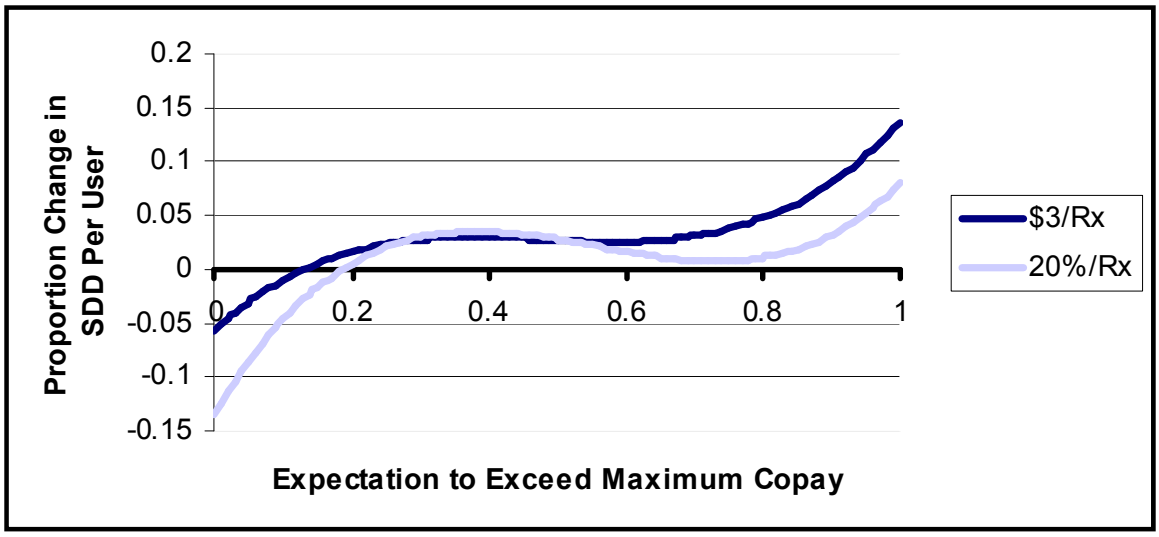

Figure 6 Estimated Policy Effect by Expectation to Exceed: Oral Anti-Hyperglycemic (OHG) Drugs

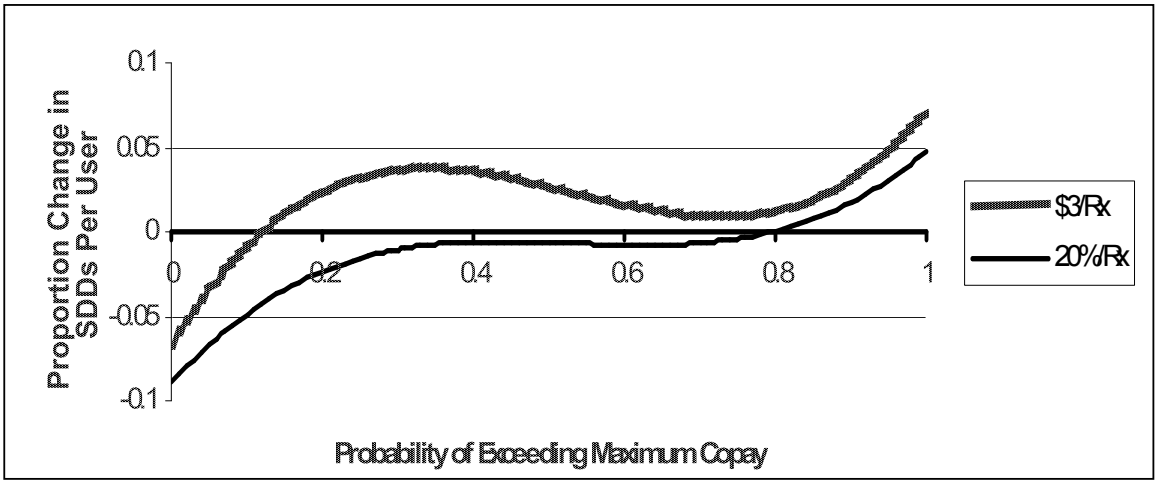

Figure 7. Percent Exceeding Annual Maximum by Month