Income-based drug benefit policy: impact on receipt of inhaled corticosteroid prescriptions by Manitoba children with asthma

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Abstract

- **Background:** Drug benefit policies are an important determinant of a population's use of prescription drugs. This study was undertaken to determine whether a change in a provincial drug benefit policy, from a fixed deductible and copayment system to an income-based deductible system, resulted in changes in receipt of prescriptions for inhaled corticosteroids by Manitoba children with asthma.
- **Methods:** Using Manitoba's health care administrative databases, we identified a population-based cohort of 10 703 school-aged children who met our case definition for asthma treatment before and after the province's drug benefit policy was changed in April 1996. The effects of the program change on the probability of receiving a prescription for an inhaled corticosteroid and on the mean number of inhaled corticosteroid doses dispensed were compared between a group of children insured under other drug programs (the comparison group) and 2 groups of children insured under the deductible program: those living in low-income neighbourhoods and those living in higher-income neighbourhoods. All analyses were adjusted for a measure of asthma severity.
- **Results:** For higher-income children with severe asthma who were covered by the deductible program, the probability of receiving an inhaled corticosteroid prescription and the mean annual number of inhaled corticosteroid doses declined after the change to the drug policy. A trend toward a decrease in receipt of prescriptions was also observed for low-income children, but receipt of prescriptions was unaltered in the comparison group. Before the policy change, among children with severe asthma, the mean annual number of inhaled corticosteroid doses was lowest for low-income children, and this pattern persisted after the change. Among children with mild to moderate asthma, those covered by the deductible program (both low income and higher income) were less likely to receive prescriptions for inhaled corticosteroids than those in the comparison group, and this difference was statistically significant for the higher-income children.
- **Interpretation:** The change to an income-based drug benefit policy was associated with a decrease in the use of inhaled corticosteroids by higher-income children with severe asthma and did not improve use of these drugs by low-income children.

Drug benefit policies play an important role in determining a population's use of pharmaceuticals. Policies that impose limits on reimbursement for prescriptions or that increase the cost that must be borne by the patient can promote optimal use of pharmaceuticals,^{1,2} but they have also led to unintended effects, such as reductions in the use of essential drugs³⁻⁶ and substitution with less effective drugs.¹ Negative health outcomes of these unintended effects have been documented.⁴⁻⁶ Low-income Canadians who must pay for their prescriptions are less likely to use prescription drugs than recipients of income assistance, who receive prescription drugs at no charge.⁷ A recent change to the drug benefit policy in

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Quebec, which required a deductible payment from social assistance recipients (who previously received prescription drugs at no cost), resulted in a decrease in the consumption of inhaled corticosteroids for asthma.^{6,8} The impact of this type of policy change is clinically relevant, since use of inhaled corticosteroids significantly reduces illness and death resulting from asthma.⁹⁻¹¹

Until March 1996, the prescription reimbursement policy for Manitoba's drug benefit program, Pharmacare, required a fixed annual deductible payment of \$237 per family plus 40% copayment on prescription costs over \$237. In April 1996, the policy was changed, and the deductible is now based on income.¹² Under the income-based policy, families with an annual income of \$15 000 or less, adjusted for dependents, are required to pay a deductible equivalent to 2% of income, whereas those with higher incomes pay a deductible of 3% of income. Once the deductible is reached, the provincial government pays 100% of all prescription costs. There has been no change in the 100% reimbursement benefit available to households receiving income assistance and to federal-treaty First Nations households.

This study was undertaken to determine if the change in Manitoba's drug benefit policy, from a fixed deductible and copayment system to an income-based deductible system, affected the receipt of prescriptions for inhaled corticosteroids among children with asthma living in different socioeconomic environments.

Methods

We conducted a population-based cohort study of the receipt of prescriptions for inhaled corticosteroids, before and after introduction of the income-based drug policy, among school-aged children (5 to 15 years old) treated for asthma. The data were obtained from 4 computerized databases maintained by the Manitoba Health Service Insurance Plan (MHSIP): registration files, physician reimbursement claims, hospital discharge abstracts and prescriptions dispensed in retail pharmacies. The MHSIP registration file contains a unique numeric identifier for every registrant, which allows linkage of the health care records. MHSIP's prescription and health care administrative databases have been shown to have good reliability and validity.^{13,14} The study protocol was approved by the Human Research Ethics Committee, University of Manitoba, and permission to access the data was obtained from the Manitoba Health Access and Confidentiality Committee.

Children were selected for inclusion if they had received prescriptions for asthma drugs in the 1-year period before and the 2year period after introduction of the income-based policy on Apr. 1, 1996, as follows: at least 1 prescription for a bronchodilator, inhaled corticosteroid or cromone, ketotifen, or oral corticosteroid, in conjunction with at least one physician visit or admission to hospital related to a diagnosis of asthma or bronchitis; or, in the absence of such a diagnosis, at least 1 prescription for an inhaled corticosteroid or cromone or for ketotifen in conjunction with a bronchodilator, or at least 2 prescriptions for a bronchodilator. Because our definition excluded children with one-time bronchodilator prescriptions and no diagnosis of asthma,¹⁵ it was more stringent than definitions used by others.16

In the absence of direct measures of household income, we used 1996 census information on average household income reported for enumeration areas to rank households into quintiles, from the 20% of the population in the lowest-income neighbourhoods to the 20% of the population in the highest-income neighbourhoods.¹⁷ Three groups were identified: children in households receiving prescriptions reimbursed in full by the income assistance and treaty First Nations prescription programs, as defined in the prescription database (the non-Pharmacare group), children in households receiving Pharmacare benefits that were located in neighbourhoods in the lowest-income quintile (the low-income Pharmacare group) and children in households receiving Pharmacare benefits that were located in neighbourhoods in the 4 higher-income quintiles (the higher-income Pharmacare group). The non-Pharmacare group was the comparison group, because there was no change in the drug reimbursement policy for this group.

To diminish confounding by disease severity,¹⁸ the children were stratified by asthma severity, as derived from the asthma prescription drug profile¹⁹ and the history of hospital admissions, as follows: mild to moderate asthma was defined as use of bronchodilators with or without inhaled corticosteroids or cromones. and severe asthma was defined as high use of bronchodilators (greater than the 90th percentile of doses) with use of inhaled corticosteroids or cromones or admission to hospital for asthma, or use of oral corticosteroids. Children who did not receive any inhaled corticosteroids were classified as having severe asthma if they used oral corticosteroids or high doses of bronchodilators. The severity measure was found to have good reliability (kappa = 0.82) and validity through its association with other markers of severity, such as admission to an intensive care unit.²⁰ By applying the severity criteria to health care data from before and after introduction of the income-based drug policy, we obtained 2 subgroups: 6612 children with mild to moderate asthma before and after introduction of the income-based policy (referred to here as stable, mild to moderate asthma) and 1420 children with severe asthma before and after introduction of the new policy (referred to here as stable, severe asthma). Children with decreasing (n = n)1223) or increasing (n = 1448) severity of asthma over time were excluded because of the difficulty in distinguishing changes in prescriptions for inhaled corticosteroids that were secondary to changes in asthma severity from changes associated with the drug benefit policy.

Two measures of inhaled corticosteroid use, computed for the 1-year period before and the 2 consecutive 2-year periods after the policy change, were determined: the proportion of children who received a prescription and the mean number of doses per childyear among children whose prescriptions were filled, derived from the prescription quantity and the standard unit sizes of inhalers. Inhaled corticosteroid drugs included beclomethasone, budesonide, fluticasone, flunisolide and triamcinolone. Comparisons between time periods of the likelihood of receiving an inhaled corticosteroid prescription, adjusted for monthly variation and stratified by income status and asthma severity, were assessed with Mantel-Haenszel odds ratios (ORs) and 95% confidence intervals (CIs). The Breslow-Day test of heterogeneity was applied to assess whether the likelihoods for the non-Pharmacare and the lowincome and higher-income Pharmacare groups were statistically different. A split-unit analysis, reported as least-square means and 95% CI, was conducted to determine the mean number of inhaled corticosteroid doses before and after the policy change in relation

to income status. Assuming an α of 0.05, a β of 0.2, and one-sided and paired (before and after) comparisons, 496 children were required per stratum to find an OR of 0.80, and 371 children were required per stratum to detect a 10% decrease in dose.

Results

A total of 10 703 children were identified on the basis of the asthma treatment criteria. Seventy-five percent of the children lived in higher-income neighbourhoods and 8% in the lowest-income neighbourhoods; the comparison group, accounting for 17%, consisted of those who lived in households receiving prescriptions at no charge. During the 1year period before the policy change, 45% of the children had received a prescription for an inhaled corticosteroid, mainly beclomethasone. There was a decreasing trend over the study period in the proportion of children who received prescriptions for inhaled corticosteroids (Fig. 1), with peaks in use observed in May, September and December.

When the second year after the introduction of the income-based policy is compared with the year before this policy was introduced, the likelihood of receiving a prescription for an inhaled corticosteroid decreased for all groups of children with stable, mild to moderate asthma. The same result was observed for both groups of Pharmacare children with stable, severe asthma, although the decreased likelihood was not statistically significant for the low-income group (Table 1). Across groups of children, the likelihood of receiving a prescription was significantly lower for higher-income Pharmacare children than for



Fig. 1: Monthly percentage of children receiving a prescription for an inhaled corticosteroid, for 1 year before and 2 years after introduction of the income-based drug benefit policy (Pharmacare) in Manitoba.

Table 1. Likelihood of a child obtaining a prescription for an inhaled corticosteroid before and after introduction of an income-based drug benefit policy in Manitoba, adjusted for monthly variation*

	Drug program and income level; OR (and 95% CI)			
-	Pharmacare			
Comparison; severity of asthma	Higher income	Low income	Overall	Non-Pharmacare
1 yr before v. 1st yr after change in policy				
Stable, mild to moderate asthma	0.81† (0.77–0.85)	0.86 (0.73-1.01)	0.81 (0.78-0.85)	0.95 (0.85–1.06)
Stable, severe asthma	0.83† (0.77–0.89)	0.80 (0.64–1.00)	0.83 (0.77-0.88)	1.03 (0.90–1.17)
1 yr before v. 2nd yr after change in policy				
Stable, mild to moderate asthma	0.68† (0.65–0.71)	0.68† (0.57–0.80)	0.68 (0.65-0.71)	0.87 (0.78–0.97)
Stable, severe asthma	0.82† (0.77–0.88)	0.86 (0.69–1.08)	0.82 (0.77–0.88)	1.00 (0.88–1.14)

Note: OR = Mantel-Haenszel odds ratio, CI = confidence interval. If CI spans 1.0, there was no statistically significant change after introduction of the income-based policy. *Numbers of children with mild to moderate asthma: in higher-income Pharmacare group, 4978; in low-income Pharmacare group, 509; in non-Pharmacare group, 1125. Numbers of children with severe asthma: in higher-income Pharmacare group, 1044; in low-income Pharmacare group, 125; in non-Pharmacare group, 251. †Breslow-Day test indicating heterogeneity with non-Pharmacare group (p < 0.05). non-Pharmacare children at both levels of asthma severity (Breslow–Day test for heterogeneity).

A total of 7221 children received at least one prescription for an inhaled corticosteroid. In the second year after the change in policy, the mean number of inhaled corticosteroid doses that were dispensed decreased among Pharmacare children with stable, mild to moderate asthma (184 doses/year [95% CI 174–194] during the year before the change in policy v. 131 doses/year [95% CI 122–139] during the second year after the change in policy) and among non-Pharmacare children with this level of asthma severity (151 doses/year [95% CI 129–173] v. 134 doses/year [95% CI 115–153]), but the decrease was statistically significant for the Pharmacare group only. Within the Pharmacare group, the decrease in mean number of corticosteroid doses was statistically significant for the higher-income but not the low-income children (Fig. 2).

There was no difference in the mean number of corticosteroid doses dispensed to non-Pharmacare children with stable, severe asthma between the year before and the second year after introduction of the policy (373 doses/year [95% CI 336–411] v. 415 doses/year [95% CI 382–448]), but a decrease was observed among Pharmacare children with stable, severe asthma (344 doses/year [95% CI 326–362] v. 288 doses/year [95% CI 272–304]). This decrease was statistically significant for the higher-income but not the low-income children (Fig. 3). Both before and after introduction of the income-based policy, the mean number of corticosteroid doses used by low-income Pharmacare children with severe asthma was significantly lower than the number of doses used by non-Pharmacare children, whose families received prescriptions at no charge.



Fig. 2: Mean number of inhaled corticosteroid doses (and 95% confidence interval [CI]) for children with stable, mild to moderate asthma for 1 year before and 2 years after introduction of the income-based policy.



Fig. 3: Mean number of inhaled corticosteroid doses (and 95% CI) for children with stable, severe asthma for 1 year before and 2 years after introduction of the income-based policy.

Interpretation

After a change in drug benefit policy from a fixed deductible and copayment system to an income-based deductible system, children with severe asthma who were covered by the policy were less likely to receive prescriptions for inhaled corticosteroids, and among children with prescriptions for these drugs, there was a reduction of more than 15% in the mean number of annual doses. No change in prescriptions for inhaled corticosteroids was observed in a comparison group of children. These findings were statistically significant for higher-income but not low-income children insured under the income-based deductible program. All children with mild to moderate asthma were less likely to receive prescriptions for inhaled corticosteroids as time went on; this finding is consistent with the natural history of wheezing in childhood, whereby wheezing ceases in some children as they grow older.²¹ However, among children with this level of asthma severity, the likelihood of using inhaled corticosteroids was significantly lower in the higher-income group than in the comparison group, which suggests that the income-based policy also affected children with less severe forms of the disease.

An analysis of the financial impact of the income-based policy provides possible reasons for our findings. Under the fixed deductible and copayment policy, a family with typical prescription costs of \$980 paid \$534 out of pocket (i.e., deductible of \$237 plus 40% copayment on the remaining \$743).²² Under the income-based policy, even among families in the lower income range in our study, higher-income households might have experienced significantly higher out-of-pocket prescription costs; at a 3% deductible for family incomes above \$15 000, the cost would be \$720 for a family with an adjusted income of \$24 000. Thus, the change in the drug benefit policy increased the costs to beneficiaries and had the unintended effect of reducing use of prescription drugs; this type of unintended effect has already been well documented.^{3,6,8,23} Furthermore, the receipt of prescriptions for inhaled corticosteroids by low-income children did not improve (increase) after introduction of the income-based policy and may in fact have decreased. Under the income-based policy, an adjusted household income of \$18 000 would result in a deductible payment of \$540, not much different from the payment by a lowincome family before the policy was introduced. Prescription costs impose barriers on the ability of low-income families to purchase asthma drugs,24 which may explain why low-income children with severe asthma insured under the deductible policy received fewer corticosteroid doses than the comparison children, who were insured under the 100% reimbursement programs.

Threats to internal validity were minimized in this study through the use of a repeated-measures design in a welldefined population, which included an internal comparison group not exposed to the change in drug benefit policy. Adjustments were made for seasonal variation in inhaled

corticosteroid use secondary to exposure to allergens and respiratory viruses.^{25,26} Intermittent use of high-dose inhaled corticosteroids is recommended in the treatment of acute asthma,¹⁹ and parents anticipating seasonal exacerbations may increase their children's supply of corticosteroid inhalers. Findings were also stratified by asthma severity because severity is greater in lower-income children,18 and children with severe asthma are less likely "to grow out of their asthma."27 There were insufficient numbers of lowincome children with severe asthma to detect a 20% decrease in the likelihood of receiving inhaled corticosteroid prescriptions and a 10% decrease in the number of doses. However, because this was a population-based study of a cohort of children with asthma, increases in sample size could only have been achieved by including children from other jurisdictions.

This study has demonstrated that altering drug benefits can have unintended consequences on the receipt of prescription drugs for the management of asthma. Lower use of inhaled corticosteroids has been associated with increased admissions to hospital for asthma.¹⁰ Hospital admission contributes substantially to the costs of managing the disease and affects patients' quality of life.^{28,29} Despite more widespread use of inhaled corticosteroids during the past decade,^{30,31} these drugs remain underused.^{32,33} It is therefore imperative that drug benefit policies not deter patients and their families from using these drugs.³⁴ In this era of cost containment, income-based drug benefit policies appear to be good choices for equitably distributing the burden of prescription costs. However, their impact on the use of prescription drugs necessitates evaluation of potential unintended effects. Furthermore, reducing prescription costsharing for low-income children with asthma, among whom hospital admission rates are highest, has the potential to improve their health.³⁵ These are important considerations in the design of drug benefit policies by provincial governments, third-party payers and the federal government, should it decide to pursue a national pharmacare program.

Competing interests: None declared.

Contributors: Dr. Kozyrskyj had primary responsibility for designing and executing the study, analyzing the data and writing the manuscript. Dr. Mustard and Ms. Cheang participated in study design and data analysis and contributed to writing the manuscript. Dr. Simons participated in study design and contributed to writing the manuscript.

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