

# Cost is a major barrier to the use of inhaled corticosteroids for obstructive lung disease

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Inhaled corticosteroids (ICS) are widely recognised as effective for controlling symptoms and reducing the risk of exacerbations in patients with obstructive lung diseases such as asthma and chronic obstructive pulmonary disease (COPD).<sup>1-4</sup> These drugs are most effective when used continuously, although, for asthma, symptoms are not usually present all the time.

Current international asthma guidelines recommend regular ICS treatment for all patients who, without treatment, experience symptoms on 2 or more days per week.<sup>5</sup> Asthma can be well controlled in most people with low doses of ICS,<sup>6</sup> with or without long-acting  $\beta_2$ -agonists (LABA). Current COPD guidelines recommend regular ICS treatment for patients with severe COPD and repeated exacerbations.<sup>7</sup> ICS are also used sporadically for other conditions (eg, post-viral cough), but the extent of such prescribing is unknown, and evidence supporting such treatment<sup>8</sup> is less well established.

Health survey data indicate that the use of ICS for managing obstructive lung disease is suboptimal. Some ICS prescriptions are never filled.<sup>9</sup> A 1997 study showed that only 43% of people in New South Wales with persistent asthma reported using ICS regularly,<sup>10</sup> and in the 2004–05 National Health Survey (NHS), only 28.4% of young adults with asthma reported using ICS in the previous 2 weeks.<sup>11</sup> Dispensing patterns of ICS prescriptions are also inconsistent with regular use by most recipients.<sup>12,13</sup> A recent study showed that a 24% increase in the patient copayment for medications had significant effects on the dispensing of some

## ABSTRACT

**Objective:** To examine the effect of the level of patient copayment on the rate of purchase of inhaled corticosteroids (ICS) by patients with obstructive lung disease.

**Design and setting:** Cross-sectional study of records of all prescriptions for ICS dispensed to general and concessional beneficiaries aged 15 years or over in the period January 2003 to December 2006. Data were obtained from the Pharmaceutical Benefits Scheme, which subsidises medication costs for all Australians.

**Main outcome measures:** The number of prescriptions for ICS dispensed to government concession card holders compared with the number dispensed to general beneficiaries, expressed as a rate ratio.

**Results:** ICS prescriptions were dispensed to over 1.6 million people during the study period. Concession card holders were dispensed ICS prescriptions at a higher rate than general beneficiaries, both overall (43.7 v 9.1 ICS prescriptions per 100 person-years) and in all population subgroups. After adjusting for age, sex, remoteness category and socioeconomic status, people holding a concession card were dispensed over 2.5 times the number of ICS prescriptions (alone or in combination with a long-acting  $\beta_2$ -agonist) compared with general beneficiaries. Similar patterns were seen after adjusting for differences between the two groups in the prevalence of obstructive lung disease.

**Conclusions:** As the patient copayment for general beneficiaries is over six times higher than for concession card holders, our findings imply that cost is a barrier to the purchase of ICS prescriptions for obstructive lung disease, independent of socioeconomic status.

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essential drugs, including asthma medicines, especially among Australians receiving social security benefits.<sup>14</sup> Taken together, these findings imply that economic factors contribute to underuse of ICS by people with obstructive lung disease.

The price differential between general beneficiaries and concession card holders in Australia (Box 1) offers an opportunity to examine the effect of price on rate of purchase (and by assumption, use) of essential medications (specifically ICS-containing medications) for patients with obstructive lung disease. We have previously shown, using linked unit record data from the Pharmaceutical Benefits Scheme (PBS), that concession card holders fill more ICS prescriptions than general beneficiaries.<sup>12</sup> Here we extend that analysis to assess whether the observed differences in ICS usage were independent of demographic and socioeconomic characteristics and disease prevalence.

## METHODS

A dataset comprising all dispensed ICS and LABA prescriptions subsidised by the PBS

for people aged 15 years or over was extracted from the PBS database for the period January 2003 to December 2006. The dataset included the type and strength of medication subsidised, 5-year age group, sex, residential postcode, dispensing date and beneficiary status (general or concession), together with an encrypted patient identification number (PIN) based on the patient's Medicare number. This allowed anonymous identification of prescriptions dispensed to the same individual, as well as linkage to data on age, sex and residential postcode. Records with missing PINs and patients whose concessional category changed within the study period were excluded from our analysis.

We calculated the number of prescriptions dispensed for ICS, alone or in combination with LABA. Dispensed prescriptions were reported for the whole population and for subgroups classified by beneficiary status, age group, sex, remoteness category (based on the Australian Standard Geographical Classification [ASGC]),<sup>15</sup> and socioeconomic status (based on the Index of Relative Socio-Economic

## Abbreviations

|       |   |
|-------|---|
| ASGC  | Australian Standard Geographical Classification |
| COPD  | Chronic obstructive pulmonary disease           |
| ICS   | Inhaled corticosteroids                         |
| LABA  | Long-acting $\beta_2$ -agonists                 |
| NHS   | National Health Survey                          |
| PBS   | Pharmaceutical Benefits Scheme                  |
| PIN   | Patient identification number                   |
| SEIFA | Socio-Economic Indexes for Areas                |

### 1 The Australian Pharmaceutical Benefits Scheme (PBS)

The PBS subsidises medication costs for all Australians, with a copayment required in most instances (\$23.10–\$29.50 during the study period for general beneficiaries, and \$3.70–\$4.70 for concession card holders). The concessional rate is available to people receiving government benefits (eg, unemployment, low income, sickness or seniors' benefits) and for repatriation (veterans') items. The government also provides a "safety net", whereby general beneficiaries who have spent more than a defined sum during a calendar year (\$708.40–\$960.10 during the study period) qualify for the lower copayment amount for the remainder of the year.

The PBS database records information on all eligible, dispensed prescriptions for which a benefit was payable, including most essential drugs that require a prescription. However, general beneficiaries do not obtain a benefit for drugs that cost less than their copayment amount, so dispensing of these items to general beneficiaries is not recorded in the PBS database. Fortunately for our analysis, nearly 100% of prescriptions for inhaled corticosteroids (ICS) and long-acting  $\beta_2$ -agonists cost more than the general copayment amount, and hence are recorded in the PBS database and included in our analysis.

Each dispensed item of ICS is for one inhaler, which provides sufficient medication for about 1 month of treatment at standard doses.

The PBS data do not include any information about the medical condition for which a prescription was dispensed. ◆

Disadvantage, one of the Socio-Economic Indexes for Areas (SEIFA).<sup>16</sup> If a patient's SEIFA or ASGC category (assigned on the basis of residential postcode) changed during the study period, the category that pertained when the first prescription was dispensed was retained for all records for that patient. General beneficiaries who qualified for the government "safety net" (Box 1) during the course of the year were analysed as general beneficiaries for the whole year. Dispensing rates were calculated using the Australian estimated resident populations<sup>17</sup> — classified by age group, sex, remoteness category and socioeconomic status — as a denominator. The population distribution of beneficiary categories was estimated using data from the 2004–05 NHS,<sup>18</sup> which collected information on whether respondents held a government concession card.

To estimate the prevalence of obstructive lung disease for all combinations of age group, sex, remoteness category and beneficiary status that were defined in the PBS dataset, we used data from the 2004–05 NHS.<sup>18</sup> Patients were classified as having obstructive lung disease if they reported that they had emphysema or chronic bronchitis, or that they had been diagnosed with asthma and still had asthma.

We calculated two indicators of individual use of ICS:

- The average number of ICS prescriptions dispensed to patients over the 4-year study period, calculated as the sum of all prescriptions dispensed per PIN, divided by the total number of PINs.
- The proportion of patients who were dispensed three or more ICS prescriptions in

any 12-month period. We identified an index prescription for ICS purchased at any time within the first 3 years of the study period, then calculated the proportion of patients who were dispensed two or more additional ICS prescriptions in the 12 months after the index prescription.

We assessed the effect of beneficiary status on both these indicators using multivariate generalised linear models in which ICS use was the dependent variable, beneficiary status was the main independent variable, and age group, sex, remoteness category and prevalence of obstructive lung disease were covariates. As we did not have access to data jointly classified by socioeconomic status and the prevalence of obstructive lung disease, we adjusted for socioeconomic status in a separate model.

For the first indicator, we initially fitted a Poisson model. However, due to overdispersion in this model, a negative binomial error distribution was assumed.<sup>19</sup> Rate ratios were calculated from this model.

For the second indicator, we used a binomial error distribution with a log link. Relative risks were calculated from this model. All analyses were performed using SAS, version 9.1 (SAS Institute Inc, Cary, NC, USA).

Our study was approved by the University of Sydney Human Research Ethics Committee.

## RESULTS

Between January 2003 and December 2006, there were 17 139 629 records from 2 242 495 patients who were dispensed prescriptions for ICS. After exclusions, there

were 14 321 274 records (83.6% of the total) from 1 996 233 patients, of whom 1 673 233 were aged 15 years or over (Box 2). A concession card was held by 55% of these patients, compared with 34% of patients in the Australian population as a whole.<sup>18</sup> As expected, concession card holders tended to be older and to be living in more socioeconomically disadvantaged areas than general beneficiaries. The age-standardised prevalence of obstructive lung disease (asthma or COPD) was 10.4% (95% CI, 9.6%–11.2%) among general beneficiaries and 15.2% (95% CI, 14.0%–16.4%) among concession card holders.<sup>18</sup>

The rate of dispensing of ICS prescriptions (ICS or ICS–LABA combination) was significantly lower for general beneficiaries than for concession card holders, both overall (9.1 v 43.7 prescriptions per 100 person-years) and in all population subgroups (Box 2). The difference was most marked in older age groups. The same pattern was seen when ICS–LABA combination prescriptions were examined separately (data not shown). The dispensing rate for ICS was highest for people living in the least socioeconomically disadvantaged areas, regardless of beneficiary status. Dispensing rates were lowest for people aged 15–34 years. Among concession card holders, those aged 65 years or over had the highest number of ICS prescriptions dispensed per 100 person-years. In contrast, among general beneficiaries, those aged 35–64 years had the highest rate of ICS prescriptions dispensed, but only 4% of patients aged 65 years or over did not have a concession card.

After adjusting for differences in age, sex, remoteness category and the prevalence of obstructive lung disease, the rate of ICS dispensing was over 2.5 times higher for concession card holders than for general beneficiaries (rate ratio [RR], 2.68 [95% CI, 2.34–3.07] for ICS alone and 2.50 [95% CI, 2.15–2.90] for ICS–LABA combination). The effect of beneficiary status was similar in a separate model that adjusted for age, sex, remoteness category and socioeconomic status (RR, 2.93 [95% CI, 2.92–2.94] for ICS alone and 2.86 [95% CI, 2.85–2.87] for ICS–LABA combination).

Concession card holders were also dispensed ICS more frequently than general beneficiaries. Among people who filled any ICS prescription between 2003 and 2006, 70% of concession card holders filled more than one prescription, compared with 54% of people without concession cards. Over this period, concession card holders who

## 2 Number of patients dispensed inhaled corticosteroids (ICS)\* and prescription rates, by beneficiary status and demographic characteristics, among Australians aged 15 years or over, 2003–2006

|                             | Concession card holders |   | General beneficiaries |   | Rate ratio<br>(95% CI) |
|-----------------------------|-------------------------|---|-----------------------|---|------------------------|
|                             | Number of patients      | ICS prescriptions per 100 person-years <sup>†</sup> | Number of patients    | ICS prescriptions per 100 person-years <sup>†</sup> |                        |
| Total                       | 921 508                 | 43.7  | 751 725               | 9.1   | 4.82 (4.81–4.82)       |
| Sex                         |                         |   |                       |   |                        |
| Male                        | 362 996                 | 43.5  | 342 897               | 8.5   | 5.15 (5.14–5.15)       |
| Female                      | 558 512                 | 43.7  | 408 828               | 9.8   | 4.47 (4.46–4.48)       |
| Age group (years)           |                         |   |                       |   |                        |
| 15–34                       | 163 219                 | 13.8  | 293 622               | 6.8   | 2.03 (2.02–2.04)       |
| 35–64                       | 315 156                 | 42.0  | 439 753               | 10.9  | 3.86 (3.86–3.87)       |
| ≥ 65                        | 443 133                 | 60.2  | 18 350                | 7.7   | 7.87 (7.85–7.88)       |
| SEIFA quintile <sup>‡</sup> |                         |   |                       |   |                        |
| 1                           | 199 031                 | 32.9  | 71 266                | 9.5   | 3.47 (3.46–3.48)       |
| 2                           | 200 924                 | 41.2  | 107 533               | 6.1   | 6.75 (6.74–6.77)       |
| 3                           | 193 481                 | 47.5  | 141 065               | 8.4   | 5.68 (5.67–5.70)       |
| 4                           | 168 913                 | 46.4  | 165 839               | 8.4   | 5.53 (5.52–5.54)       |
| 5                           | 154 674                 | 62.7  | 258 423               | 12.1  | 5.17 (5.16–5.18)       |
| Remoteness category         |                         |   |                       |   |                        |
| Major cities                | 611 639                 | 46.1  | 558 872               | 9.7   | 4.77 (4.76–4.77)       |
| Inner regional areas        | 201 352                 | 43.3  | 119 946               | 7.9   | 5.49 (5.48–5.51)       |
| Other areas <sup>§</sup>    | 103 417                 | 32.8  | 69 809                | 8.0   | 4.12 (4.11–4.13)       |

SEIFA = Socio-Economic Indexes for Areas. \*ICS alone or in combination with long-acting  $\beta_2$ -agonists.

<sup>†</sup> Population is the total Australian population with ("concession card holders") or without ("general beneficiaries") a government health concession card, as estimated by the 2004–05 National Health Survey.<sup>11</sup>

<sup>‡</sup> Categories are based on national quintiles: "1" = most disadvantaged; "5" = least disadvantaged.

<sup>§</sup> Other areas include outer regional, remote and very remote areas. ◆

had been dispensed any ICS filled an average of 9.8 ICS prescriptions (2.5 per year), compared with 5.5 prescriptions (1.4 per year) for general beneficiaries. The probability of a person having three or more ICS prescriptions filled within a 12-month period was higher for a concession card holder than for a general beneficiary (RR, 1.29 [95% CI, 1.28–1.30] for ICS alone and 1.24 [95% CI, 1.23–1.25] for ICS–LABA combination). The model was adjusted for age, sex, remoteness category and socioeconomic status.

### DISCUSSION

For conditions such as obstructive lung disease that require daily medication to reduce symptoms and prevent long-term complications, the cost of medications constitutes an important component of the burden of illness. Our analysis of a dataset that covers dispensed prescriptions for virtually

the entire Australian population over a 4-year period shows that concession card holders, who obtain medications for about a sixth of the cost that general beneficiaries pay, are dispensed over 2.5 times more ICS (alone or in combination with LABA) than patients without a concession card. These differences are not explained by sociodemographic differences or differences in the prevalence of obstructive lung disease, thus supporting our hypothesis that price is a substantial barrier to the use of essential asthma medicines.

Current asthma guidelines<sup>5,20</sup> recommend that adults with persistent asthma (ie, those who, without treatment, experience symptoms on 2 or more days per week) should use ICS every day. COPD guidelines<sup>7,21</sup> currently recommend daily use of ICS by patients with severe COPD who experience frequent exacerbations, although debate continues about the relative

benefits and risks.<sup>22</sup> However, there is increasing awareness that use of prescribed medications for asthma and COPD — as for most other chronic conditions — is suboptimal. Poor adherence is associated with greater risk of hospitalisation for asthma<sup>23</sup> and COPD.<sup>24</sup> Hence, there is a need to identify modifiable factors that may affect patient use of prescribed ICS treatment.

Prescription databases provide a useful resource for identifying patterns of medication use and assessing patient adherence to guideline-based treatment.<sup>25–27</sup> Although primary non-adherence (failure to present a prescription for dispensing) can not be identified from dispensing records, and it can not be assumed that dispensed medication has actually been used, dispensing records provide an objective measure of a patient's *maximum* potential usage over a period of time, provided the dispensing database captures all prescriptions. While many studies have been based on administrative datasets from managed care organisations,<sup>23,28</sup> our study, using data from the PBS database, provides information about the purchasing behaviour of over 20 million patients nationally, including over 2.2 million who purchased ICS, across the full range of socioeconomic circumstances in Australia.

For most patients in the PBS dataset, regular use of ICS at standard doses would require the dispensing of about 12 prescriptions per year. The observed dispensing rates (averaging 1.4 prescriptions per year for general patients and 2.5 prescriptions per year for concessional patients) suggest that only a small proportion of Australian patients are using these medications regularly, and that the cost of medications may have a significant impact on patient medication behaviour. Dispensing rates for ICS in our study were lower than rates reported from other countries. In a managed care organisation in the United States, patients filled an average of 2.35 prescriptions per year for ICS and 4.35 per year for ICS–LABA combinations.<sup>28</sup> In the Netherlands, where there is usually no patient copayment at purchase, patients filled an average of 11.6 prescriptions for ICS over 5 years (each refill lasting for up to 3 months). However, it should be noted that those filling only one ICS prescription during this period were excluded.<sup>29</sup>

In our study, the lowest dispensing rates were seen in the youngest patients (aged 15–34 years), consistent with findings from other studies.<sup>25</sup> Among concession card holders, the highest rate was seen in patients

aged 65 years or over. By contrast, among general beneficiaries, the dispensing rate was lower in this age group than in the 35–64-years age group, but only 4% of patients aged 65 years or over did not hold a concession card.

As might be expected, lower dispensing rates were seen for patients living in the most socioeconomically disadvantaged areas and for those living in remote areas. The interacting nature of many of these factors has led to an assumption in the past that low-income patients are more sensitive than high-income patients to copayment level.<sup>30</sup> However, our analysis showed that the magnitude of patient copayment, as indicated by beneficiary status, markedly affected the rate ratio for dispensing and for refilling of ICS prescriptions, regardless of socioeconomic status.

A major constraint of our study was that PBS data do not include any information about the patient's diagnosis and can not, at present, be linked to any clinical or other health utilisation data. However, we were able to adjust for the prevalence of obstructive lung disease, stratified by sociodemographic characteristics, using NHS data. Another possible limitation is that the index used to classify socioeconomic status (SEIFA), while based on the collective socioeconomic status of people living in a small area, does not apply to all individuals within that area. Nevertheless, there is evidence to suggest that these community-level measures of disadvantage are highly relevant to health outcomes.<sup>31,32</sup> In addition, no information was available about disease severity. However, without a difference in prevalence of obstructive lung disease between concession card holders and general beneficiaries, it is unlikely that a difference in dispensing of this magnitude (2.5-fold) could be explained by a difference in disease severity.

Several countries have established government-funded subsidy systems to reduce the burden of chronic illness, many of which require a copayment from patients for medications. Even so, the price paid for medications, along with all other goods, substantially influences purchasing decisions. We have shown that economic forces have a profound effect, even within a subsidised pharmaceutical scheme. While educational and behavioural interventions may have beneficial effects on patients' adherence to treatment for asthma and other chronic diseases, the improvements are modest,<sup>33</sup> and it is clear that economic barriers to access need to be addressed

before substantial improvements in ICS usage can be achieved. Economic modelling could be used to assess the impact of various approaches to reducing these barriers on net health expenditure, taking account of the savings that may flow from reduced use of health care services for management of disease exacerbations.

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## COMPETING INTERESTS

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