

1 Introduction

Key points

- Drug therapy is the cornerstone of asthma care and is used to relieve and prevent day-to-day symptoms, and prevent and treat exacerbations.
- Drug classes commonly used to treat asthma include short-acting beta agonists, which are used for short-term symptom relief; inhaled corticosteroids and long-acting beta agonists, used for symptom prevention and disease control; and oral corticosteroids, which are used during episodes of more severe asthma.
- The Pharmaceutical Benefits Scheme (PBS) data comprises records of all prescriptions subsidised by the scheme.
- All prescriptions for inhaled corticosteroids and long-acting beta agonists are subsidised by the PBS. Prescriptions of short-acting beta agonists and oral corticosteroids are only consistently subsidised for patients with concession cards.
- Recently, the PBS has enabled the linkage of multiple prescriptions for the same person and includes some of their basic demographic details. Here, this information is used to investigate the patterns of asthma medications in Australia.

1.1 Background

Asthma is a National Health Priority Area in Australia because it is a common chronic disease that has a sizeable impact on individuals and the community, but with well-trying treatments that can reduce this impact. Drug therapy is the cornerstone of asthma treatment and is used to relieve and prevent day-to-day symptoms, and prevent and manage episodes of disease exacerbation.

Drugs commonly used to treat asthma include short-acting beta agonists, which are used, as needed, for short-term bronchodilation to relieve symptoms, and inhaled corticosteroids, which are used to control the underlying disease process and hence prevent symptoms and also prevent exacerbations.

Some people with asthma may choose to rely solely on short-acting beta agonists to manage their disease. However, people with asthma who rely on short-acting beta agonists, without using inhaled corticosteroids, have been shown to be more likely to suffer exacerbations or attacks of asthma requiring an emergency department visit or an admission to hospital (Anis et al. 2001; Suissa et al. 2002).

Inhaled corticosteroids are most effective when used regularly (usually twice daily) and continuously, including when the person does not have any symptoms of asthma. It has been shown that regular use of inhaled corticosteroids can control asthma symptoms (Adams N et al. 2003, 2004, 2005), prevent hospital admissions (Rowe et al. 2000) and possibly also reduce lung damage (Dijkstra et al. 2006; Lange et al. 2006) among people with asthma. Asthma in most people can be well controlled with quite low doses of inhaled corticosteroids resulting in a low risk of harmful effects (Powell & Gibson 2003).

When the disease cannot be well controlled with a regular, modest dose of inhaled corticosteroids, a long-acting beta agonist is often added. This allows equivalent or greater effectiveness in disease control with lower doses of inhaled corticosteroids (Greening et al. 1994; Ind et al. 2003; Woolcock et al. 1996). Formulations combining a long-acting beta agonist with an inhaled corticosteroid are now available.

Other classes of drugs may also be used regularly to control symptoms and prevent exacerbations. These include theophylline, leukotriene receptor antagonists and cromones. During episodes of more severe asthma, oral corticosteroids may also be used to gain control of the disease. A very small number of people with asthma need long-term treatment with oral corticosteroids to control their disease.

Current international (GINA 2006) and Australian (NAC 2006) guidelines recommend that people with persistent asthma of all levels of severity use inhaled corticosteroids regularly. These guidelines are based on the latest research and give clear information to guide doctors in the current best practice standards for the care of asthma. They are updated regularly and circulated to all general practitioners, respiratory physicians and others, such as asthma educators, throughout Australia, as well as being available on the internet.

The investigation of the pattern of use of asthma medications and how this varies by age, sex, socioeconomic status and remoteness of residence matters for our understanding of how the condition is being managed and the extent to which this is consistent with current evidence and practice guidelines. It can also help in identifying population groups that may be at risk of poor quality treatment practice and in planning policy responses to areas of concern.

Overseas, there are already several examples of studies that have used prescription information to review trends in asthma care and compliance with guidelines, including in the United States (Stafford et al. 2003; Terr & Bloch 1996), United Kingdom (Majeed et al. 1999), Italy (Poluzzi et al. 2002) and Canada (Lynd et al. 2002; Stafford et al. 2003). Often, these studies have found that many people with persistent asthma do not regularly use inhaled corticosteroids (Janson et al. 2005; Poluzzi et al. 2002). For instance, Lynd and colleagues (2002) in Canada found that, despite the active development and distribution of asthma management guidelines, the use of inhaled corticosteroids fell and the use of inhaled short-acting bronchodilators rose between 1996 and 1998, particularly among those receiving social assistance. More encouraging was a study from the United Kingdom that found that there was a rise in prescriptions for inhaled corticosteroids between 1992 and 1998 (Majeed et al. 1999).

Currently, there is limited information about the use of asthma medications in Australia, although a study in New South Wales in 1997 reported that only 43% of people who had features of persistent asthma used inhaled corticosteroids daily or on most days (Marks et al. 2000). In 2004–05, the National Health Survey (NHS) reported that only 28.4% of young adults with asthma had used inhaled corticosteroids in the previous 2 weeks (ACAM 2007). These studies suggest that inhaled corticosteroids are probably also underused here.

The Australian Centre for Asthma Monitoring (ACAM) has previously explored asthma medication use in Australia using pharmaceutical supply data from Intercontinental Medical Statistics in Health Pty Ltd and prescription data from the PBS (ACAM 2005). However, these studies were limited because there was no information about the people who received the drugs.

Since early 2002, PBS prescriptions have included the patients' Medicare numbers. Use of the Medicare number has created the ability to anonymously identify prescriptions for the same

individuals within the PBS data and also to link information on age, sex and home postcode. This is done using an encrypted Medicare patient identification number (PIN) so that patient confidentiality is protected.

ACAM has obtained these data from the Australian Government Department of Health and Ageing for people who were prescribed asthma medications during the period July 2002 to June 2004. In this study ACAM has used these newly available PBS data to investigate the patterns of use of asthma medication by Australians.

The University of Sydney Human Research Ethics Committee provided ethical approval for this study.

1.2 Study aims

This study investigates the pattern of use of medications for asthma in Australia including the demographic variation in their use. The observed pattern of use is compared with the use recommended in asthma management guidelines. The study aims to answer the following questions:

1. How does the use of asthma medications vary with demographic factors, namely age, sex, socioeconomic status and remoteness of residence?
2. What is the frequency of their use by individuals in Australia?
3. How potent are the inhaled corticosteroids prescribed to most people in Australia, and how does this vary with demographic factors?
4. How does the pattern of inhaled corticosteroid use relate to the use of other classes of asthma medication?

1.3 Study data

In Australia, national prescribing data are available from the PBS, which has been administered by the Australian Government for over 50 years (DoHA 2006b). For drugs that are included in this scheme, the person to whom the medication is dispensed pays the cost of that medication up to a 'copayment' amount, and the PBS pays the balance of the total cost if this is more than the copayment amount. At time of this report, this amount was \$30.70 for general patients and \$4.90 for people with government concession cards. In this way, all drugs that are listed on the PBS do not cost any more to the patient than their respective copayment amounts, with the remainder subsidised by the PBS. All prescriptions for which this subsidy was paid are recorded on the PBS database. The PBS currently subsidises the cost of approximately 80% of prescription medications dispensed in Australia (DoHA 2006c).

The PBS data for this study were obtained from the data custodians at the Pharmaceutical Pricing and Estimates Section of the Department of Health and Ageing. These data were in the form of one data record per subsidised PBS item. Fields included:

- anonymous unique PIN
- demographic variables (5-year age group, sex, postcode)
- date the prescription was supplied
- beneficiary category (general, concessional or Repatriation Pharmaceutical Benefits Scheme (RPBS), and safety net status)

- PBS item number (uniquely identifies a medication at a particular strength)
- number of prescriptions supplied on the occasion.¹

The PBS data do not contain any information on the condition for which the drug was prescribed. The medications that are used for asthma are also used for the treatment of some other medical conditions, in particular, chronic obstructive pulmonary disease (COPD). However, COPD mostly occurs in older individuals and for this reason secondary analyses were conducted among people in the age group 5 to 34 years, in whom the medications were most likely to have been prescribed for asthma.

Inclusions and exclusions

The data set for this study included all prescriptions in Australia for medications that were subsidised by the PBS in the selected classes between July 2002 and June 2004 inclusive. This comprised 19,177,841 records from 2,597,951 separate individuals. Appendix 1 shows the PBS item codes included, the medication names and their classifications.

As oral corticosteroids are also used to treat many non-respiratory conditions, 281,204 individuals who were only dispensed oral corticosteroids and no other asthma medications were excluded, leaving 17,834,976 records after exclusion of those PINs. This was to increase the likelihood that the oral corticosteroid prescriptions in the data set were used for obstructive airways disease (asthma and COPD). However, it remains possible that some people with asthma and COPD may have used oral corticosteroids for other, unrelated illnesses.

Of the remaining records, 174,202 (0.98%) had PINs that were 'dummy' PINs. Data entry staff used these when the patient's Medicare number was not available with the prescription details to link records of the same individual. These were removed, leaving 17,660,774 records and 2,277,294 'real' PINs.

In analyses that were based on PINs and their associated demographic information, two further exclusions were applied:

1. In each medication class, individuals whose first date of supply was after 23 June 2004 (that is, in the last week of the study period) were further excluded. This was to avoid overestimating average medication use from first date of supply to the end of the study, and excluded between 0.5% and 0.7% of PINs from each medication class.
2. Where a person had filled more than 96 prescriptions for an item in a single medication class (that is, on average more than four prescriptions per month), that person's records for the item were excluded from the analyses of that medication class. This was to leave out observations in which it appeared likely that there were clerical errors in the generation of the PIN, and also excluded only a small proportion of subjects (0% to 0.4%) from the analysis.

Appendix 2 gives details of the data processing steps and exclusions.

1. This was greater than 1 in only 0.2% of records, where, under the provisions of regulation 24 of the National Health (Pharmaceutical Benefits) Regulations 1960, a medical practitioner may authorise all the repeats to be dispensed at one time (Medicare Australia 2006).

The impact of concessions on the data analysis

The PBS copayment differs between patients who are general (non-concessional) beneficiaries and those who are concession card holders. As the database only includes records for prescriptions that were subsidised by the PBS, prescriptions for items that were not subsidised because they cost less than the copayment are not included in the database. However, as the copayment for concession card holders is much lower, a wider range of medications are subsidised by the PBS (and hence included in the PBS database) for patients who are concession card holders.

Virtually all inhaled corticosteroid preparations, all long-acting beta agonist preparations and all combined long-acting beta agonist and inhaled corticosteroid preparations are dispensed at a price that is higher than all PBS copayment. Hence the PBS database contains a complete record of prescriptions in Australia for these medication classes, and the entire data set has been included in analyses that involve only these classes of medications.

Short-acting beta agonists and oral corticosteroids, however, cost less and are only subsidised by the PBS when the patient is a concession card holder. For this reason, analyses involving these medication classes have been limited to prescriptions dispensed to concessional patients.

Short-acting beta agonists are also available 'over the counter', that is, without a prescription. However, the over-the-counter cost is greater than the copayment for a concession card holder who uses a prescription, which means there is a financial incentive for concession card holders to purchase short-acting beta agonists with a doctor's prescription. Therefore, it is assumed that most short-acting beta agonists dispensed to concessional patients are supplied with a prescription and recorded on the PBS database.

One potential difficulty with this approach is that it is possible for individuals to change concession card holder status over time (for example, people who change from being unemployed to employed). Such individuals would potentially have different medications recorded in the PBS database when they are concession card holders from when they are not. The extent to which people who were dispensed inhaled corticosteroids changed beneficiary status in the study data set was evaluated. Approximately 4% were recorded as both general beneficiaries and concessional beneficiaries during the study period (6% among those aged 5 to 34 years) (Table 1.1). Hence, change between general and concessional beneficiary status by individuals during the study period is likely to have had only a very small effect on the estimates contained in this report.

Table 1.1: Beneficiary status among people who received at least one prescription of inhaled corticosteroids, July 2002 to June 2004

Beneficiary status	All ages	Age 5 to 34 years
Always general	42%	52%
Always concessional	54%	42%
Both	4%	6%

A further issue affecting the inclusion of data in the PBS is that once an individual or family reaches a threshold level of out-of-pocket expenses in a given calendar year, their copayment reduces. This threshold level is referred to as the 'safety net', and both the level of copayment and safety net thresholds has often changed since the PBS was introduced.

Table 1.2 shows the changes in copayments and safety net thresholds for general and concessional beneficiaries during the study period from 2002 to 2004.

General patients who have reached the safety net have the same copayment as concession card holders and, therefore, the same prescriptions are captured on the PBS data set for general patients who have reached the safety net as for concession card holders. However, as these general patients changed copayment threshold during the course of the calendar year, their data were not included in those analyses that were restricted to concession card holders (see Section 2.2).

Table 1.2: PBS copayments and safety net thresholds applicable during the period July 2002 to June 2004

Date of change	Concessional beneficiaries			General beneficiaries		
	Pre-safety net copayment (\$)	Safety net copayment (\$)	Safety net threshold (\$)	Pre-safety net copayment (\$)	Safety net copayment (\$)	Safety net threshold (\$)
1.1.2002	3.60	Nil	187.20	22.40	3.60	686.40
1.1.2003	3.70	Nil	192.40	23.10	3.70	708.40
1.1.2004	3.80	Nil	197.60	23.70	3.80	726.80

Source: DoHA 2004.

1.4 Structure of this report

This chapter introduces the background to the study, the questions posed, the data that were used and the issues taken into account in the analyses. The subsequent chapters will address each of the four main study questions described in the study aims (Section 1.2).

In Chapter 2, asthma medication use in different demographic groups in the population is evaluated and compared. In Chapter 3, the average daily use of each of the main medication classes dispensed to individuals is estimated. In Chapter 4, the potency of inhaled corticosteroids dispensed to individuals is evaluated. Also, the relationship of inhaled corticosteroid potency to people's demographic characteristics is examined. The last study question is addressed in Chapter 5, where the relationships between asthma medication classes is examined through the comparison of each individual's use of inhaled corticosteroids with their use of the other medication classes. The concluding chapter of this report summarises the main findings across all chapters and considers the limitations as well as the future possibilities for studies using these data.