Australian Government
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Respiratory medication use in Australia 2003–2013

Treatment of asthma and COPD

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Authoritative information and statistics to promote better health and wellbeing

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Contents

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Abbreviations

ABS	Australian Bureau of Statistics
ACAM	Australian Centre for Airways disease Monitoring (formerly Australian Centre for Asthma Monitoring)
AIHW	Australian Institute of Health and Welfare
ASGC	Australian Standard Geographic Classification
COPD	Chronic obstructive pulmonary disease
COPD-X	This is the name for Australian clinical practice guidelines for COPD. The name is an acronym for the key components of COPD management.
DUSC	Drug Utilisation Sub-Committee
DHS	Department of Human Services
ICS	Inhaled corticosteroids
IgE	Immunoglobulin E
LABA	Long-acting beta$_2$-agonists
LAMA	Long-acting muscarinic antagonists
LSAC	Longitudinal Study of Australian Children
LTRA	Leukotriene receptor antagonists
OCS	Oral corticosteroids
pMDI	Pressurised metered dose inhaler
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
SABA	Short-acting beta$_2$-agonists
SAMA	Short-acting muscarinic antagonists
SEIFA	Socioeconomic Index for Areas
SES	Socioeconomic status

Summary

This report focuses on medications dispensed for asthma (a chronic airways disease affecting children and adults) and chronic obstructive pulmonary disease (COPD, which primarily affects older adults who have been smokers). In 2013, one or more respiratory medications were dispensed to 2,042,104 people in Australia (9.1% of the population).

Inhaled corticosteroids (ICS) are highly effective in reducing symptoms and flare-ups of asthma. They are also used to reduce the frequency of disease flare-ups in people with COPD. ICS represent the most common class of respiratory medication dispensed on prescription in Australia with 6.3% of the population dispensed the drug in 2013. In that year, ICS were dispensed to slightly more females (6.9%) than males (5.7%), and to more people residing in areas of higher socioeconomic status. Dispensing of ICS was also higher among people living in major cities and regional centres compared to those in remote localities. Compared to younger Australians, people aged 65 and over were dispensed more ICS prescriptions in a year and more potent ICS formulations.

Australian guidelines for the management of asthma and COPD recommend that ICS be taken regularly rather than intermittently. However we observed that among people aged 65 and over who received any ICS in 2013, only 30% had dispensing frequencies consistent with regular use; the rate was even lower for those aged 35–64 (15.8%) and for those aged 15–34 (7.3%). Of adults (aged 15 and over) dispensed ICS in 2013, 36% received only one prescription and among these, 59% were dispensed no other respiratory medications during that year, suggesting that they did not have obstructive airways disease.

Oral corticosteroids (OCS) are recommended for treatment of flare-ups of asthma and COPD. Among those who were dispensed any respiratory medications in 2013 (and could therefore be assumed to be at risk of flare-ups of asthma and/or COPD) only 1.6% were dispensed OCS in the same year.

Long-acting bronchodilators, given as a single medication inhaler, are indicated for treatment of patients with mild to moderate COPD—who comprise the majority of people with COPD. However, in 2013, only 0.4% of Australians aged 65 and over were dispensed a long-acting bronchodilator as a single-medication inhaler. This is lower than expected in this age group.

Anti-IgE monoclonal antibody therapy (omalizumab) is the first biological medication approved for asthma management in Australia, and dispensing of this drug has steadily increased since it was listed on the Pharmaceutical Benefits Scheme (PBS) in mid-2011. The use of this medication is still quite rare in Australia, with just 298 people (0.001% of the population) being dispensed this drug in 2013.

The data analysed in this report provide evidence of substantial over- and under-use of certain classes of medications for management of asthma and COPD. These findings are important, both in terms of the missed opportunities for improved disease control, and resulting additional costs and risk of adverse effects. Further exploration of the implications of these findings will require analysis of PBS data linked to other data sources such as hospitalisation and death records, which provide more information about the patients and their medical conditions. Our findings indicate the potential both for better health outcomes and for cost savings to patients and governments by better targeting of treatment for asthma and COPD.

1 Introduction

Obstructive airways disease is a major cause of disease burden in Australia (ACAM 2011). It encompasses several conditions affecting the airways, the most significant being asthma and chronic obstructive pulmonary disease (COPD). These are long-term conditions that are rarely permanently 'cured'. However treatments exist that can control symptoms and improve the quality of life of people with these diseases. Further description of these conditions is in Box 1.1.

Box 1.1: What is obstructive airways disease?

Obstructive airways disease encompasses asthma and chronic obstructive pulmonary disease (COPD) as well as other, poorly defined, but related, conditions.

Asthma is a common chronic inflammatory condition of the airways which can be controlled, but not cured. People with asthma experience episodes of wheezing, shortness of breath, cough and chest tightness due to widespread narrowing of the airways. The symptoms of asthma vary over time and may be present or absent at any point in time (NACA 2015). Asthma affects people of all ages and has a substantial impact on the community.

COPD is a serious long-term lung disease that mainly affects older people, but also those who are still of working age. It is characterised by airflow limitation that is not fully reversible with bronchodilator medications. Some people with COPD also have frequent cough with sputum due to excessive mucus production in the airways. This condition is often referred to as 'chronic bronchitis'. People with COPD may also have evidence of destruction of lung tissue with consequent enlargement of the air sacs and further impairment of lung function. This condition is known as 'emphysema' (Thurlbeck 1990). In everyday language, the terms COPD, emphysema and chronic bronchitis tend to be used interchangeably. The main cause of COPD is smoking.

Exacerbations (flare-ups or attacks) of asthma and COPD are characterised by a worsening of the patient's symptoms that is beyond their normal day-to-day variation, and that requires a change in treatment.

Rationale for this report

Medication is the mainstay of the management of patients with obstructive airways disease. The overall goals of the use of medications to treat obstructive airways disease are to:

1. Minimise symptoms, such as breathlessness
2. Minimise the risk of adverse outcomes due to the disease or its treatment.

Appropriate use of medications for asthma (Adams et al. 2003, 2004, 2005) and COPD (Calverley et al. 2007; Tashkin et al. 2008) improves disease outcomes. Therefore, disparities in the use of medication are almost certainly relevant to disparities in the outcomes of asthma and COPD, and to the cost of managing obstructive airways disease in Australia. Monitoring medication use enables identification of possible over-use and under-use of medications, both in the population as a whole, and among sub-groups within the population. Trends over time are useful in identifying concordance of treatment with evidence-based guidelines (Abramson et al. 2014; NACA 2015). Investigating the pattern of use of medications for obstructive airways disease and how these vary by age, sex, socioeconomic status and remoteness of residence can assist in identifying population

sub-groups that may be at risk from poor quality treatment or practice, and in planning policy responses where there are areas of concern (ACAM 2007).

This report describes patterns of dispensing of respiratory medications in Australia to draw inferences about respiratory medication usage among patients with asthma and COPD.

Classes of medications

Classes of medication that are indicated for management of obstructive airways disease include:

- **Short-acting bronchodilators**
  - Short-acting beta$_2$-agonists (SABA)
  - Short-acting muscarinic antagonists, (SAMA) (also known as short-acting anticholinergics)
- **Corticosteroids**
  - Inhaled corticosteroids (ICS)
  - Oral corticosteroids (OCS)
- **Long-acting bronchodilators**
  - Long-acting beta$_2$-agonists (LABA)
  - Long-acting muscarinic antagonists (LAMA) (approved only for COPD at the present time)
- **Anti-immunoglobulin E (Anti IgE) monoclonal antibody therapy** (a new medication indicated only for severe allergic asthma)
- **Leukotriene receptor antagonists (LTRA)** (indicated only for asthma).

Other medications that may be indicated for management of obstructive airways disease, but that are only infrequently prescribed due to relative lack of efficacy, include:

- Cromones (indicated only for asthma)
- Xanthines (theophylline)
- Mucolytics.

In Australian asthma guidelines, respiratory medications are classified as 'relievers' (SABA, SAMA), 'preventers' (ICS, ICS/LABA, LTRA, cromones) and 'other medications'.

The next sections describe how the available respiratory medications work, and also when and how these medications can be used to manage chronic respiratory conditions as well as the evidence to support their use.

Short-acting bronchodilators

Short-acting beta$_2$-agonists (SABA)

Inhaled short-acting beta$_2$-agonists (SABA) are the most common class of drugs used in the management of obstructive airways diseases. They act to open (dilate) the airways by relaxing the muscle within the airways and they also have some other actions. They are used to:

- relieve breathlessness and wheeze due to airway narrowing

- prevent exercise-induced airway narrowing in people with asthma.

The most commonly recognised SABA is Ventolin©. The onset of action of SABA is rapid, and the duration of therapeutic effect is approximately 4 hours. As SABA inhalers are generally used in response to the onset of symptoms of breathlessness or wheezing, this class of drugs is often referred to as 'relievers'. In people with asthma, when the disease is well controlled, SABA should not be required more than twice per week. Frequent use of SABA (especially daily or more often) is a sign of poor asthma control (NACA 2015). There is evidence that excessive use of SABA (for example, more than 10 doses per day) is associated with an increased risk of exacerbations and an increased risk of death due to asthma (Taylor 2009). However, it is not clear whether this is a direct effect of frequent use of SABA. An alternative explanation is that frequent use of SABA is a feature of poor asthma control, which is associated with an increased risk of exacerbations and death. The use of SABA is also recommended in management of exacerbations of asthma.

In people with COPD, SABA inhalers have often been prescribed 'regularly', rather than 'as needed' to ease symptoms. However recent studies have shown that this did not improve overall function (Abramson et al. 2014) and these medications are now usually prescribed for relief of breathlessness, rather than for regular use. The use of SABA is also recommended to reduce breathlessness in the management of exacerbations of COPD.

Short-acting muscarinic antagonists (SAMA)

Short-acting muscarinic antagonists (SAMA) (also known as anti-cholinergic bronchodilators) are another type of bronchodilator which have a slower onset but longer duration of effect than SABA. Their peak effect is not reached for 1.5–2 hours and the duration of action is approximately 6 hours. This type of medication is not normally used for immediate relief of symptoms.

In the management of asthma, SAMA may be used to manage symptoms during exacerbations, but are not recommended for maintenance therapy. In people with COPD, SAMA may be used for relief of symptoms in COPD instead of, or as well as, a SABA (Lung Foundation Australia 2014) and have been associated with greater improvements in quality of life than SABA. However, the COPD-X guidelines also cite a number of recent studies and a meta-analysis that found adverse outcomes with SAMA, including cardiovascular events and mortality (Abramson et al. 2014).

Corticosteroids

This class of drugs, which includes inhaled corticosteroids (ICS) and systemic (oral or injectable) corticosteroids, acts to suppress inflammation.

Inhaled corticosteroids (ICS)

In people with asthma, ICS-containing medications are used as long-term maintenance treatment. They are highly effective in reducing symptoms and preventing exacerbations (Adams et al. 2003, 2004, 2005) and have been shown to reduce the risk of asthma-related death (Suissa et al. 2000).

Analyses of data from clinical trials have demonstrated that, in most people, asthma is well controlled with low doses of ICS, resulting in a minimal risk of adverse effects (Powell & Gibson 2003). The addition of LABA to ICS, available in combined formulations, allows equivalent or greater effectiveness for asthma control and exacerbations, with lower doses of

ICS (Kuna et al. 2007; Greening et al. 1994). There is no role for LABA without concurrent ICS in the management of people with asthma (NACA 2015).

In the management of most patients with asthma, ICS are recommended for use initially at low doses, alone, or if a step-up is needed, with LABA (NACA 2015). ICS are best used regularly, either twice or once daily (see also 'Management guidelines for asthma' section later in this Chapter).

In people with COPD who have frequent exacerbations and low lung function, ICS have been shown to reduce the likelihood and intensity of exacerbations and reduce decline in quality of life (Yang et al. 2012). For COPD, higher doses of ICS are recommended than for asthma, and the ICS should always be administered together with a LABA or LAMA (Abramson et al. 2014). However, with long-term use, ICS have been associated with adverse effects, including voice hoarseness and oral candidiasis. ICS have also been implicated in increased risk of pneumonia among people with COPD, particularly with some medications in this class. ICS are not recommended for use in patients with COPD who do not have frequent exacerbations and low lung function.

Oral corticosteroids (OCS)

Systemic (including oral) corticosteroids are used for short-term treatment of exacerbations of asthma and COPD, to reduce the duration and severity of the episodes. As long-term use of systemic corticosteroids is associated with a high risk of adverse outcome, this is not generally recommended. However, on rare occasions, people with very severe asthma that cannot be controlled with maximum conventional inhaled therapy need long-term treatment with OCS to control their disease.

Long-acting bronchodilators

Long-acting beta$_2$-agonists (LABA)

In the management of asthma, inhaled long-acting beta$_2$-agonists (LABA) are used in combination with ICS to improve asthma control, where this is not achieved with ICS alone. The mechanism of action for LABA is similar to SABA, but the duration of effect is greater (approximately 12 to 24 hours of bronchodilation). Inhalation devices combining LABA and ICS were introduced in Australia in 2000. In subsequent years, the proportion of all ICS that were supplied in combination with LABA steadily increased. By 2009, 80% of ICS dispensed were in combination with LABA (ACAM 2011).

In the management of asthma, there are strong recommendations against use of LABA alone, as this has been associated with adverse outcomes (NACA 2015; Weatherall et al. 2010). Several combination ICS/LABA inhalers are available. Combination budesonide/eformoterol (ICS/LABA) is indicated in Australia for use either as a regular maintenance preventer inhaler, or, in low doses, as both a regular maintenance preventer and a reliever taken in response to asthma symptoms. This latter approach may be referred to as maintenance and reliever therapy, and is based on evidence of fewer exacerbations and similar or better symptom control with lower average ICS doses than with conventional maintenance treatment with SABA as a reliever (Bateman et al. 2010). Other ICS/LABA combination preparations are not approved for use in this regimen.

In contrast with the situation for asthma, use of LABA without concomitant ICS is encouraged in the management of patients with mild to moderate COPD to improve lung function, symptoms and quality of life, and to reduce the frequency of exacerbations. An

ultra-long-acting beta$_2$-agonist (indacaterol) has recently been introduced for use in COPD. In the long-term management of COPD, LABA may be used alone or together with other medications (ICS and/or LAMA).

Long-acting muscarinic antagonists (LAMA)

Long-acting muscarinic antagonists (LAMA) are not currently approved in Australia for use in the management of asthma.

In the management of COPD, LAMA may be used alone or together with (or in combination with) other medications. LAMA inhalers have been shown to improve lung function and reduce exacerbations in COPD and may avert the need for adding high dose ICS. LAMA and SAMA should not be used together (Abramson et al. 2014). Combination LABA/LAMA inhalers were recently approved for the management of COPD in Australia, but were not available under subsidy on the Pharmaceutical Benefits Scheme (PBS) during the period of data collection for this report.

Anti-immunoglobulin E therapy

Anti-immunoglobulin E therapy is a relatively new class of medication for the management of asthma and, within this class, omalizumab (trade-name Xolair) is the first biological agent approved for managing patients with asthma in Australia. It is a synthetic monoclonal antibody directed against circulating immunoglobulin E (IgE), which is a key molecule involved in the allergic response. It was listed on the PBS under the Highly Specialised Drugs Program in July 2011. This medication is approved for use in people with moderate to severe allergic asthma that cannot be adequately controlled with optimal doses of ICS/LABA (NACA 2015). Other biological drugs are in various stages of development and are likely to be available for use in patients with asthma in the future. Until recently, there has been no systematic reporting on the use of this therapy for asthma. However, the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee has recently published a report on usage of this drug during the first 24 months after its listing (DUSC 2014).

Leukotriene receptor antagonists (LTRA)

Leukotriene receptor antagonists (LTRA) are approved in Australia for use in the management of asthma in children aged 2–14 years. They are provided as tablets, and may be used as an alternative or adjunct to ICS, in children. They are often preferred by clinicians and by parents as they do not contain corticosteroids nor require the child to be able to use an inhaler, and adherence with a once-daily tablet could potentially be better than with a twice-daily inhaler. LTRA are recommended in the Australian asthma guidelines as a first-line preventer in the management of asthma in children aged 2–14 years (NACA 2015), although their efficacy in children with persistent asthma is less than that of low-dose ICS. They are also subsidised by the PBS for regular use by children who have frequent exercise-related symptoms despite taking regular ICS. Guidelines state that LTRA may also be used before exercise, although intermittent use is not covered by PBS subsidy.

Other medications

Cromones have been used in the management of asthma for several decades. However, they are now rarely prescribed because of their relatively low efficacy. There are also practical

difficulties in their administration, with the need for multiple doses per day and daily inhaler cleaning.

Low-dose theophylline is sometimes prescribed for patients with obstructive airway disease that cannot be adequately controlled with other drugs. However, use of this drug at conventional doses is not recommended for most patients as it may have adverse effects, and it interacts with several other commonly prescribed medications.

Antibiotics may be prescribed to treat bacterial infection in patients with acute exacerbations of COPD (Celli & Barnes 2007). However, bacterial infections are rarely the underlying cause of asthma exacerbations, so antibiotics are rarely needed in the management of asthma (AIHW ACAM 2012).

Mucolytics are sometimes used to loosen and clear mucus from the airways. They are available over the counter (in tablet and liquid formulations), hence are not captured in PBS data and have not been covered in this report.

Management guidelines for asthma

Guidelines for the management of asthma are available in the Australian Asthma Handbook (AAH), Version 1.1, which is an online resource and available at <www.asthmahandbook.org> (NACA 2015). These guidelines supersede six editions of the Asthma Management Handbook (1989–2006). The AAH provides evidence-based approaches for primary health care professionals in the diagnosis and management of asthma, sets out preferred choices among the medications described above, and recommends ways of prescribing them for optimal benefit.

Clinical practice guidelines for asthma are based on the concept of adjusting patient treatment according to the patient's level of asthma control. The AAH provides a stepped approach to the use of medications for asthma as follows:

1. All patients should have a reliever medication for as-needed use.
2. Most adult patients and some children should also have regular low-dose ICS. For children, an LTRA may be used as an alternative.
3. Some adult patients should have regular inhaled combined low-dose ICS and LABA. For children, the recommended treatment when asthma is not well-controlled with low-dose ICS is either a higher dose ICS, or low-dose ICS plus either LTRA or LABA.
4. A few adult patients may need regular inhaled combined moderate- or high-dose ICS with LABA.
5. Referral for specialist advice is recommended if asthma cannot be well-controlled with the above steps.

For each step, clinicians are cautioned to check inhaler technique and medication adherence, and to confirm that the symptoms are due to asthma, before going up to a higher treatment step. In cases of severe, treatment-refractory allergic asthma, anti-immunoglobulin E therapy may be prescribed after specialist referral (NACA 2015).

In addition to the above treatment, all patients should have a written asthma action plan to deal with worsening asthma and flare-ups (exacerbations). Additional medication classes that may be used short-term to manage acute exacerbations of asthma include oral and other systemic corticosteroids and SAMA (NACA 2015).

Management guidelines for COPD

Australian guidelines for the management of COPD by the Lung Foundation Australia are called COPD-X (Abramson et al. 2014). COPD-X represents an acronym for the key goals of COPD management:

- **C**onfirm diagnosis
- **O**ptimise function
- **P**revent deterioration
- **D**evelop support
- Manage e**X**acerbations.

Medications should be administered in combination with non-medication approaches to achieve the goals listed above in the effective care of people with COPD. Non-respiratory medication strategies include smoking cessation, pulmonary rehabilitation, self-management support, influenza and pneumococcal immunisation, osteoporosis prevention and management, and surgical intervention and/or oxygen therapy (if appropriate).

Confirm diagnosis

A diagnosis of COPD should be considered in patients over the age of 35 years:

- with symptoms such as breathlessness, cough and/or sputum production
- who are smokers/ex-smokers.

The first step in COPD diagnosis is a thorough history and examination. Smoking history, current smoking status, work history including occupational exposure, and respiratory symptoms (including in childhood) should be documented.

The diagnosis is confirmed by the presence of persistent airflow limitation when the patient is stable. Further investigations should be performed to assess the presence/absence of other conditions with similar presentation to COPD, such as asthma, and to assess the severity of COPD.

COPD severity should be assessed at least annually to guide ongoing management. This involves measurement of spirometry, assessment of symptoms and signs of COPD complications such as heart failure, and a review of flare-ups.

Specific guidelines on the use of respiratory medications to achieve the treatment goals of COPD management are as follows:

Optimise function

- Short-acting inhaled bronchodilators (SABA, SAMA) for short-term relief of symptoms.
- Long-acting inhaled bronchodilators (LABA, LAMA) for patients with persistent symptoms such as dyspnoea.
- High-dose ICS in combination with LABA in people with moderate to severe COPD and frequent exacerbations.
- Low-dose theophylline may also be considered for severe COPD.

Prevent deterioration

- Mucolytics may reduce the frequency and duration of exacerbations.

Manage exacerbations

- Inhaled bronchodilators (SABA, LABA and muscarinic antagonists) to relieve and prevent symptoms, and shorten the duration of exacerbations.
- Short-term use of systemic (including oral) corticosteroids to reduce the severity of acute exacerbations and shorten recovery.
- Antibiotics where there is clinical evidence of infection.

A notable issue among people with COPD is that because most are aged 55 years and over, they are at increased risk of having multiple medical conditions, such as co-morbid cardiovascular disease and diabetes. Medications used in the management of COPD have the potential to affect the outcomes of other conditions and interact with the medications that are being co-administered for different diseases in the one individual.

Context of this report

This report follows up and extends previous work by the Australian Centre for Airways disease Monitoring (ACAM) investigating the use of medications for obstructive airways disease in Australia. In this report we have analysed Pharmaceutical Benefits Scheme (PBS) data that include individual dispensing histories (for medications subsidised under the PBS) and basic demographic information, as well as data from the Longitudinal Study of Australian Children (LSAC) and NSW Health Survey (NSWHS).

In 2007, ACAM released its first analysis of PBS data in the report *Patterns of asthma medication use in Australia* (ACAM 2007). This report used PBS records of medications commonly used to treat asthma that were dispensed during the period July 2002 to June 2004. A key finding was that there was evidence of excessive intermittent use of ICS (alone or in combination with LABA) that was inconsistent with appropriate regular use of these medications. The report also found that people living in remote areas used fewer asthma medications, and suggested that this may be related to their having less access to medical care than those living in cities. The report also suggested there was evidence that cost may be a barrier to the regular use of ICS among non-concession card holders.

In 2011, ACAM included a section that reported on PBS data in its signature report *Asthma in Australia.* These analyses updated the previous period of analyses to the end of 2009 and, in the context of a focus chapter on COPD, expanded the medications to include LAMA prescriptions (ACAM 2011). The report highlighted the finding that the majority of prescriptions for ICS dispensed in Australia were for combination ICS/LABA, at moderate or high potency. Analysis of SABA data suggested that many patients were using these medications more often than would be consistent with the criteria in treatment guidelines describing well-controlled asthma.

In 2012, ACAM released a second report based on PBS data that provided information focusing on the use of antibiotics and ICS among people who took respiratory medications (AIHW ACAM 2012). This report found that a large proportion of people who were dispensed only one ICS prescription in a one-year period, and no other respiratory medications, were co-dispensed antibiotics. The high rate of co-dispensing with antibiotics suggests that ICS are often inappropriately prescribed for the treatment of symptoms of short-term conditions such as respiratory infections. Furthermore, consistent with the 2007 report, supply patterns for ICS were often not consistent with treatment guidelines for the management of asthma and COPD.

Questions considered in this report

This report considers the following questions:

- What are the trends, over time, in dispensing of medications for obstructive airways disease?
- Do dispensing patterns of medications for obstructive airways disease differ by socio-demographic characteristics of the patient?
- Is there evidence of inappropriate or irregular dispensing of preventer medications for obstructive airways disease?
- Are dispensing patterns consistent with the guidelines for the management of obstructive airways disease?
- What has been the uptake of new medications for asthma?

In endeavouring to answer these questions we conducted detailed analyses of data collected through the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS), comprising records for respiratory medications dispensed during the period 1 July 2002—31 December 2013. We also used data from the Longitudinal Study of Australian Children (LSAC) and the NSW Health Survey.

This report provides a valuable update and new information about the use of medicines for asthma and COPD, thus improving our knowledge and understanding about how these diseases are managed in Australia. The timing of this work is opportune in that it will also provide a baseline for monitoring the future impact of the recently-introduced Australian Asthma Handbook (NACA 2015) and assist in identifying factors associated with inappropriate disease management that can be used to guide future policies in this area.

2 Data and methods

The University of Sydney Human Research Ethics Committee Low Risk Subcommittee approved this project (study number: 2013/1011) in December 2013.

Data sources

This report includes findings based on analyses of data from the Pharmaceutical Benefits Scheme, the NSW Health Survey and the Longitudinal Study of Australian Children. Figure 2.1 compares the levels of detail about medications and patient characteristics that are available in these data sources.

The most extensive analyses have been carried out with the PBS data (described below). This dataset provides detailed information about all prescription medications that are dispensed in Australia and are eligible for subsidy under the Pharmaceutical Benefits Scheme. However it is only possible to derive basic demographic information about patients from PBS data. The dataset contains no clinical information on diagnoses and no information about how or when medications are used by patients. To cover these limitations, the two additional data sources have been used in this report.

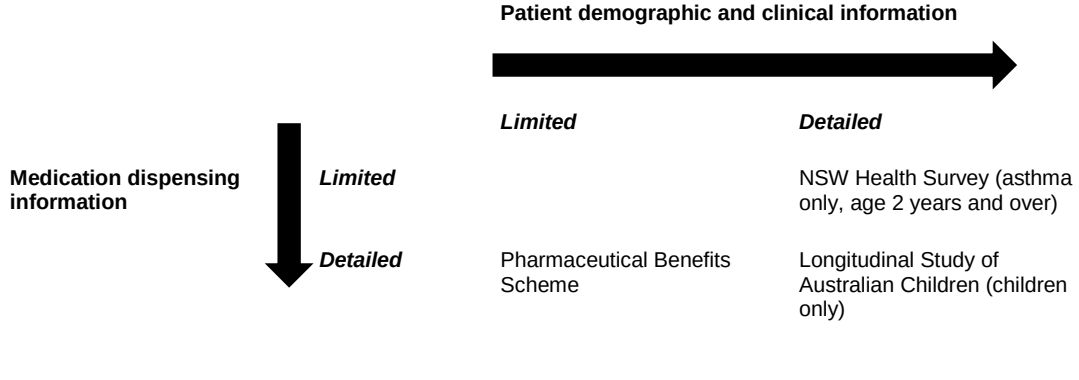


Figure 2.1: Comparison of data sources used in this report

Pharmaceutical Benefits Scheme data

The main data source for this report is the Pharmaceutical Benefits Scheme (PBS) Database (including Repatriation Pharmaceutical Benefits Scheme [RPBS]). The Australian Pharmaceutical Benefits Scheme (PBS) provides subsidies for medications that are approved under the scheme. Most prescription medications dispensed in Australia are approved under the PBS. Medications dispensed are recorded on the PBS and the Repatriation Pharmaceutical Benefits Scheme (RPBS) databases. These databases are primarily designed to facilitate the administration of the programs. However they are also a valuable source of information for understanding the epidemiological pattern of medication use in Australia. Increasingly, barcoded data from prescriptions are scanned in the pharmacy for automatic transfer to the PBS database, avoiding the possibility of transcription errors within the pharmacy.

Limitations of the PBS and RPBS datasets

There are several important limitations inherent in the PBS and RPBS datasets:

- Data do not provide information on prescriptions written by a health professional that are not filled by the patient.
- Data indicate prescriptions that have been filled by the patient, but not whether or how often the medication was actually used.
- Medications that are purchased over-the-counter (for example, salbutamol [Ventolin] and mucolytics) are not captured in these data.
- Medications that are obtained through remote Aboriginal Health Service organisations are not captured in these data. For this reason, our report does not draw any inferences about the management of obstructive lung disease among Indigenous Australians.
- There is no clinical information about the reason for the prescription or the nature or severity of the condition for which the medication was prescribed.
- Until April 2012, data were only included in the PBS and RPBS if a subsidy was paid (see next section in this chapter, 'Effects of copayments and subsidies on the data').
- The PBS/RPBS subsidies include a safety net, which, once reached in a calendar year, substantially reduces the copayment amount for the individual (discussed further in the next section, 'Effects of copayments and subsidies on the data').

Effects of copayments and subsidies on the data

For all dispensed medications that are covered by the scheme, the PBS pays the cost that is in excess of the defined copayment amount. The copayment amount refers to the amount the consumer pays. The copayment amount is set by government policy and differs substantially between general patients and those who hold government health-care concession cards. For general patients, the copayment amount ranged from $22.40 in 2002 to $36.10 in 2013, whereas for concession card holders, the copayment amount ranged from $3.60 in 2002 to $5.90 in 2013. Once a threshold value of out-of-pocket expenses has been accrued by a patient or family in a calendar year (Safety Net Threshold) the copayment amount decreases for the remainder of the calendar year. This threshold corresponds to 60 prescriptions for a concession patient, and 38 or more prescriptions for a general patient.

The Repatriation Pharmaceutical Benefits Scheme (RPBS) is subsidised by the Department of Veterans' Affairs (DVA), and can be used by veterans who have white, gold or orange DVA cards. These cards provide eligibility for all PBS medicines, as well as other medicines listed on the RPBS, depending on the DVA entitlement. All medicines supplied under the RPBS are dispensed at the concessional rate (or free if the patient has reached their Safety Net Threshold).

Until April 2012, an important limitation of these data was that the database only included records for prescriptions for which the PBS or RPBS actually paid a subsidy. In other words, it only recorded information about medications for which the dispensed price was greater than the relevant copayment amount. As the co-payment amount for concession card holder beneficiaries has always been far lower than for general beneficiaries, the dataset prior to April 2012 was considered complete only for concession card holders. For this reason, in ACAM's previous reports several analyses have been limited to concession card holders and in this report, time series analyses are limited to concession card holders.

As of April 2012, information on below-copayment dispensed medications is also recorded (as this information contributes to defining when a person has passed the safety net threshold). Hence, since that date, all PBS listed medications dispensed through pharmacies have been captured in these databases irrespective of whether a subsidy was actually paid. This presents the opportunity to analyse the patterns of prescriptions, particularly in relation to patient demographic characteristics, for all people, not just concession card holders.

Unique patient identifiers in PBS data

The PBS database has included Medicare numbers with all prescription details since 2002. Use of the Medicare number has allowed the anonymous identification of prescriptions for the same individuals within the PBS data and also allowed linkage to information on age, sex and home postcode using an encrypted patient identification number (PIN). In this way, patient anonymity is protected while enabling study of the patterns of medication use by individuals and according to a limited range of socio-demographic characteristics.

Covering for lack of diagnosis information in the PBS database

A major limitation in data from the PBS dataset is the absence of information on the condition or illness for which the medication was prescribed. Therefore, in this report, which is on medications for obstructive airways disease, it was not possible to directly determine the underlying condition associated with the prescriptions dispensed.

As in previous reports, some inferences have been made through analyses of specific age groups. For instance, among people aged 5–34 years, COPD is very uncommon, and in children, non-asthma wheezing illness is generally limited to those under 5 years; therefore, it can be assumed that for people aged 5–34 years, respiratory medications were most likely to have been prescribed for asthma. By contrast, medications dispensed to people aged 65 years and over are likely to include those prescribed for either asthma or COPD.

However, as there is no information about diagnoses in the PBS data, it is not possible to discern whether ICS or LABA were dispensed for COPD or for asthma, and we cannot therefore draw conclusions about the appropriateness of the prescriptions dispensed.

Unlike the PBS, the NSW Health Survey and the LSAC (see descriptions below) include information about respondents' asthma status, as well as frequency of use of specific medications for asthma. As all information about diagnoses and medications were self-reported, this has its own potential limitations, including dependency on the respondent's ability to recall. Nonetheless, we drew on data from these surveys as a means of investigating the connections between clinical profile (that is, current asthma) and respiratory medication use.

We also analysed data from the LSAC that were linked to the PBS. This provided the opportunity to compare information about self-reported medication use among children with wheeze and asthma with dispensing information obtained through the PBS.

The dispensing information available through the PBS is not influenced by recall, but it also only identifies that a medication was dispensed, with no information about how often it was actually used by the patient. We have therefore analysed both PBS and self-reported data in this report, with their complementary advantages and limitations, to provide more clues as to the true patterns of respiratory medication use in Australia.

NSW Health Survey

The NSW Ministry of Health conducts an ongoing health survey designed to be representative of the NSW population. In several, recent years (2009, 2010 and 2012), the NSW Health Survey included questions about the types and frequency of medication used by people with current asthma.

As stated earlier, in contrast to the PBS, NSW Health Survey data include information about the respondent's asthma status as well as frequency of use of specific medications for asthma. All information about diagnoses and medications are self-reported. This potentially introduces some limitations because survey questions may be influenced by the respondent's ability to recall and their ability to interpret the questions as intended. Nonetheless, in contrast to the dispensing information recorded on the PBS, it may have the advantage of being a more accurate indication of whether the medication was actually taken by the respondent.

Longitudinal Study of Australian Children

The third data source is the Longitudinal Study of Australian Children (LSAC) (FaHCSIA et al. 2011). This cohort study collects detailed health and demographic information from participants. Further, it uses linkage to the PBS to accurately attribute information about dispensing of prescription medications. Therefore, it includes comprehensive information about participant characteristics and medication dispensing. This information, however, is restricted to children aged up to 15 years who are participating in the study.

Population denominators

As indicated above, trend analyses from 2002 until 2013 presented in this report used the estimated number of concession card holders as a denominator population. The total number of concession card holders per year in Australia for the period 2003 to 2013 was estimated using quarterly data from the Australian Department of Human Services (from the December quarter) on the number of concession card holders aged 15 years and over.

For this report, socio-demographic analyses were carried out using prescription records for medications dispensed between 1 January 2013 and 31 December 2013. During this period, all PBS-listed medications dispensed were included in the PBS database, irrespective of whether a PBS co-payment was made. Therefore the source of the denominator population of interest for 2013 was the estimated resident population of Australia in 2011, obtained from the ABS, since this was the closest Census year to 2013 and estimated resident populations are available at a finer level in Census years.

Methods of data analyses

Medication categories used in this report

Medications for respiratory disease were grouped into medication classes, reflecting pharmacological properties, as shown in *Appendix 2: PBS data* .

In this report, the medication classes analysed in detail were:

- any ICS (alone or in combination);

- ICS in combination with LABA (See Table A1.2);
- OCS;
- LABA and LAMA (without ICS); and
- LTRA (Note: LTRA were limited to children aged 0–14 years because only children are approved for a PBS subsidy for this medication class).

The data sources for each of the medication classes are summarised in Table 2.1.

An estimation of the use of these medication classes, as indicated by a record of these drugs being dispensed in the PBS dataset, was calculated for each of the socio-demographic characteristics listed in the next section, 'Defining socio-demographic characteristics'.

Table 2.1: Summary of medication classes and data sources used in this report

	Data source		Notes
Medication class	**PBS**	**Survey**	
Short-acting bronchodilators			
SABA	×	✓	These medications may be prescribed and dispensed under the PBS. However, in Australia, they can also be purchased from pharmacies 'over the counter' without a prescription, and, therefore, with no record of the medication in the PBS dataset, or in any other available national dataset. For this reason we have relied on data from the NSW Health Survey to report SABA use.
SAMA	✓	✓	In this report, we have used information from the PBS as well as the NSW Health Survey to describe overall information about the use of SAMA in Australia and we have further analysed PBS data to describe patterns of SAMA use in more detail.
Corticosteroids			
ICS	✓	✓	In this report, we have used information from the PBS as well as the NSW Health Survey and LSAC to describe overall information about the use of ICS in Australia. We have further analysed PBS data to describe patterns of ICS use in more detail, including potency. Information on self-reported frequency of use was obtained from the NSW Health Survey.
OCS	✓	✓	Main analyses performed using PBS data. As these medications can be used for the treatment of other conditions, such as arthritis, we have limited our analysis to those who were also dispensed other medications used in the treatment of obstructive airways disease.
Long-acting bronchodilators			
LABA	✓	✓	Main analyses performed using PBS data.
LAMA	✓	✓	Main analyses performed using PBS data. Note: Combination LABA/LAMA inhalers were recently approved for the management of COPD in Australia but were not PBS-subsidised during the period of data collection for this report.
Anti-IgE therapy	✓	✓	Main analyses performed using PBS data.
LTRA	✓	✓	Main analyses performed using PBS data. Some analysis of LSAC data and NSWHS data included as well.
Cromones	✓	✓	Very limited analyses (only the proportion of the population dispensed this class of medication) because it is rarely prescribed in Australia.
Xanthines	✓	✓	Very limited analyses (only the proportion of the population dispensed this class of medication) because it is rarely prescribed in Australia.
Mucolytics	×	×	The availability of mucolytics over the counter and without a prescription, means that its use is not recorded in any available national dataset. Also, this medication class is not used very frequently.

Defining socio-demographic characteristics

The PBS data use encrypted Medicare Numbers to link records of the same individual and their socio-demographic information, including age, sex and postcode of residence at the time when the medication was dispensed. Where an individual's demographic characteristics changed during the study period, the characteristics were categorised based on the earliest record for that individual in the study.

Socio-demographic characteristics of patients in the PBS for 2013 were categorised as follows:

- **Age** of the individual at their earliest prescription in 2013—this was categorised into broad age groups: 0–4 years, 5–14 years, 15–34 years, 35–65 years, and 65 years and over. Children comprised those aged 0 to 14 years, and adults were those aged 15 years and over.
- **Level of socioeconomic advantage** was classified using the Socioeconomic Index for Areas (SEIFA) to group postcode at earliest 2013 record for each patient into five quintiles of socioeconomic advantage where 1= most disadvantaged localities and 5 = most advantaged localities (ABS 2013). For the analyses presented here, this report used the Index of Relative Socio-Economic Disadvantage, which is derived from Census data on educational attainment, income, occupation, wealth, living conditions and access to services. It is important to note that for the data presented in this report, socioeconomic status is based on the area of usual residence and, hence, reflects the relative disadvantage of all people living in an area, not necessarily that of an individual.
- **Remoteness** of residence was classified into five categories: *Major cities, Inner regional, Outer regional, Remote* and *Very remote*, using the Australian Statistical Geography Standard (ABS 2011). The ASGS was developed by the ABS as an indicator of remoteness to service centres and allows a quantitative comparison between 'city' and 'country' Australia. We based the remoteness classification on each patient's postcode in their earliest PBS record in 2013. In some cases, we have combined the *Remote* and *Very remote* categories.
- **State or territory** of residence was classified based on the postcode of the earliest record for the patient in 2013.

Generating time trends

The analysis of long-term time trends was based on data covering the period July 2002 to June 2013, and included any respiratory medications, including those that were dispensed at a cost that was less than the general co-payment amount. However, as explained earlier in the section, 'Effects of copayments and subsidies on the data', the PBS dataset prior to April 2012 is considered complete only for concession card holders. Time trends extending before April 2012 are therefore restricted to concession card holders.

Once medications had been combined into their respective classes, we calculated the proportion of concession card holders dispensed each class of medication in each year between July 2002 and June 2013 as a rate per 100,000 (see 'Population denominators', page 13).

These trends were compared to asthma and COPD treatment guidelines to investigate the concordance between clinical guidelines and management practices.

Frequency of ICS dispensing

In Australia, one prescription of maintenance treatment at the typically recommended dose generally provides enough therapy for 1 month. Although a patient taking a medication every day should generally therefore have 12 prescriptions dispensed in a year, we consider that around 7 prescriptions of any one medication in a year would be the minimum number of prescriptions consistent with regular use. Filling of fewer than 7 prescriptions of a medication in a year suggests that either it has not been prescribed for continuous use, or that it has not been obtained regularly by the patient—for example, due to patients not taking the medication as often as prescribed (low patient adherence). Filling of more than 12 prescriptions in a 12-month period could indicate that the medication has been prescribed at a higher dose requiring more than 1 prescription per month to be dispensed, or that the patient has been using it more often than prescribed.

We quantified the annual number of ICS prescriptions dispensed per individual into frequency-of-prescription categories (1, 2–3, 4–6, 7–12 and 13 or more prescriptions). To clarify the circumstances of single prescriptions, we further classified this category as: (1) people who were not dispensed any other respiratory medications in the year (which we have called 'one-off' dispensing) and (2) people who were dispensed other respiratory medications in the same year.

We investigated these patterns over time and by age group.

We similarly quantified the annual number of long-acting beta$_2$-agonist prescriptions (in combination with ICS or alone), dispensed per individual into frequency-of-prescription categories and examined this by age group.

Inhaled corticosteroid potency

Previous reports by ACAM have investigated patterns of ICS use by an assigned level of potency to understand whether dispensing of low-dose (least potent) and high-dose (most potent) corticosteroids corresponds with guidelines for their use. This is particularly important, as low-potency ICS used without LABA are often sufficient for controlling asthma in the majority of patients, and their use reduces the cost of treatment and the likelihood of side-effects, compared with use of higher potency ICS (with or without LABA). However, previous analyses by ACAM have shown that, in Australia, most ICS are dispensed in high-dose formulations, and in combination with LABA (ACAM 2011). Among older people, this may be appropriate as COPD is more likely to be present in older people, and higher dose ICS are generally used to manage COPD compared with asthma.

In this current report, ICS medication–dose combinations (alone and in combination with LABAs) were categorised into three levels of potency (See *Appendix*, Table A3.1). We then categorised the number of prescriptions dispensed per person by broad age groups (0–4, 5–14, 15–34, 35–64, and 65 and over) to estimate the potency of ICS dispensed by age. We also investigated the number of prescriptions dispensed per concession card holder by year between 2003 and 2012 (prior to complete capture of prescription information among all general patients, not just concession card holders).

Please note that there have been some minor changes to the way we have categorised ICS in this report compared to previous reports. In past reports, doses of each type of ICS-containing medication were classified as 'least', 'intermittent' and 'most potent' on the basis of the available formulations, with the lowest marketed dose classified as 'least potent', the next lowest classified as 'intermediate potency', and the highest dose (where relevant) as

'most potency'. However, the potency classification is now based on tables of low, medium and high doses for the different types of ICS. These tables have been developed from pharmacokinetic data and have been published in peer-reviewed journals (Raissy et al. 2013) and in guidelines documents (GINA 2014; NACA 2015; National Heart Lung and Blood Institute 2012).

Consistent with the 2014 Australian asthma guidelines (NACA 2015), and the recommended number of actuations per dose for each formulation, we have classified the potency of ICS (alone or in combination with LABA) into 2 levels for children and 3 levels for adults. The potency levels are shown in Table 2.2 (for children) and Table 2.3 (for adults), as defined in the Australian Asthma Handbook v1.1 2014, available at <http://www.asthmahandbook.org.au/management/adults> and <http://www.asthmahandbook.org.au/management/children>.

This has resulted in 2 drugs moving from classification as medium potency in past reports to low potency in the present report (Pulmicort Turbuhaler 200 mcg and Symbicort Turbuhaler 200/6), and 2 drugs moving from high potency to medium potency (Pulmicort Turbuhaler 400 and Symbicort Turbuhaler 400/12). In addition, new ICS/LABA combinations that have become available in Australia since our last analyses of PBS data have been included in the analyses presented in this report (Symbicort Rapihaler 50/3, Symbicort Rapihaler 100/3, Symbicort Rapihaler 200/6, Flutiform 50/5, Flutiform 125/5, Flutiform 250/10). See also Appendix 3: Inhaled corticosteroid potency classification.

Table 2.2: Classification of ICS dose levels in children

	Total daily dose (mcg)	
Inhaled corticosteroid	**Low**	**High**
Beclomethasone dipropionate[(a)]	100–200	>200
Budesonide	200–400	>400
Ciclesonide[(b)]	80–160	>160
Fluticasone propionate	100–200	>200

(a) Dose equivalents for *Qvar* (CFC-free formulation of beclomethasone dipropionate currently available in Australia).

(b) Ciclesonide is registered for use in children aged 6 and over.

Source: Adapted from a table in the Australian Asthma Handbook (NACA 2015). Available at: <www.thoracic.org.au/professional-information/position-papers-guidelines/asthma/>.

Table 2.3: Classification of ICS dose levels in adults

	Total daily dose (mcg)		
Inhaled corticosteroid	**Low**	**Medium**	**High**
Beclomethasone dipropionate[(a)]	100–200	250–400	>400
Budesonide	200–400	500–800	>800
Ciclesonide	80–160	240–320	>320
Fluticasone propionate	100–200	250–500	>500

(a) Dose equivalents for *Qvar* (CFC-free formulation of beclomethasone dipropionate currently available in Australia).

Note: The potency of generic formulations may differ from that of original formulations. Check TGA-approved product information for details.

Source: Australian Asthma Handbook (NACA 2015). Available at: <www.asthmahandbook.org.au/management/adults/initial-treatment/preventers/ics-based-preventers>.

Dispensing of oral corticosteroids (OCS)

During exacerbations of asthma or COPD, oral corticosteroids (OCS) are often used for short-term treatment. A difficulty in examining the use of OCS for obstructive airways disease is that OCS may be used for many other conditions, for example rheumatoid arthritis. We therefore restricted PBS data for our analysis of OCS to people who had also been dispensed any other respiratory medications. However, it is still likely that some people in this restricted population used OCS for reasons other than exacerbations of asthma or COPD, hence our estimates of the use of OCS for exacerbations of asthma or COPD may be over-estimates.

Using PBS data, among people who had been dispensed any respiratory medications, we quantified the number of people who had been dispensed OCS in the most recent year of available data (2013). We also calculated this as a proportion of the Australian population, and separately for children aged 0–14 years and adults aged 15 years and over.

Since, in current standard practice, OCS are not generally prescribed for maintenance treatment in asthma or COPD, we grouped the annual number of OCS prescriptions dispensed per person in 2013 into number-of-prescription categories (1, 2, 3, and 4 or more prescriptions).

Dispensing of long-acting bronchodilators (LABA and LAMA) without ICS

Asthma guidelines recommend strongly against the use of long-acting $beta_2$ agonists (LABA) alone (without ICS). However, COPD guidelines recommend LABA in a separate inhaler as one of the options for treatment in mild or moderate COPD.

Further, long-acting muscarinic antagonists (LAMA) are not recommended in the management of asthma in Australia, but may be used in the management of COPD.

Using records from the PBS, we quantified the annual frequency of use of LABA and LAMA medications when used without inhaled corticosteroids, for insights into whether dispensing patterns were consistent with Australian guidelines—although we cannot tell from the data which of the two conditions—asthma or COPD—these medications were used for.

Uptake of new medications (anti-immunoglobulin E therapy)

In mid-2011, omalizumab, a newly approved anti-immunoglobulin E monoclonal antibody therapy that is indicated for treatment of severe allergic asthma, was listed in the PBS and RPBS under the Highly Specialised Drugs Program (Section 100). Evidence of clinical response must be provided in order for treatment with omalizumab to be continued beyond 28 weeks (Medicare Australia 2014).

Using PBS data, we summed the number of people for whom omalizumab was first dispensed between July 2011 and December 2013. Cumulative monthly number of prescriptions dispensed from July 2011 were plotted to display the rate of uptake over time. We quantified the age and sex of people who were dispensed this therapy under the PBS/RPBS and also graphed the number of new patients commencing this therapy per month since it became available.

To assess the proportion of people who stopped taking omalizumab before the first scheduled reassessment for PBS eligibility (that is, less than 28 weeks after commencement),

we singled out the first prescription and last prescription for each person. We then calculated the proportion of all people dispensed omalizumab, who had their last prescription dispensed less than 28 weeks after the initial prescription. If the last recorded dose was after 20 November 2013, then we assumed that the patient was still continuing the medication at the end of the study period (31 December 2013). Finally, we conducted a life table analysis (using SAS Proc Lifetest) to describe the population distribution of the duration of usage of this medication.

Dispensing of leukotriene receptor antagonists (LTRA)

Leukotriene receptor antagonists (LTRA) are recommended in the Australian asthma guidelines as a first-line preventer in the management of asthma in children aged 2–14 years. LTRA is provided as a tablet and may be used as an alternative or adjunct to ICS, in children. This medication class may also be used before exercise.

We quantified the number of children who had been dispensed LTRA in the most recent year of PBS data (2013). We also calculated this as a proportion of the Australian population aged 0–14 years and further reported these by socio-demographic characteristics.

We also grouped the annual number of ICS prescriptions dispensed per child in 2013 into frequency-of-prescription categories (1, 2–3, 4–6, 7–12, and 13 or more prescriptions) and examined these by age group.

To further clarify the circumstances when only one LTRA prescription was dispensed in the year, we classified these as LTRA with no other respiratory medications (one-off) and those that were dispensed other respiratory medications in that year.

Self-reported medication use

We used data obtained from NSW Health Survey respondents in analysing asthma medication use among NSW residents, as described below.

Respondents with 'current asthma' were identified as those who answered yes to both of these questions:

- Have you ever been told by a doctor that you have asthma?
- Have you had symptoms of asthma or taken asthma treatment in the last 12 months?

Respondents with current asthma were then asked:

- What are the names or brands of all medications taken for asthma in the last 12 months?
- How often was each medication taken in the last 4 weeks?

Based on the responses to the above questions, we estimated:

1. The proportion of respondents with current asthma who used each class of asthma medication in the previous 12 months.
2. How often these individuals reported using selected asthma medication classes in the previous four weeks.
3. The level of asthma control that may be inferred from the frequency of SABA use.

Use of asthma medication in children

The Longitudinal Study of Australian Children (LSAC) is a cohort study of a representative sample of Australian children that collects information on a wide range of socio-demographic and health information, including the presence of diagnosed asthma, and parent-reported wheeze. The data from LSAC are also linked to the PBS dataset, so this provided the opportunity to obtain information about medication use among children linked to clinical information, which is not available from the PBS alone.

Among children with parent-reported wheeze or asthma, we compared self-reported use of asthma medications in the last 12 months with PBS records of medications dispensed.

3 Use of medications for obstructive airway disease

The medications described in this report can be used for several clinical indications, including asthma and COPD. Since the information available from the PBS dataset is dispensing information and not clinical information, it is not possible to present results in the form of proportions dispensed for a particular condition/disease. Therefore, results are presented as the proportion of the Australian population to whom the medications are dispensed.

Please note that individuals taking only non-prescription medications to manage their respiratory disease, for example, over-the-counter bronchodilators (SABA), antihistamines and/or mucolytics, are not included in these analyses.

Overall medication use

From PBS data, there were 2,042,104 individuals dispensed any PBS-listed respiratory medication in 2013, representing 9.1% of the Australian population. A total of 12,553,247 prescriptions for respiratory medications was dispensed. More than two-thirds of these medications (8,966,864 prescriptions, or 71.4%) were dispensed at the concessional rate, that is, with a health concession card. Please note that because these overall results do not include medications that were purchased over the counter (as described above), these numbers would be an underestimate of total use of respiratory medication in Australia.

Steroid-containing inhaled medications were the most commonly-dispensed prescription medications for the treatment of respiratory disease. In 2013, 6.3% of the Australian population were dispensed ICS (either alone or in combination with a LABA), 5.1% were dispensed combination therapy (ICS plus LABA) and 1.3% were dispensed ICS-only inhalers (Table 3.1). Few people were dispensed oral corticosteroids (1.6%), and even fewer were dispensed LABA-only inhalers (0.02%) or anti-immunoglobulin E therapy (omalizumab) (0.001%).

From PBS data, 5.1% of the Australian population were dispensed PBS-subsidised SABAs in 2013. This is likely to be an underestimate as it does not include SABAs purchased over the counter, which in a 2004–05 Victorian pharmacy survey was found to represent 40% of SABA purchases (Douglass et al. 2012).

Table 3.1: Number and proportion of the Australian population dispensed each class of respiratory medication, Australia 2013

Medication class	Number of patients dispensed this class of medication	Proportion (%) of total population that were dispensed this class of medication
Short-acting bronchodilators		
Short-acting $beta_2$-agonists (SABA)	1,129,427	5.1[(a)]
Short-acting muscarinic antagonists (SAMA)	63,209	0.3
Corticosteroids		
Any ICS (includes ICS-only inhaler and ICS/LABA combined therapy)	1,406,240	6.3
ICS/LABA combined therapy	1,144,223	5.1
ICS-only inhaler	299,635	1.3
OCS	356,751	1.6
Long-acting bronchodilators		
Any LABA (includes LABA and ICS/LABA combined therapy)	1,154,542	5.2
LABA-only inhaler	13,817	0.1
Long-acting muscarinic antagonist (LAMA)	275,152	1.2
Anti-immunoglobulin E therapy		
Omalizumab	298	0.001
Leukotriene receptor antagonist (LTRA)	**44,453**	**1.1**[(b)]
Other medications		
Cromone	30,501	0.1
Xanthine	13,498	0.1
Any respiratory medication	**2,042,104**	**9.1**

(a) SABA are limited to those who were dispensed these medications through a prescription and will not capture those who obtained SABA over-the-counter (that is, without a prescription).

(b) LTRA prescription is subsidised by PBS if dispensed to children (0–14 years). Hence, the proportion of children of this age who were dispensed this medication is shown.

Notes

1. Records with missing patient ID were excluded (1.2% of records).
2. Drug classes are not mutually exclusive. Some people may have received more than one type of corticosteroid within the study period, therefore, the sum of 'any ICS' does not necessarily equal the sum of 'ICS-only inhaler' and 'ICS/LABA combined therapy'.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

From the NSW Health Survey, 93.6% of people with current asthma had taken medication for their asthma in the 12 months before the survey. Among those with current asthma in 2009, 2010 or 2012, 52.4% (95% CI 51.0–53.8) reported that they had used ICS (alone or in combination with LABA) and 6.0% (95% CI 5.4–6.7) reported that they had used OCS in the previous 12 months (Table 3.2).

Table 3.2: Proportion of the population with current asthma, by the medication classes that they reported taking in the 12 months before the survey, NSW, aged 2 and over, 2009, 2010 and 2012

Medication class	Proportion (95% CI)
Short-acting bronchodilators	
Short-acting beta-agonists (SABA)	75.8% (74.5–77.0)
Short-acting muscarinic antagonists (SAMA)	3.0% (2.5–3.5)
Corticosteroids	
Any ICS (includes ICS-only inhaler and ICS/LABA combined therapy)	52.4% (51.0–53.8)
ICS/LABA combined therapy	40.4% (39.0–41.8)
ICS-only inhaler	13.7% (12.8–14.7)
OCS	6.0% (5.4–6.7)
Long-acting bronchodilators	
Any LABA (includes LABA-only inhaler and ICS/LABA combined therapy)	41.6% (40.2–43.1)
LABA-only inhaler	1.5% (1.2–1.9)
Long-acting muscarinic antagonists (LAMA)	3.6% (3.1–4.2)
Leukotriene receptor antagonist (LTRA)	**1.7% (1.3–2.1)**
Other medications	
Cromones	1.1% (0.8–1.4)
Xanthines	0.2% (0.1–0.4)
Respondents who had taken medications for their current asthma (n=4,494)	*93.6% (92.9–94.3)*
Respondents with current asthma (n=4,801)	**100% (99.99–100)**

CI = confidence interval; SABA = short-acting beta-agonist; ICS = inhaled corticosteroid; LABA = long-acting beta-agonist.

Note: Drug classes are not mutually exclusive. Some people received more than one type of corticosteroid within the study period, therefore, the sum of 'any ICS' does not necessarily equal the sum of 'ICS only inhaler' and 'ICS/LABA combined therapy'.

Source: NSW Health Survey (2009, 2010, 2012), NSW Ministry of Health.

Use of SABA for asthma (NSW Health Survey)

It was not possible to reliably examine the use of short-acting bronchodilators such as salbutamol and terbutaline by using data from the PBS alone because of the availability of

the drug over the counter (and without a prescription) in Australia, and the consequent incomplete capture in the PBS dataset. To cover for this we analysed data from the NSW Health Survey on people with current asthma who had been asked about their medication use. This enabled us to provide some estimates, based on self-report, of SABA use among people with current asthma (including both over-the-counter and prescription purchases); however we were not able to comprehensively report on the use of SABAs for obstructive airways disease in Australia.

Data from the NSW Health Survey describe self-reported use of SABA in people with current asthma and these are presented here. No data are available on the use of SABA by people with COPD.

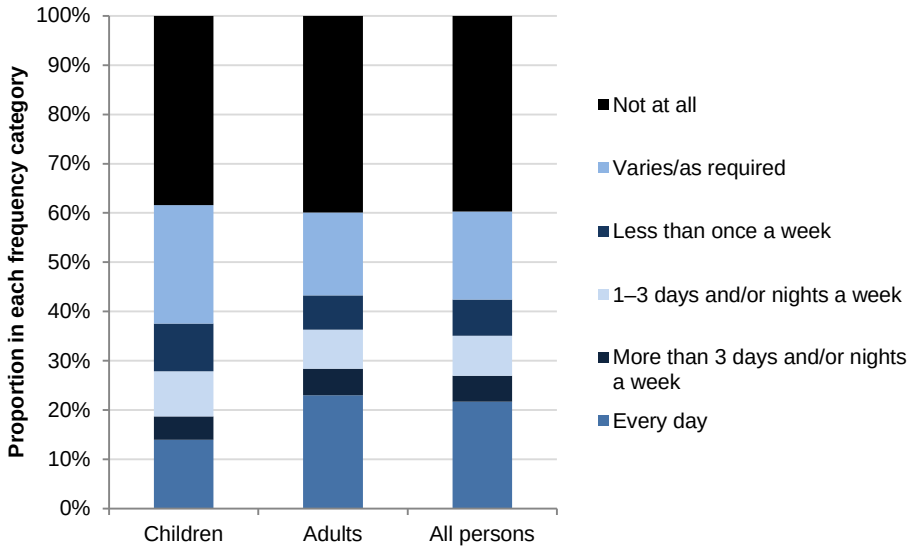
In NSW, 75.8% (95% CI 74.5–77.0) of people with current asthma in 2009, 2010 or 2012 reported that they had used SABA in the previous 12 months (Table 3.2). SABA were the most commonly used respiratory medication reported by respondents with current asthma.

Asthma guidelines recommend that frequency of use of SABA forms part of the assessment of asthma symptom control (NACA 2015). Current asthma guidelines (NACA 2015), for both adults and children, classify asthma as well-controlled if SABA are needed for relief of symptoms 2 days a week or less. In the NSW Health Survey, at least 18.7% of children with asthma had a frequency of SABA use consistent with poorly-controlled asthma (more than 3 times per week), while at least 28.4% of adults with asthma reported using SABA at a frequency consistent with poorly-controlled asthma.

Among children aged 2–14 years in NSW with current asthma, 14.0% reported using SABA every day in the previous 4 weeks, and 4.7% more than 3 days/nights in a week; hence around one-fifth of children reported a frequency of SABA use that was consistent with poorly-controlled asthma. SABA use was reported on 1–3 days a week by 9.1% and less than once a week by 9.7% of children. More than one-third (38.4%) of children reported not using SABA at all in the previous 4 weeks (Figure 3.1).

Adults tended to report using SABA more frequently than children. Among adults in NSW with current asthma, around one-quarter (23.0%) reported using SABA every day in the previous 4 weeks and 5.4% had used it more than 3 days and/or nights a week; these participants would be considered to have SABA use consistent with sub-optimal asthma control. On the other hand, 39.8% reported not using SABA at all and a further 7.0% reported using SABA less than once a week in the previous 4 weeks. These participants (around 46.8% of adults with current asthma) would be considered by current guidelines to have SABA use consistent with well-controlled asthma.

It is difficult to attribute a level of asthma control for the 16.8% of adults and 24.0% of children who selected the 'varies/as required' response about their SABA use, since this tells us nothing about how often they actually did use it over the preceding 4 weeks.



Notes

1. Children aged 2–14, adults aged 15 and over.
2. Current asthma includes people who have ever been diagnosed with asthma by a doctor and have taken asthma medication or experienced asthma symptoms in the last 12 months.
3. 'Not at all' includes people with current asthma who reported that:
   – they took SABA in the last 12 months, but not in the last 4 weeks;
   – they did not take SABA in the last 12 months; and
   – they did not take any medications for their asthma in the last 12 months but qualified as having current asthma on the basis of experiencing symptoms of asthma in the last 12 months.

Source: NSW Health Survey Program, NSW Ministry of Health 2009, 2010, 2012.

Figure 3.1: The proportion of children and adults with current asthma, by self-reported frequency of SABA use in the last 4 weeks, NSW, 2009, 2010 and 2012 (combined data), people aged 2 and over

Corticosteroids

Inhaled corticosteroids

ICS-containing medications are the most commonly dispensed prescription medications for the treatment of obstructive airways disease in Australia. In 2013, 6.3% of the Australian population were dispensed ICS, either alone or in combination with LABA (Table 3.3). Among children aged 0–14 years, 4.3% were dispensed at least one ICS prescription, while among Australian adults aged 15 and over, 6.8% were dispensed at least one ICS prescription, either alone or in combination with LABA.

The proportion of the population dispensed ICS-containing medications increased with age. A substantially higher proportion of people aged 65 and over were dispensed ICS (14%) compared to those aged less than 65 years. ICS were dispensed to more boys (5.0%) than girls (3.6%), and to more adult females (7.7%) than adult males (5.8%). These differences are consistent with known differences in the prevalence of asthma and COPD (ACAM 2011).

ICS-containing medications were dispensed to more people residing in areas of higher socioeconomic status than those in areas of lower socioeconomic status.

Dispensing of ICS was also higher among people living in major cities and regional centres compared to those in remote localities. Dispensing was lower in the Northern Territory than in other states and territories of Australia. A possible explanation for these findings is that remote localities and the Northern Territory have the highest proportions of Indigenous people in their populations. Indigenous people may obtain medications through Aboriginal Health Services that are not recorded on the PBS and therefore absent in the analyses presented here.

Table 3.3: Number and proportion of the Australian population dispensed inhaled corticosteroids (alone or in combination with long-acting beta$_2$-agonists), by demographic characteristics, Australia, 2013

Demographic characteristics	All ages		Children (aged 0–14)		Adults (aged 15 and over)	
	Number	Per cent	Number	Per cent	Number	Per cent
Sex						
Male	631,265	5.7	109,555	5.0	521,710	5.8
Female	774,639	6.9	73,829	3.6	700,810	7.7
Age group (years)						
0–4	44,170	3.0	44,170	3.0	. .	. .
5–14	139,214	5.0	139,214	5.0	. .	. .
15–34	232,923	3.7	. .	. .	232,923	3.7
35–64	557,089	6.4	. .	. .	557,089	6.4
65 and over	432,507	14.0	. .	. .	432,507	14.0
Socioeconomic status						
SES 1 (Lowest)	242,555	5.5	31,282	3.5	211,273	6.0
2	263,962	5.9	32,067	3.8	231,895	6.4
3	275,457	6.3	36,289	4.5	239,168	6.7
4	279,356	6.2	36,459	4.3	242,897	6.6
SES 5 (Highest)	329,060	7.3	45,457	5.6	283,603	7.6
Remoteness category						
Major cities	965,154	6.2	130,911	4.5	834,243	6.5
Inner regional	281,601	6.9	33,098	4.1	248,503	7.5
Outer regional	125,630	6.2	15,164	3.7	110,466	6.8
Remote	14,350	4.6	1,897	2.8	12,453	5.0
Very remote	4,958	2.5	647	1.0	4,311	2.8

(continued)

Table 3.3 (continued): Number and proportion of the Australian population dispensed inhaled corticosteroids (alone or in combination with long-acting beta$_2$-agonists), by demographic characteristics, Australia, 2013

Demographic characteristics	All ages		Children (aged 0–14)		Adults (aged 15 and over)	
	Number	Per cent	Number	Per cent	Number	Per cent
State/territory						
NSW	490,539	6.8	71,398	5.2	419,141	7.2
Vic	334,228	6.0	38,559	3.8	295,669	6.5
Qld	280,080	6.3	33,664	3.8	246,416	6.9
WA	131,457	5.6	18,987	4.2	112,470	5.9
SA	104,475	6.4	12,078	4.2	92,397	6.8
Tas	35,361	6.9	4,563	4.8	30,798	7.4
ACT	22,447	6.1	3,214	4.8	19,233	6.4
NT	7,115	3.1	881	1.7	6,234	3.5
All people	**1,406,240**	**6.3**	**183,384**	**4.3**	**1,222,856**	**6.8**

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Australian Bureau of Statistics Estimated Resident Population.

Of all the individuals who had ICS dispensed in 2013, the majority (81.4%) were dispensed the ICS in the form of a combination ICS/LABA inhaler (that is, ICS plus LABA in the same inhaler). This proportion was much lower among children than adults. Among children, for whom ICS/LABA combination inhalers are generally not recommended, 42.3% of those dispensed any ICS were dispensed in the form of a combination ICS/LABA inhaler. Among adults, the proportion dispensed ICS in the form of a combination ICS/LABA inhaler was 87.2% (Table 3.4).

For adults receiving ICS it is not possible, using information available in the PBS dataset, to distinguish those with asthma (for whom guidelines recommend that most should be adequately controlled with ICS alone) from those with COPD (for whom guidelines recommend against using ICS alone). In contrast, the only indication for this class of medications in children is asthma, since COPD does not occur in children. Hence, dispensing patterns can be more readily compared with treatment recommendations. For children aged 6–14 years, asthma guidelines recommend that only children with severe asthma, which should be a small proportion of all children with asthma, should receive an ICS/LABA combination—yet ICS was delivered as ICS/LABA for 50.3% of children aged 5–14 years. For children aged 5 years and younger, asthma guidelines recommend against using ICS/LABA combinations because of lack of evidence for safety—yet for 17.1% of children aged 0–4 years receiving ICS, it was delivered as ICS/LABA.

Table 3.4: Number and proportion of people dispensed inhaled corticosteroids by combination status, Australia, 2013

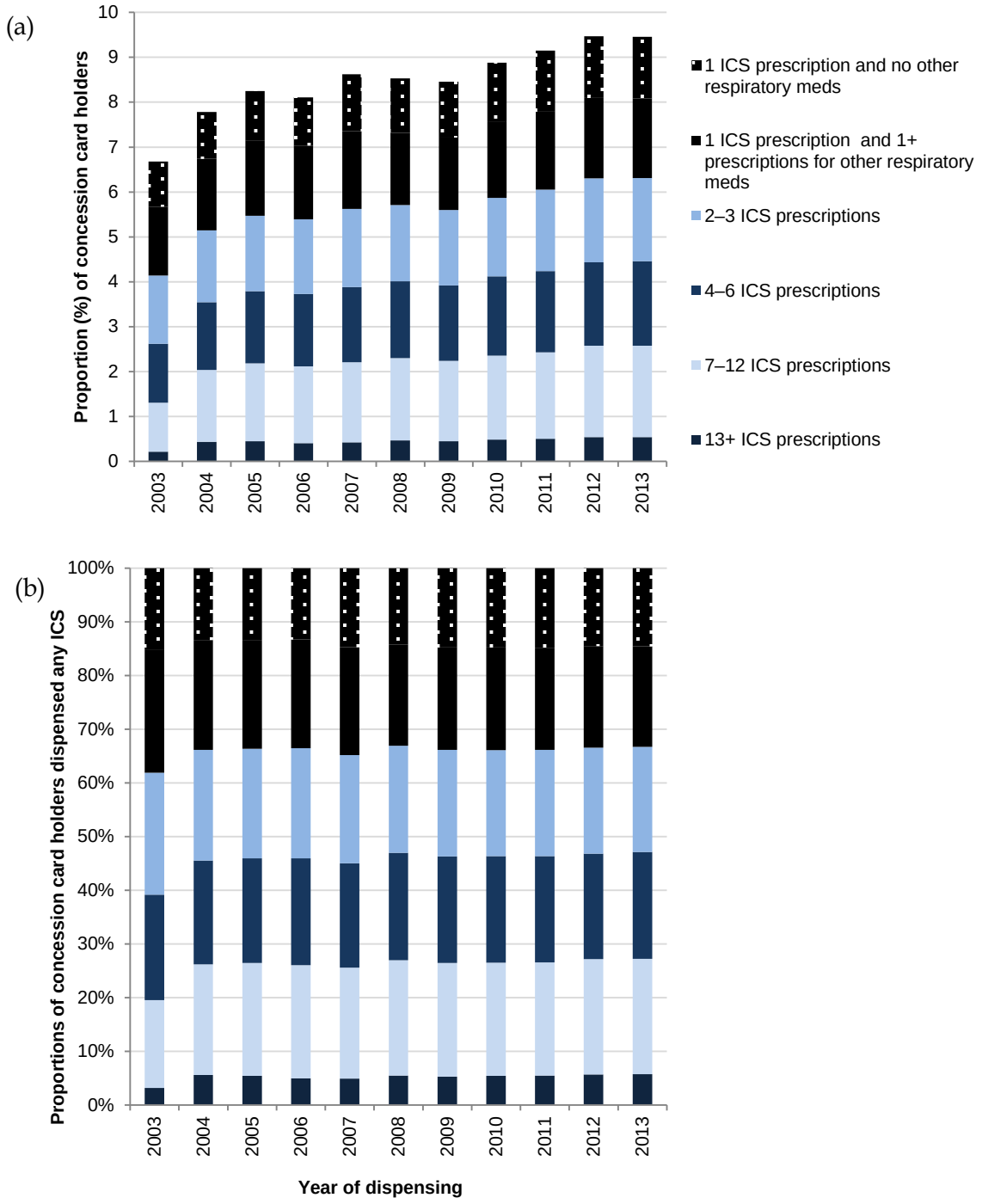
Type of ICS	Children (0–14 years)		Adults (15+ years)		All ages	
ICS alone	111,462	60.8%	188,173	15.4%	299,635	21.3%
ICS in combination with LABA	77,612	42.3%	1,066,611	87.2%	1,144,223	81.4%
All ICS	**183,384**	**100%**	**1,222,856**	**100%**	**1,406,240**	**100%**

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Australian Bureau of Statistics Estimated Resident Population.

Trends in frequency of dispensing of ICS

Between 2006 and 2013, the proportion of concession card holders aged 15 and over who were dispensed any ICS (that is, alone or in combination with LABA), increased (see Figure 3.2). This may have been due to an increase in prescribing by clinicians, for example due to increased awareness of COPD guidelines, and/or improved primary adherence (that is, improved filling of prescriptions) by patients.

Among PBS-subsidised maintenance medications, 1 prescription at the typically recommended dose generally provides enough therapy for 1 month. For asthma, treatment with ICS at a low daily dose is associated with a reduced risk of asthma-related death, provided it is taken regularly rather than intermittently (Suissa et al. 2000). Therefore, we have proposed that 7 or more prescriptions of any ICS medication in a year would be the minimum number of prescriptions consistent with regular use (ACAM 2007, 2011). Filling of fewer than 7 prescriptions of a medication in a year may indicate that it was not prescribed for continuous use, that the medication was commenced or ceased during the course of the year, that the medication was not used at the standard dose, or that the medication was not used regularly by the patient during that year. Electronic monitoring of inhaler use shows that poor adherence is common in the community (Foster et al. 2014), which would be consistent with the last of these explanations. However, all potential explanations are probably contributing to the observed findings.



Notes

1. The denominator population in this figure is concession card holders because below copayment prescriptions were not captured in the PBS data prior to April 2012.
2. Includes ICS dispensed alone or in combination with long-acting beta-agonists.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.2: (a) Concession card holders aged 15 and over dispensed any ICS as a proportion of the whole Australian concession card holder population, and (b) Proportions of concession card holders dispensed any ICS; by number of ICS prescriptions dispensed and by year, Australia, 2003 to 2013

Between 2006 and 2013, among concession card holders prescribed any ICS, 44–47% were dispensed 4 or more ICS in a given year, and just over a quarter (26–27%) were dispensed 7 or more ICS in each year, a pattern of dispensing that is consistent with regular and appropriate use of these medications (Figure 3.2 (b)). This pattern changed little over that period.

Around one-third were dispensed only 1 ICS prescription in any given year, and among these, the proportion dispensed no other respiratory medications during that year, and therefore considered unlikely to have asthma or COPD, increased from 40% to 44% between 2003 and 2013. However, these figures are likely to be overestimates, as some of these individuals could also have purchased SABA over the counter for asthma or COPD, and this would not have been included in the PBS dataset.

The high proportion of individuals dispensed few ICS prescriptions in any given year is consistent with findings in previous ACAM reports (ACAM 2007, 2008, 2011).

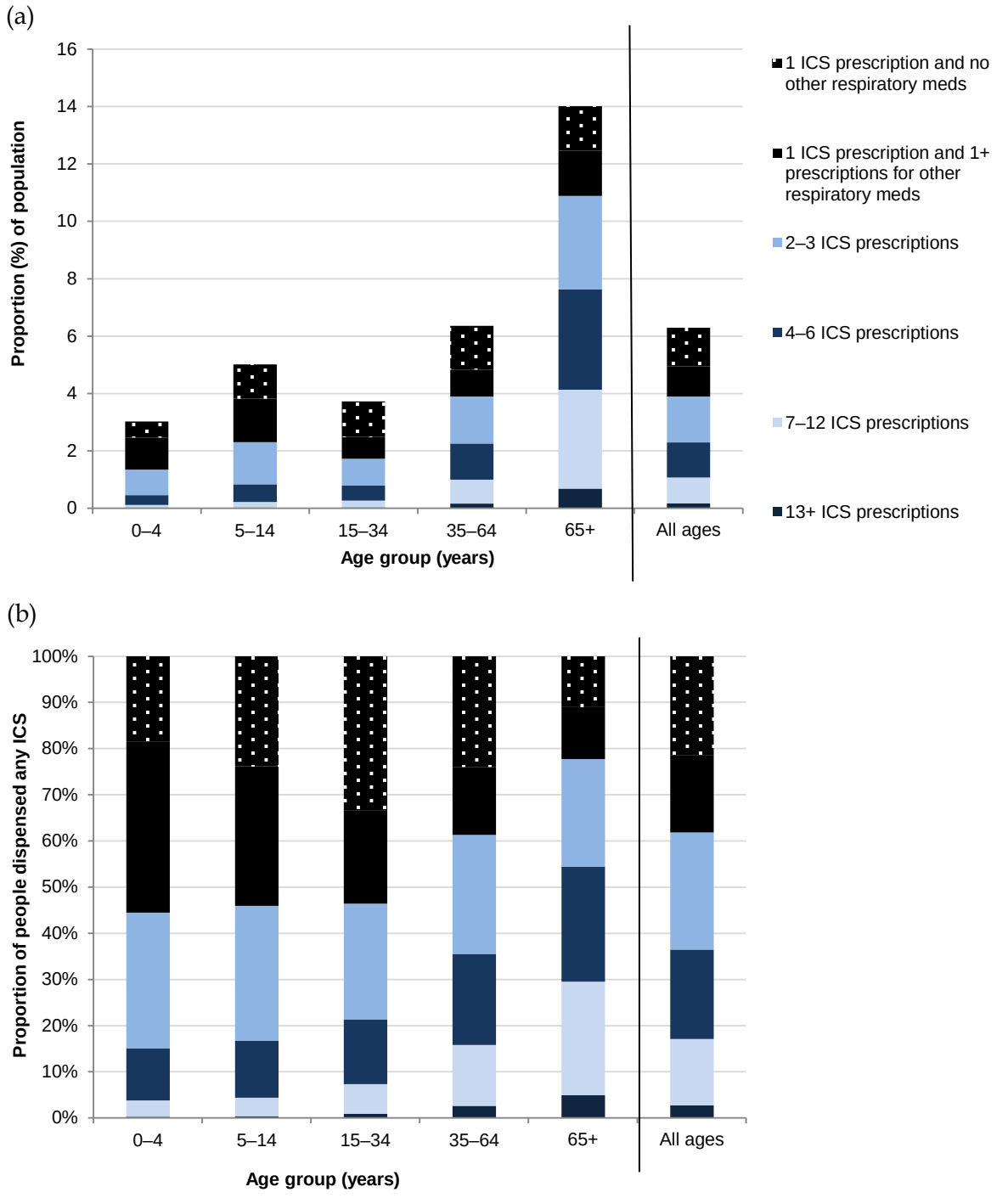
Variations in ICS dispensing patterns by age

Among Australian adults aged 15 years and over, 5.1% were dispensed at least one ICS prescription, either alone or in combination with a LABA, in 2013.

The proportion of children dispensed any ICS increased with age (Table 3.3; Figure 3.3). In 2013, 3.0% and 5.0% of children aged 0–4 and 5–14 years, respectively, had one or more ICS prescriptions dispensed.

Among children, the majority (83.7%) of those dispensed any ICS were only dispensed 1–3 prescriptions in a year. This suggests that much of the use of ICS medications among children was relatively short-term; this is not necessarily contrary to guidelines, which recommend that the need for ICS treatment should be reassessed frequently among children.

Similarly, the proportion of adults dispensed any ICS increased with age. In 2013, 3.7%, 6.4% and 14.0% of people aged 15–34, 35–64, and 65 years and over, respectively, had one or more prescriptions of ICS dispensed. Further, the proportion of adults dispensed 7 or more ICS prescriptions in a year increased with age.



Note: Includes ICSs dispensed alone or in combination with long-acting beta-agonists.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.3: People dispensed any ICS as a proportion of (a) the whole Australian population and (b) the Australian population that were dispensed any ICS, by number of ICS prescriptions in a year and age group, Australia, 2013

Not only was the proportion of people aged 65 and over who were dispensed any ICS higher than in any other age group, but also the *frequency* of ICS dispensing (that is, the number of prescriptions dispensed per year) was greater in people aged 65 years and over compared to younger adults. In 2013, among those who had at least one prescription for ICS dispensed, 7.3% of people aged 15–34, 15.8% of those aged 35–64 years and approximately 30.0% of people aged 65 years and over, had 7 or more prescriptions dispensed, the minimum rate of dispensing consistent with regular use (Figure 3.3b).

Filling of more than 12 prescriptions in a 12-month period may indicate that the medication has been used at a higher daily dose than is standard. We found that this was most common in people aged 65 and over, among whom 4.9% of those who received any ICS were dispensed 13 or more in 2013. This suggests that older patients were more likely to be prescribed higher ICS doses that required more than one inhaler per month, and/or were more likely to over-use the inhaler. Use of ICS at higher doses than necessary increases the cost of treatment and the risk of adverse effects.

Among adults aged 15 and over who were dispensed any ICS in 2013, 59.3% of those who had been dispensed only one ICS in the year had no other respiratory medications dispensed during that year. This pattern was observed more among younger adults (aged 15–64) than those aged 65 and over, and was most common among those aged 15 to 34.

This pattern appears to be inconsistent with appropriate use of ICS medications, because they are only approved and PBS-subsidised for the treatment of asthma or COPD, and clinical practice guidelines for these conditions recommend that, in adults, ICS medications should be prescribed on a regular basis for extended periods of time.

Although some of these dispensing events may represent patients with asthma or COPD who had a single dispensing of ICS in a year but who also purchased SABA over the counter without a prescription, we hypothesise that many of these 'one-off' dispensing events for ICS and ICS/LABA are prescribed for short-term conditions that fall outside the guidelines for the use of these medications.

We have previously calculated the cost to government of these 'one-off' ICS dispensing events in a single year (2008), and showed that for 44% of these patients, the one-off ICS was co-dispensed with an antibiotic (Poulos et al. 2013). This supports our hypothesis that many 'one-off' ICS dispensing events represent prescribing for short-term treatment of respiratory infections such as acute bronchitis and post-viral cough, despite them not being approved for these indications and a lack of evidence for effectiveness. Using PBS data only for concession cardholders to ensure that all relevant medications were captured, we estimated that this apparently inappropriate prescribing of ICS medications came at a cost of almost $3 million to the Australian Government in 2008 alone, and would be even higher with the inclusion of PBS medicines dispensed to non-concession card holders.

The present report adds to these data, by showing that the proportion of adult patients with 'one-off' ICS dispensing remained consistent at about 15% of those receiving any ICS between 2003 and 2013 (Figure 3.2). Therefore, it appears that the problem of inappropriate prescribing practices for ICS is ongoing. In all Figures showing frequency of dispensing, we have distinguished people with just one ICS dispensing in a given year by whether or not the patient was dispensed other prescribed respiratory medications in that year. As there is a substantial cost to government and the community and an increased risk of adverse effects from inappropriate use of ICS medications, further investigation of the use of potent ICS outside Australian guidelines is warranted. In a recent study from the Netherlands, one-off

ICS dispensing was much less common than in Australia, at 10% of those receiving any ICS (Teichert et al. 2014).

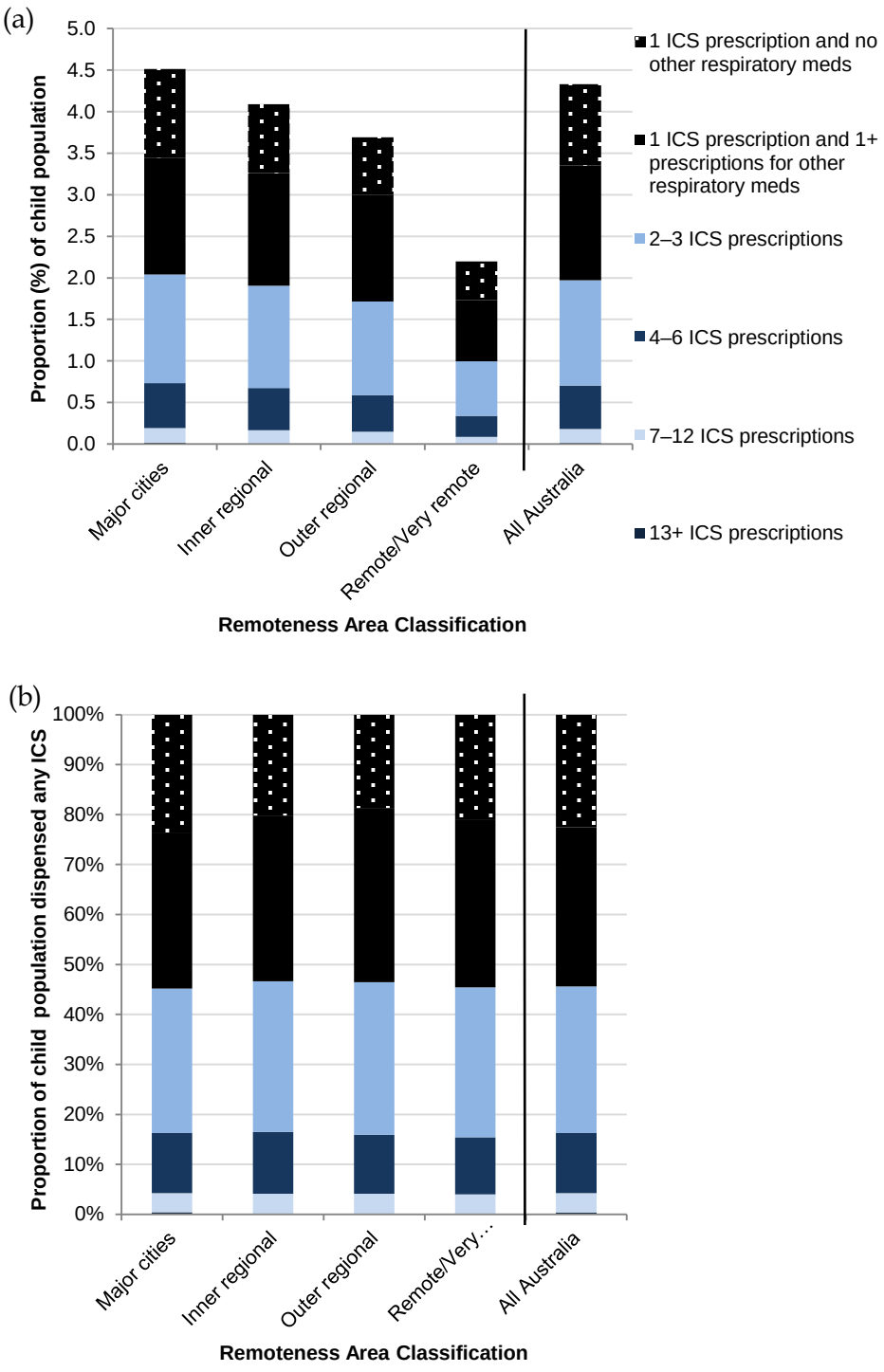
Variations in ICS dispensing patterns by remoteness

Overall, ICS were dispensed to 4.3% of Australian children in 2013, but this differed according to remoteness of residence (Table 3.3; Figure 3.4a). Among children, ICS were dispensed most commonly in *Major cities* of Australia, where 4.5% of the population aged 0–14 years were dispensed this class of medication either alone or in combination with a LABA. On the other hand, children living in *Remote/Very remote* areas of Australia were least likely to be dispensed ICS, with only 2.2% of the 0–14 child population living in these areas being dispensed this class of medication. However, it is possible that this is an underestimate of actual dispensing in *Remote/Very remote* areas of Australia because some of these medications are dispensed through remote Aboriginal Health Services, and, therefore, not captured in the PBS dataset (see Chapter 2, 'Pharmaceutical Benefits Scheme data' subsection).

In *Major cities* of Australia, 54.8% of children who were dispensed any ICS in 2013 were only dispensed one prescription of the drug. Furthermore, 43.1% of the children residing in *Major cities* and who were only dispensed one prescription of ICS in 2013 were not dispensed any other respiratory medications during that year (Figure 3.4b).

Among adults, ICS were dispensed most commonly in *Inner regional* areas of Australia, where 7.5% of the population aged 15 years and over were dispensed this class of medication, either alone or in combination with a LABA (Table 3.3; Figure 3.5a). Adults living in *Remote/Very remote* areas of Australia were least likely to be dispensed ICS, with only 4.2% of the population living in these areas being dispensed this class of medication.

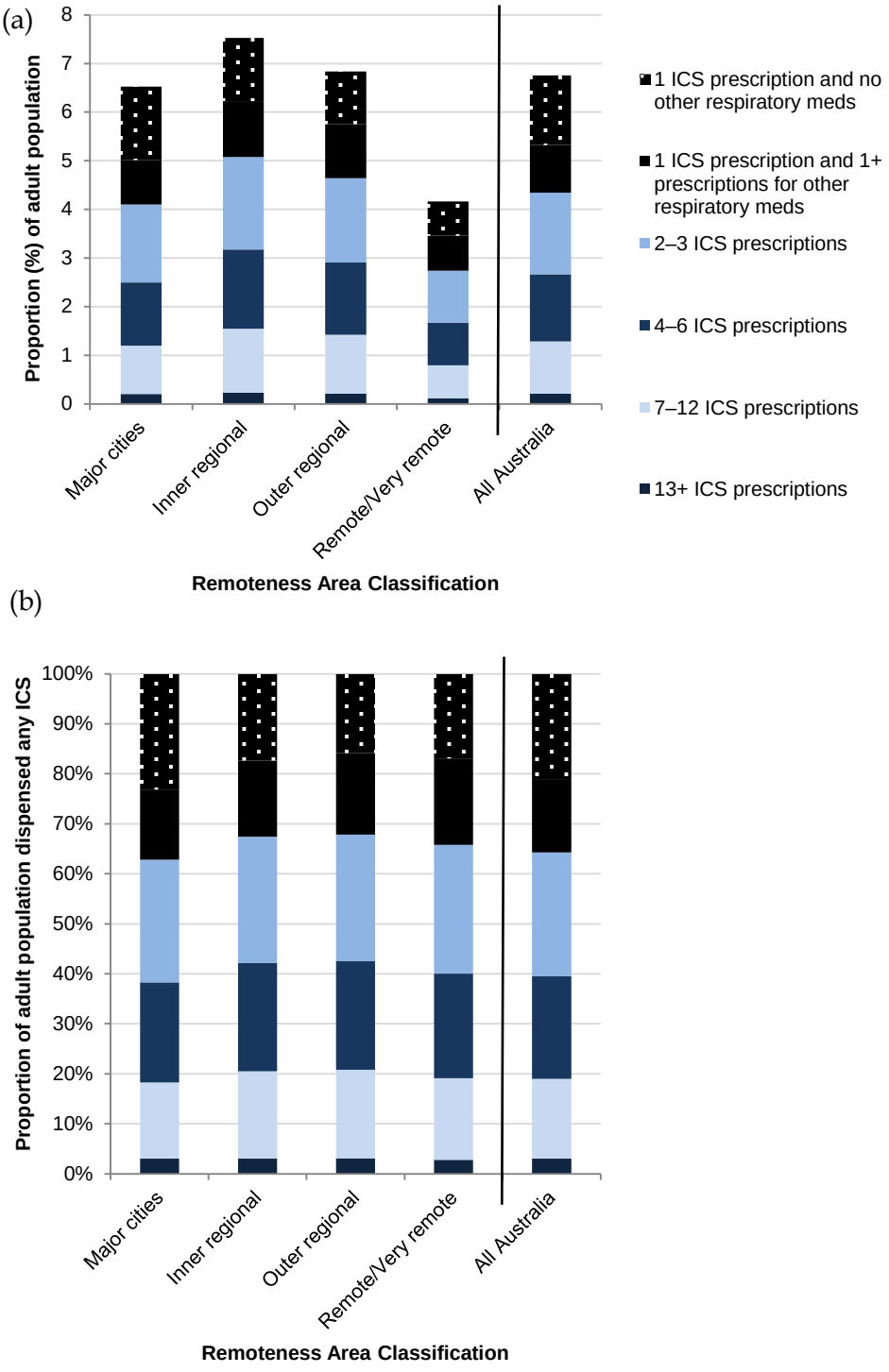
In *Major cities* of Australia, 37.1% of adults who were dispensed any ICS in 2013 were only dispensed one prescription of the drug. Furthermore, 62.2% of the adults residing in *Major cities* and who were only dispensed one prescription of ICS in 2013 were not dispensed any other respiratory medications during that year (Figure 3.5b).



Note: Includes ICS dispensed alone or in combination with long-acting beta-agonists.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.4: Children aged 0–14 dispensed ICS as a proportion of (a) the whole Australian child population and (b) the Australian child population dispensed ICS, by number of ICS prescriptions dispensed in a year and by remoteness of residence, Australia, 2013



Note: Includes ICS dispensed alone or in combination with long-acting beta-agonists.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.5: Adults aged 15 and over dispensed ICS as a proportion of (a) the whole Australian adult population and (b) the Australian adult population dispensed ICS, by number of ICS prescriptions dispensed in a year and by remoteness of residence, Australia, 2013

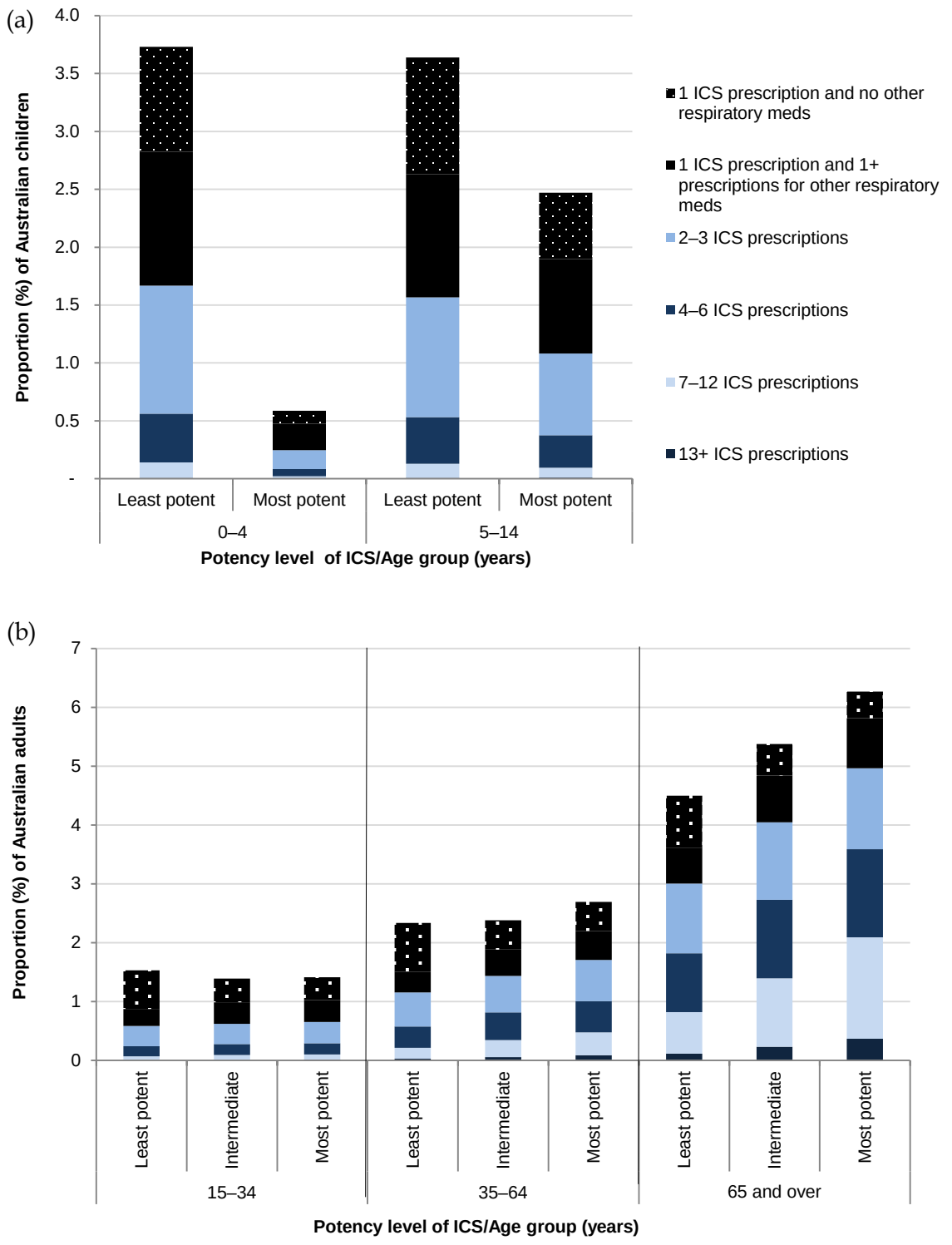
Potency of ICS

Clinical trials have established that the use of standard doses of low potency ICS without LABA is sufficient for controlling asthma in the majority of patients with the disease. Use of this regimen reduces the cost of treatment to the patient and government and the likelihood of adverse effects, compared with use of higher potency ICS and with use of ICS/LABA combinations.

Current Australian asthma guidelines state that, for most patients, good asthma control should be able to be achieved with low-dose inhaled corticosteroids. In contrast to these recommendations about best practice, ACAM has previously shown that most ICS are dispensed in the most potent formulations and in combination with LABA (ACAM 2011).

In this report, the potency classification was adjusted to reflect 2014 Australian guidelines (NACA 2015). Some formulations have been re-assigned to a lower potency classification. However, even with this new classification, we found that for 72.3% of adults receiving any ICS in 2013, they had been prescribed at the intermediate or most potent formulations, and most were dispensed in combination with LABA. We found that children are more often prescribed less potent formulations than adults. However, over one-third of children were receiving high potency ICS. This is disproportionate to the prevalence of severe asthma among children in whom high doses of ICS would be warranted.

In 2013, 3.7% of Australian children aged 0–4 were dispensed ICS (with or without LABA) categorised as the least potent formulations, while 0.6% were dispensed the most potent formulations of ICS. Among older children, aged 5–14 years, 3.6% were dispensed the least potent ICS and 2.5% were dispensed the most potent formulations of ICS (Figure 3.6a).



Note: Includes ICS dispensed alone or in combination with long-acting beta-agonists.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.6: Proportion of (a) children and (b) adults dispensed any ICS, by potency level and age group, Australia, 2013

Among adults, 1.5%, 2.3% and 4.5% of those aged 15–34, 35–64, and 65 and over, respectively, were dispensed low potency ICS. At the other end of the ICS potency spectrum, 1.4%, 2.7% and 6.3% of those aged 15–34, 35–64, and 65 and over, respectively, were dispensed the most potent ICS. In each adult age group, the frequency of dispensing increased with potency—that is, the people dispensed the most potent category of ICS were also dispensed these formulations more frequently than those taking the lower potency formulations (Figure 3.6b).

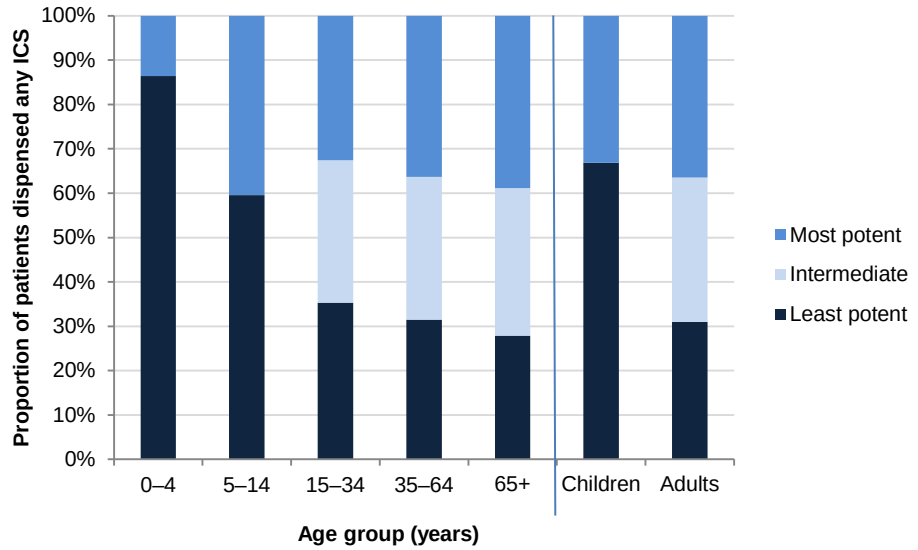
In 2013, 35.7% of Australians who were dispensed any ICS were dispensed the most potent formulations, while 36.5% were dispensed the least potent formulations. However these proportions varied greatly with age (Figure 3.7).

For children who need ICS, guidelines emphasise that low doses should be used. However, among children aged 0–14 years who were dispensed any ICS in 2013, only 66.8% were dispensed the least potent formulations while the remaining 33.2% were dispensed the most potent formulations. Among younger children, aged 0–4 years, ICS prescribing was more appropriate, with 86.4% dispensed ICS in the least potent category and only 13.6% dispensed ICS categorised as 'most potent'. Among children aged 5–14 years who were dispensed ICS, 59.6% were dispensed ICS in the least potent category and the remaining 40.4% were dispensed ICS in the most potent category.

Among adults aged 15 years and over who were dispensed any ICS in 2013, 36.5% were dispensed the most potent formulations while 31.0% were dispensed the least potent formulations. The proportion of Australian adults receiving any ICS who were dispensed the most potent ICS also increased with age—32.6% of those aged 15–34, 36.4% of those aged 35–64 and 38.9% of those aged 65 years and over were dispensed the most potent ICS. Thus, in addition to having ICS dispensed at a higher rate and more frequently, Australians aged 65 years and over were also dispensed more potent ICS than younger Australians.

Of all the children aged 5–14 years who were dispensed any ICS in the least potent category, 57.0% were only dispensed one prescription during 2013, while 28.4% were dispensed 2–3 prescriptions. Similarly, among children aged 0–4 years who were dispensed ICS in the least potent category, 55.3% were dispensed only one prescription while 29.6% were dispensed 2–3 prescriptions during 2013.

PBS data do not enable us to distinguish between ICS prescribed for asthma, for which guidelines suggest that most people can be well managed on low-dose formulations of ICS alone, and COPD, where guidelines recommend high-dose ICS in combination with LABA. It is somewhat reassuring to note that the greatest use of the most potent ICS was among older Australians who are also the sub-group with the highest prevalence of COPD. However the risk of adverse effects such as pneumonia associated with use of the most potent ICS for COPD should be taken into account (Kew & Seniukovich 2014).



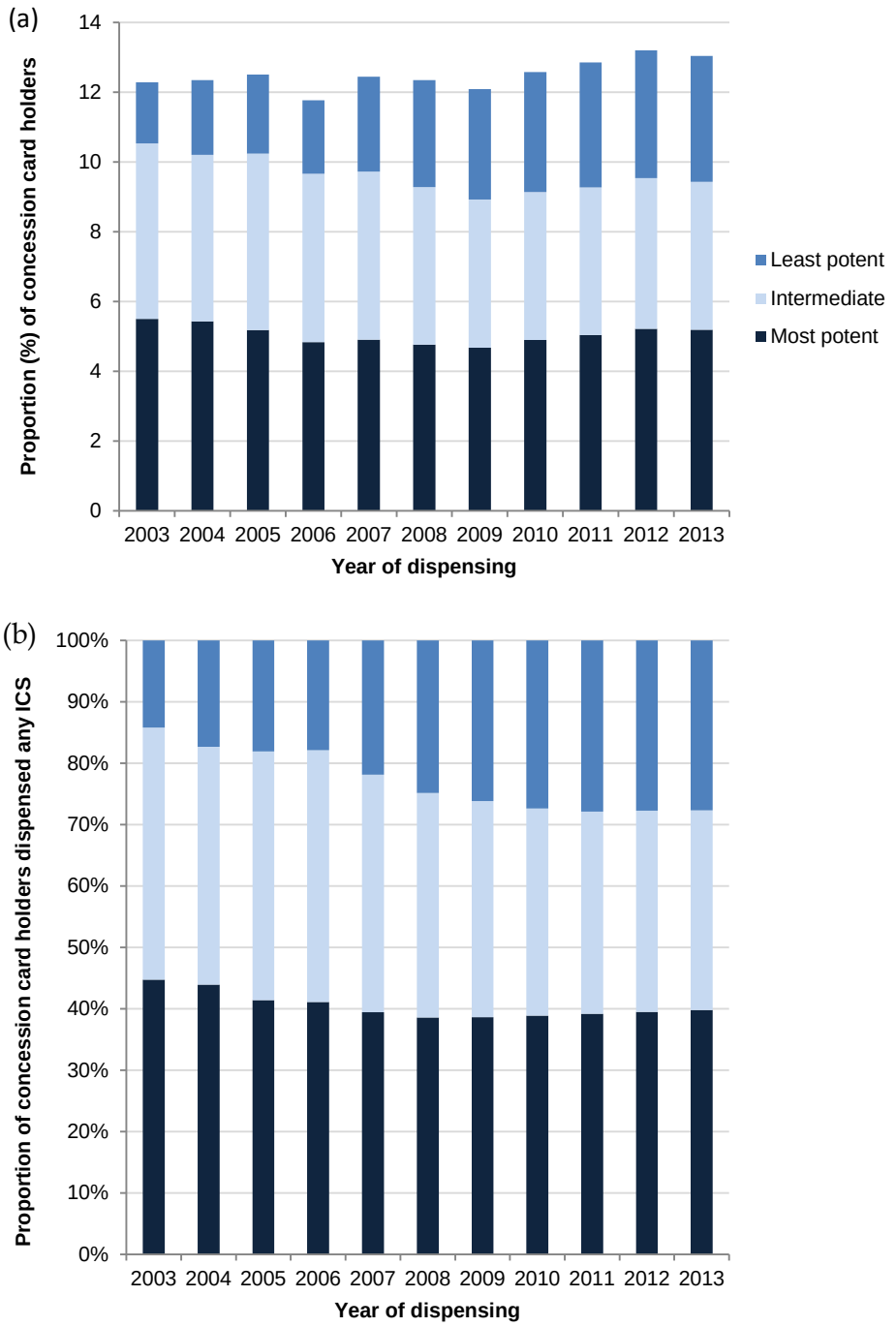
Notes

1. There are only two potency levels for children (least and most potent), and three levels for adults (least, intermediate and most potent).
2. Includes ICS dispensed alone or in combination with long-acting beta-agonists.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.7: The proportion of people dispensed any ICS in each ICS potency level, by age group, Australia, 2013

In Figure 3.8 we have presented data on the potency of ICS dispensed for concession card holders in Australia, by year, as recorded in the PBS dataset. The proportion of concession card holders dispensed any ICS was relatively stable over the period 2003 to 2013. There was a slight increase in the proportion of concession card holders dispensed any ICS between 2009 and 2012, but, among these, as shown in Figure 3.8(b), the proportions dispensed at each potency classification remained relatively stable during this time. However, Figure 3.8(b) also shows that, since 2006, an increasing proportion of ICSs dispensed are the least potent formulations, a decreasing proportion are of intermediate potency, and there has been little change in the proportion in the most potent category.



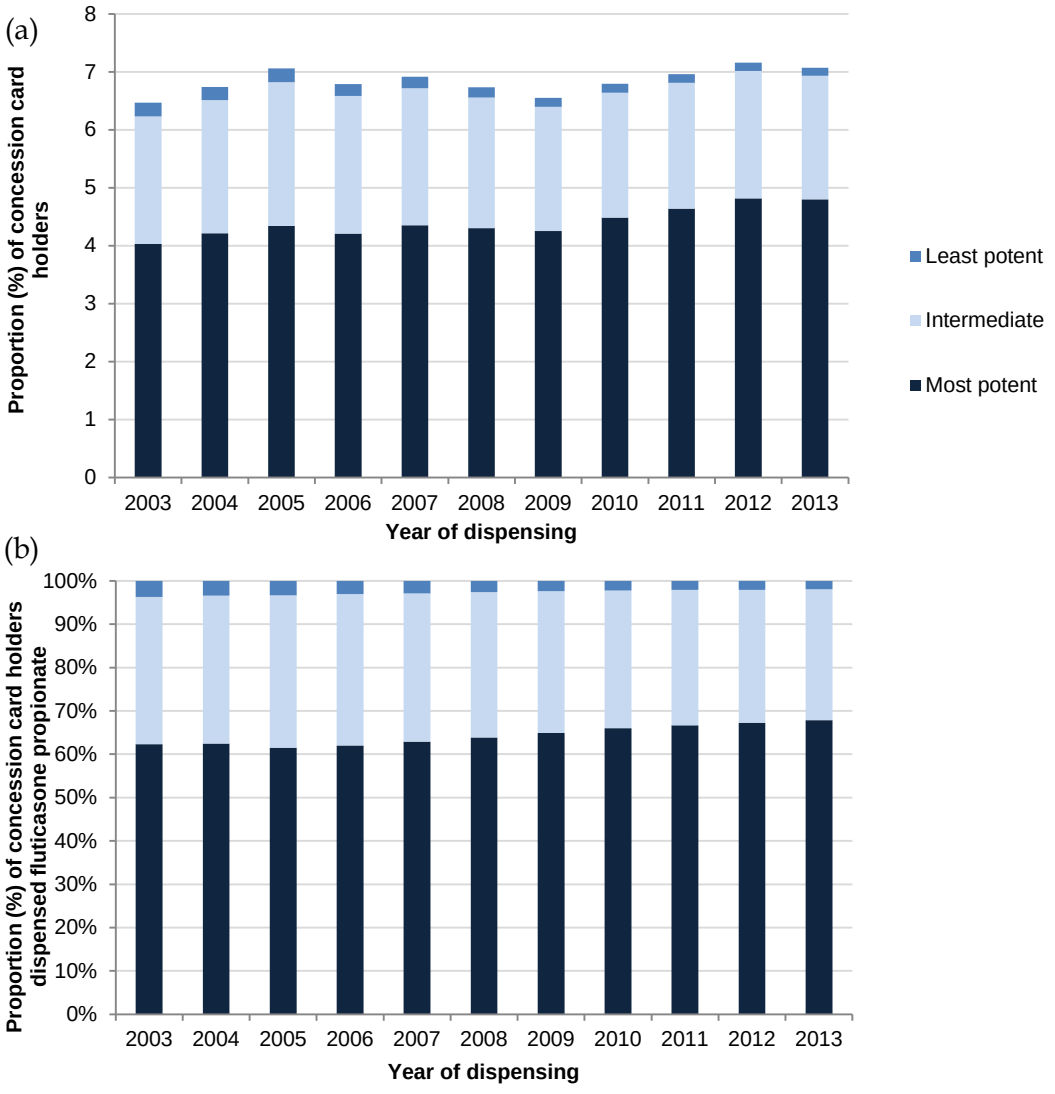
Note: Includes ICS dispensed alone or in combination with long-acting beta-agonists.

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Figure 3.8: Concession card holders aged 15 and over dispensed ICS as a proportion of (a) all concession card holders in Australia and (b) concession card holders dispensed any ICS, by potency of ICS and year dispensed, Australia, 2003–2013.

To further investigate the underlying patterns of dispensing, we separately graphed the two most commonly prescribed ICS-containing medications, namely fluticasone propionate/salmeterol (Seretide) and budesonide/eformoterol (Symbicort), by potency and

year dispensed. We found that the distribution of ICS potency in adults differed substantially between the two main ICS medications with very different patterns in the prescriptions dispensed. There was little change over time in the proportion of the population dispensed fluticasone propionate/salmeterol (Figure 3.9), and it was predominantly dispensed in the most potent ICS category. In contrast, dispensing of budesonide/eformoterol increased over time (Figure 3.10) and was predominantly dispensed in the least potent ICS category. Hence, the changes in the overall pattern of ICS dispensing are attributable to an increase in dispensing of low potency budesonide–eformoterol combination therapy.

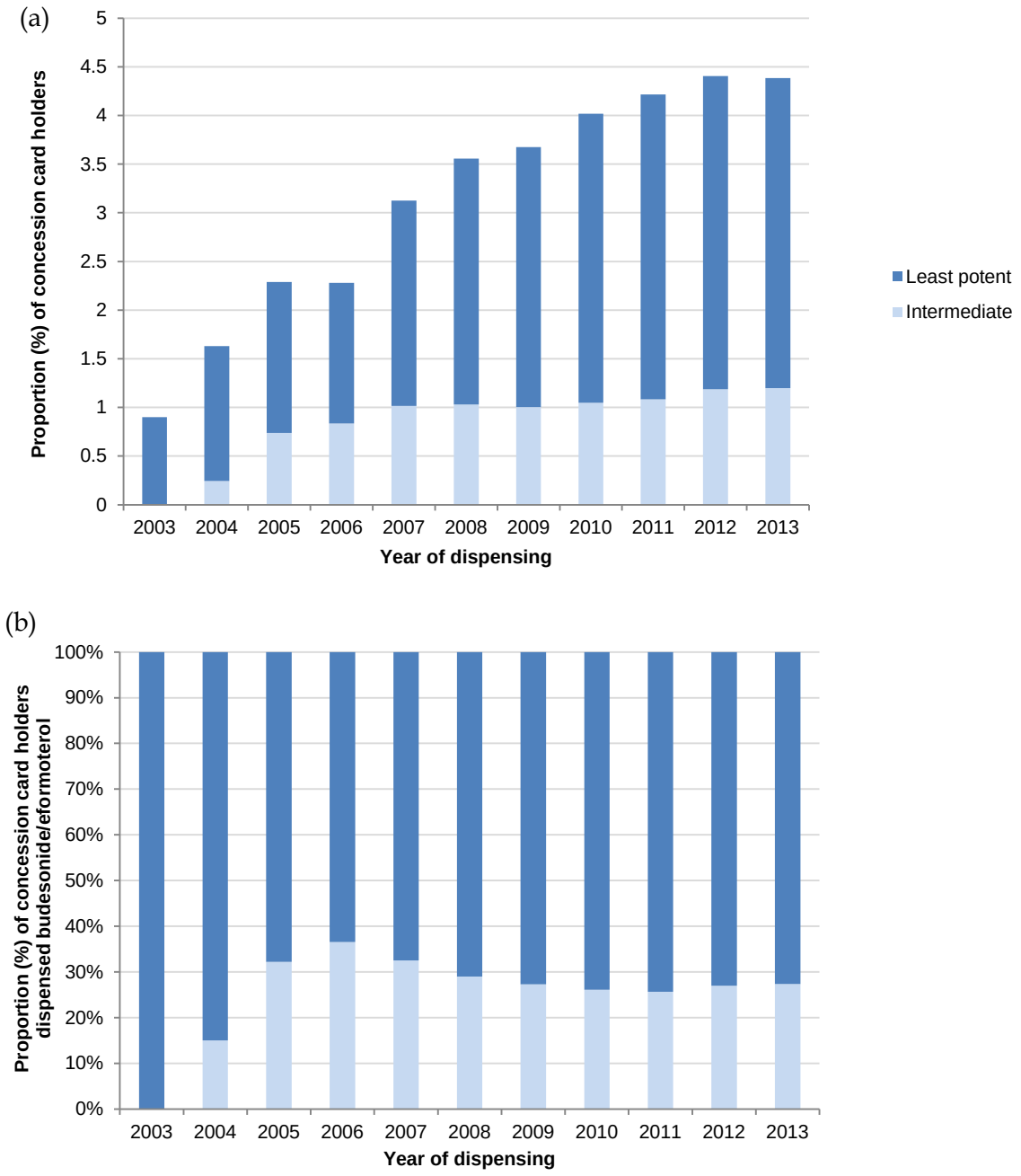


Note: Potency of fluticasone propionate categorised as follows: Least potent—pMDI 50/25mcg and ACC 100/50 mcg; Moderately potent—pMDI 125/25 mcg and ACC 250/50 mcg; Most potent—pMDI 250/25 mcg and ACC 500/50.

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Figure 3.9: Concession card holders aged 15 and over dispensed fluticasone propionate/salmeterol (Seretide) as a proportion of (a) all concession card holders in Australia and (b) concession card holders dispensed fluticasone propionate/salmeterol (Seretide), by potency and year dispensed, Australia 2003–2013

This suggests that medication-specific strategies may be required to improve prescribing of ICS medications. However, the calculation of potency is an estimate, as the information available on the PBS is limited, with no detail about the dose (number of puffs) directed by the prescriber.



Note: Potency of budesonide/eformoterol categorised as follows: Least potent—50/3 pMDI, 100/3 pMDI, 100/6 TH and 200/6 TH; Moderately potent—200/6 pMDI and 400/12 TH.

Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.10: Concession card holders dispensed budesonide/eformoterol (Symbicort) as a proportion of (a) all concession card holders in Australia and (b) concession card holders dispensed budesonide/eformoterol (Symbicort), by potency and year dispensed, age 15 and over, Australia 2003–2013

Combined ICS and long acting beta$_2$-agonist formulations

In 2013, 5.1% of the Australian population were supplied with combined formulations containing ICS plus a long-acting beta$_2$-agonist (LABA) (Table 3.5).

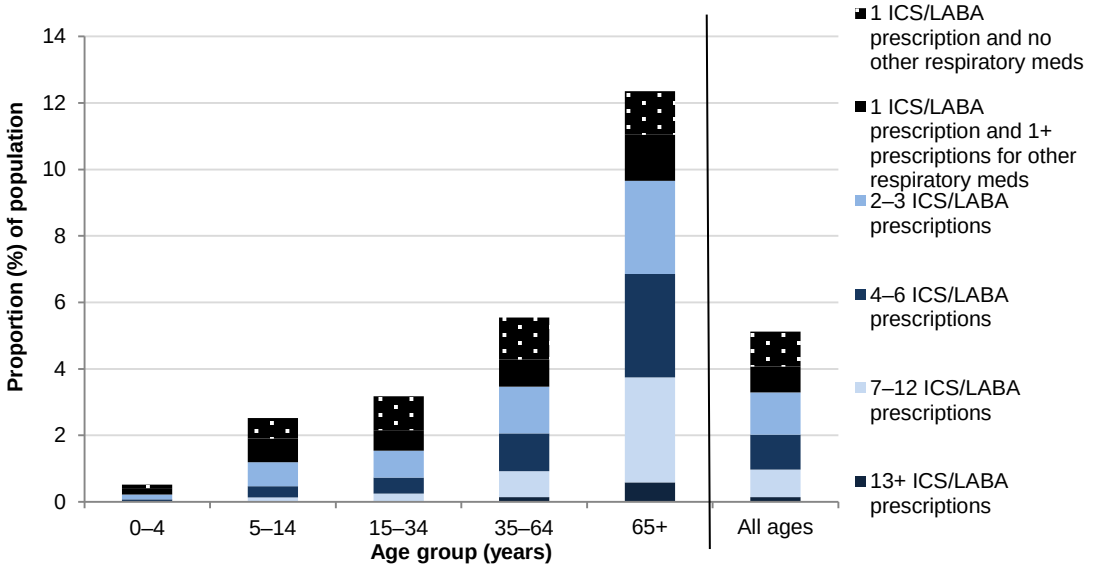
Table 3.5: Number and proportion of the population dispensed inhaled corticosteroids and long-acting beta$_2$-agonists as combination therapy, by demographic characteristics, Australia, 2013

	All ages		Children (aged 0–14)		Adults (aged 15 and over)	
Demographic characteristics	**Number**	**Per cent**	**Number**	**Per cent**	**Number**	**Per cent**
Sex						
Male	505,952	4.6	46,060	2.1	459,892	5.1
Female	638,002	5.7	31,552	1.5	606,450	6.6
Age group (years)						
0–4	7,547	0.5	7,547	0.5	. .	. .
5–14	70,065	2.5	70,065	2.5	. .	. .
15–34	198,861	3.2	. .	. .	198,861	3.2
35–64	486,068	5.5	. .	. .	486,068	5.5
65 and over	381,412	12.4	. .	. .	381,412	12.4
Socioeconomic status						
SES 1 (Lowest)	201,250	4.5	13,421	1.5	187,829	5.3
2	217,276	4.9	13,612	1.6	203,664	5.6
3	224,037	5.1	15,179	1.9	208,858	5.8
4	226,907	5.0	15,752	1.8	211,155	5.8
SES 5 (Highest)	262,104	5.8	18,961	2.3	243,143	6.5
Remoteness category						
Major cities	784,070	5.0	54,981	1.9	729,089	5.7
Inner regional	230,020	5.6	14,144	1.7	215,876	6.5
Outer regional	102,931	5.1	6,673	1.6	96,258	6.0
Remote	11,573	3.7	915	1.4	10,658	4.3
Very remote	4,037	2.0	285	0.6	3,752	2.5
State/territory						
NSW	397,442	5.5	28,052	2.1	369,390	6.3
Vic	276,487	5.0	17,504	1.7	258,983	5.7
Qld	231,363	5.2	15,526	1.7	215,837	6.0
WA	103,848	4.4	7,564	1.7	96,284	5.1
SA	82,868	5.1	5,146	1.8	77,722	5.8
Tas	28,554	5.6	2,238	2.3	26,316	6.3
ACT	17,770	4.8	1,267	1.9	16,503	5.5
NT	5,468	2.4	300	0.6	5,168	2.9
All people	**1,144,223**	**5.1**	**77,612**	**1.8**	**1,066,611**	**5.9**

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

The supply of combination ICS/LABA medications increased with increasing age. Among people aged 65 years and over, 12.4% were dispensed combined therapy during 2013 compared to 1.8% of children aged 0–14. Dispensing of combination ICS/LABA therapy was higher among boys than girls, adult females than adult males, and those living in areas of higher socioeconomic status compared with lower socioeconomic status. It was also higher among those living in major cities and regional centres compared to those in remote localities, and lower in the Northern Territory than in other states and territories of Australia (Table 3.5). A possible explanation for the latter two of these findings is that remote localities, particularly in the Northern Territory and Western Australia, have the highest proportions of Indigenous people in their populations (81% and 41% respectively, in 2006); also, the Northern Territory as a whole has the highest proportion of Indigenous people in its population compared with other states and territories (30% Indigenous population in 2011) (ABS 2007, 2014). Indigenous people may obtain medications through Aboriginal Health Services that are not recorded on the PBS and therefore absent in the analyses presented here.

People aged 65 years and over had the highest frequency of dispensing of prescriptions for combination ICS/LABA therapy (Figure 3.11). In 2013, 30.3% of people aged 65 and over who had any combination ICS/LABA therapy dispensed had 7 or more prescriptions dispensed. In contrast, among younger individuals who were dispensed combination ICS/LABA therapy, 4.4% of children aged 0–4 and 16.7% of people aged 35–64 were dispensed 7 or more prescriptions for combination ICS/LABA therapy in 2013. Again, it is likely that this reflects the shorter term use of these medications in children. Further, 4.8% of people aged 65 and over had 13 or more prescriptions for combination ICS/LABA therapy dispensed in 2013 compared to only 0.3% of children aged 0–4 and 2.6% of people aged 35–64 years. This dispensing frequency equates to more than one prescription per month which again may be explained by prescribing of higher-than-standard doses and/or overuse by patients.



Notes: Drugs included are listed in Table A1.2.

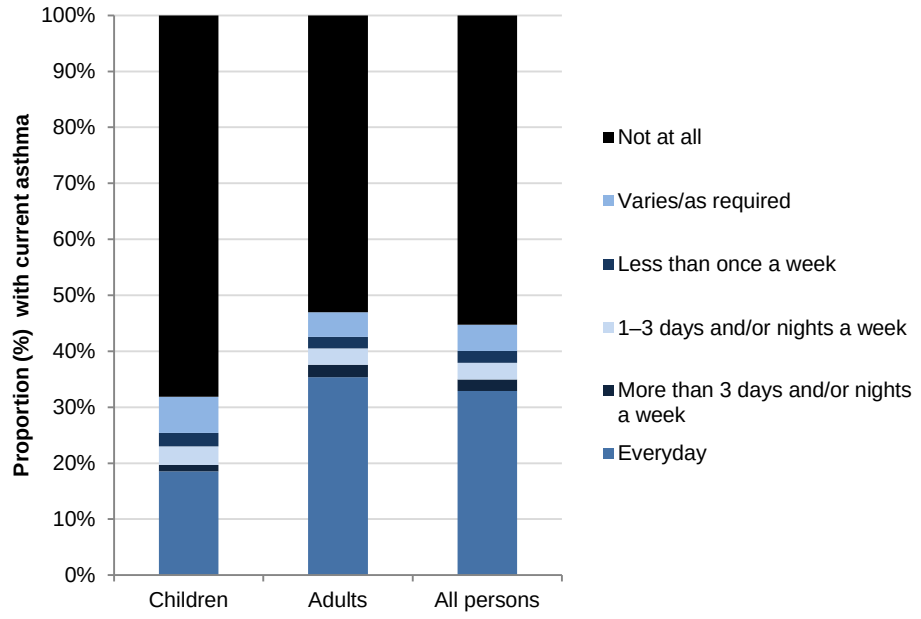
Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Figure 3.11: Proportion of the population dispensed ICS/LABA combined formulations, by age and number of prescriptions, Australia, 2013

Self-reported use of ICS for asthma (NSW Health Survey)

We further investigated the use of ICS in people with asthma using data from the NSW Health Survey. Unlike PBS data, these survey data are linked to diagnostic information (people with current asthma—that is, ever diagnosed with asthma and having asthma symptoms or treatment in the previous 12 months). Survey data may be a more valid reflection of whether the medication was actually taken by the respondent since many medications that are dispensed (and hence recorded in the PBS dataset) are not actually taken by the patients to whom they are prescribed (Andrade et al. 2006; Foster et al. 2011). On the other hand, the information is based on participants' recall of medications taken in the preceding month and hence may be subject to recall error and, potentially, bias.

Among children aged 2–14 years in NSW who reported having current asthma, 31.9% reported using any ICS medication in the previous 4 weeks (Figure 3.12). In terms of frequency of use, 18.5% reported using ICS medication every day in the previous 4 weeks and a further 1.1% reported using it more than 3 days or nights in the previous 4 weeks. However, 3.3% reported using ICS 1–3 days/week, 2.4% less than 1 day per week, and 6.4% selected the response option 'varies/as required'. The majority (68.1%) of children using any asthma medication in the last 12 months reported not using any ICS in the previous 4 weeks.



Notes

1. Children aged 2–14, adults aged 15 and over.
2. Current asthma includes people who report ever being diagnosed with asthma by a doctor and having taken asthma medication or experienced asthma symptoms in the last 12 months.
3. 'Not at all' includes people with current asthma who reported that:
   - they took ICS in the last 12 months, but not in the last 4 weeks;
   - they did not take ICS in the last 12 months; and
   - they did not take any medications for their asthma in the last 12 months but qualified as having current asthma on the basis of experiencing symptoms of asthma in the last 12 months.

Source: NSW Health Survey Program, NSW Ministry of Health 2009, 2010, 2012.

Figure 3.12: The proportion of children and adults with current asthma, by self-reported frequency of ICS use in the last 4 weeks, people aged 2 and over, NSW, 2009, 2010 and 2012 (combined data)

More adults than children reported using any ICS in the last 4 weeks (47.0%; Figure 3.11). Adults also reported using ICS more frequently than children. Among adults in NSW with

current asthma, 35.3% reported using an ICS medication every day in the previous 4 weeks and 2.2% reported using it more than 3 days and/or nights a week in the previous 4 weeks. However, 2.9% reported using their ICS only 1–3 days/week, 2.1% less than 1 day/week, and 4.4% selected 'varies/as required'. More than one-half (53.0%) of adults with current asthma reported not using ICS at all in the previous 4 weeks.

A recent Australian survey of a nationally representative population of 2,686 people aged over 15 years with current asthma found that 60.0% of participants reported using ICS-containing medication in the previous year. Of these, only 52.8% reported using the medication every day (Reddel et al. 2014). We found that 47.0% of adults with current asthma reported using any ICS medication in the last 4 weeks, and 75% of these adults who took any ICS in the past month reported using the medication every day during that period. The difference in the proportion reporting daily use may be due to the different 'time window' in which ICS use was sampled: 1 month versus 12 months. In fact, the actual prevalence of daily use of ICS in people with asthma may be even lower than reported here, as patient self-report is known to overestimate actual use as assessed from electronic recordings (Foster et al. 2011).

Oral corticosteroids

Among all people who were dispensed any medications indicated for the treatment of obstructive airways disease in 2013, 17.5% had also been dispensed OCS. This represents 1.6% of Australians (Table 3.6), including 1.8% of children aged 0–14 years and 1.5% of adults. Boys were dispensed more OCS than girls (2.2% versus 1.4%) and women (1.8%) were dispensed more OCS than men (1.2%).

For almost all patients with asthma and most patients with COPD, OCS are only used for short-term treatment of flare-ups or exacerbations. Guidelines for both asthma and COPD recommend that patients should be provided with a written action plan, with advice about starting oral corticosteroids (and, in the case of COPD, antibiotics) for severe flare-ups. Therefore, by contrast with ICS, frequent dispensing of OCS for either asthma or COPD indicates *poor* control of the disease.

Table 3.6: Proportion of population dispensed systemic (including oral) corticosteroids as well as other respiratory medications, by demographic characteristics, 2013

Demographic characteristics	All ages		Children (aged 0–14)		Adults (aged 15 and over)	
	Number	Per cent	Number	Per cent	Number	Per cent
Sex						
Male	158,547	1.4	47,863	2.2	110,684	1.2
Female	198,138	1.8	29,000	1.4	169,138	1.8
Age group						
0–4 years	30,319	2.1	30,319	2.1	. .	. .
5–14 years	46,544	1.7	46,544	1.7	. .	. .
15–34 years	34,696	0.6	. .	. .	34,696	0.6
35–64 years	116,405	1.3	. .	. .	116,405	1.3
65 years and over	128,721	4.2	. .	. .	128,721	4.2
Socioeconomic status						
SES 1 (Lowest)	72,313	1.6	15,110	1.7	57,203	1.6
2	72,699	1.6	14,342	1.7	58,357	1.6
3	71,146	1.6	15,303	1.9	55,843	1.6
4	68,414	1.5	14,968	1.7	53,446	1.5
SES 5 (Highest)	68,661	1.5	16,460	2.0	52,201	1.4
Remoteness category						
Major cities	236,186	1.5	54,434	1.9	181,752	1.4
Inner regional	76,985	1.9	14,190	1.8	62,795	1.9
Outer regional	35,376	1.7	6,653	1.6	28,723	1.8
Remote	3,741	1.2	735	1.6	3,006	1.2
Very remote	1,255	0.6	236	0.5	1,019	0.7
State/territory						
NSW	119,034	1.6	29,676	2.2	89,358	1.5
Vic	92,099	1.7	17,562	1.7	74,537	1.6
Qld	73,418	1.6	15,449	1.7	57,969	1.6
WA	26,783	1.1	5,430	1.2	21,353	1.1
SA	30,242	1.8	5,603	1.9	24,639	1.8
Tas	9,097	1.8	1,639	1.7	7,458	1.8
ACT	4,082	1.1	1,086	1.6	2,996	1.0
NT	1,883	0.8	401	0.8	1,482	0.8
All people	**356,751**	**1.6**	**76,863**	**1.8**	**279,888**	**1.5**

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

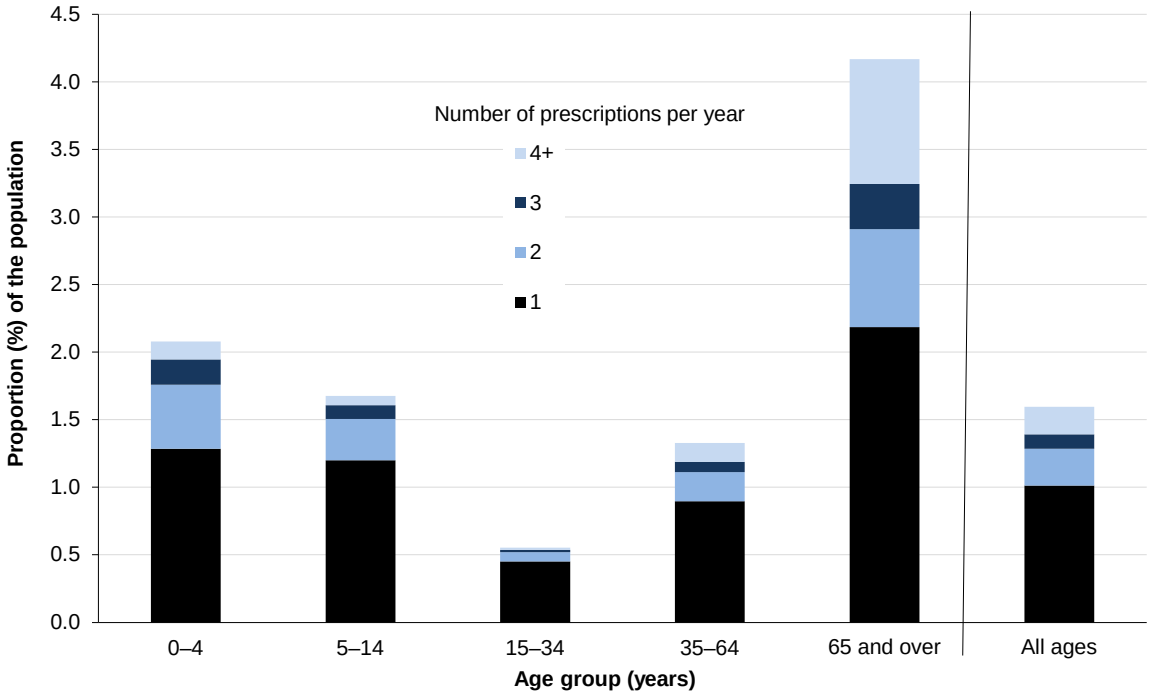
Children, particularly young children aged 0–4 years, and older Australians aged 65 and over, were most likely to have used OCS (Figure 3.13). The majority (87.2%) of people who

had OCS dispensed in 2013 as well as a medication used in the treatment of obstructive airways disease only had 1–3 prescriptions of OCS dispensed. In this subgroup of Australians, 63.4% had only 1 OCS prescription dispensed in the year.

Among children aged 0–4 years receiving OCS and other respiratory medications, 6.4% received 4 or more prescriptions in a year, implying frequent disease exacerbations or episodes and a significant risk of adverse effects in this group. Use of 4 or more courses of OCS in a year by children aged 4–17 years has been associated with an increased risk of bone fracture (van Staa et al. 2003).

Having 4 or more prescriptions for OCS dispensed during one year was most common in the oldest age group. Among people aged 65 and over, 22.3% of those who were dispensed any OCS were dispensed 4 or more OCS in a year, suggesting the possibility that these patients were having frequent exacerbations of obstructive airways disease. Other possible explanations are that OCS was prescribed for long-term treatment of COPD or for another indication, for example, rheumatoid arthritis.

As indicated in Chapter 2, PBS data do not include clinical information about the illness for which a specific medication was prescribed. This is a particular limitation for our OCS analyses, because this medication class is also indicated for a wide range of conditions other than respiratory disease. As a partial solution to this problem we only included PBS records of individuals who were dispensed at least one other medication for the treatment of obstructive airways disease. However, this approach does not completely solve the problem as children may be prescribed OCS treatment and SABA for non-asthma conditions such as croup. Many older patients have multiple co-morbid conditions and it is possible that a person receiving treatment for obstructive airways disease and, for example, rheumatoid arthritis, may have been prescribed a course of OCS as treatment for an exacerbation of either of these conditions. Nonetheless, this approach does provide some indication about the patterns of use of OCS among people with respiratory disease, within the limitations posed by the available data.



Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Figure 3.13: Proportion of people dispensed OCS as well as any respiratory medication, by age and number of prescriptions, Australia, 2013

Long-acting bronchodilators (LABA and LAMA) prescribed without ICS

In 2013, LABA-only inhalers were dispensed to only 0.06% of the Australian population—0.07% of adults and 0.01% of children. Of all the LABA prescriptions dispensed (including prescriptions for ICS/LABA combination therapy), only 1.2% were dispensed as single medication inhalers in 2013 (0.3% of prescriptions among children and 1.3% among adults). In 2013, 0.02% of the Australian population were dispensed LABA-only inhalers without any ICS.

For people with asthma, guidelines recommend strongly against the use of LABA alone (without ICS), and when addition of LABA to ICS is indicated, recommend that wherever possible it should be prescribed as a combination ICS/LABA inhaler (NACA 2015). A small proportion of patients with asthma may require treatment with separate ICS and LABA inhalers, for example, if they require a specific ICS formulation that is not available in a combination inhaler. However, this is an uncommon situation in clinical practice.

In contrast with asthma, COPD guidelines recommend LABA use alone as one of the options for treatment in people with mild or moderate COPD, and that these medications should be used before initiating ICS/LABA treatment. However, we found that prescription for LABA-alone inhalers is rare in Australia, with only 0.06% of the Australian population dispensed LABA with no ICS. The use of LABA-only inhalers is reassuringly low in children (almost

zero) and young adults, but is also low in older people, which is the population in which COPD is diagnosed.

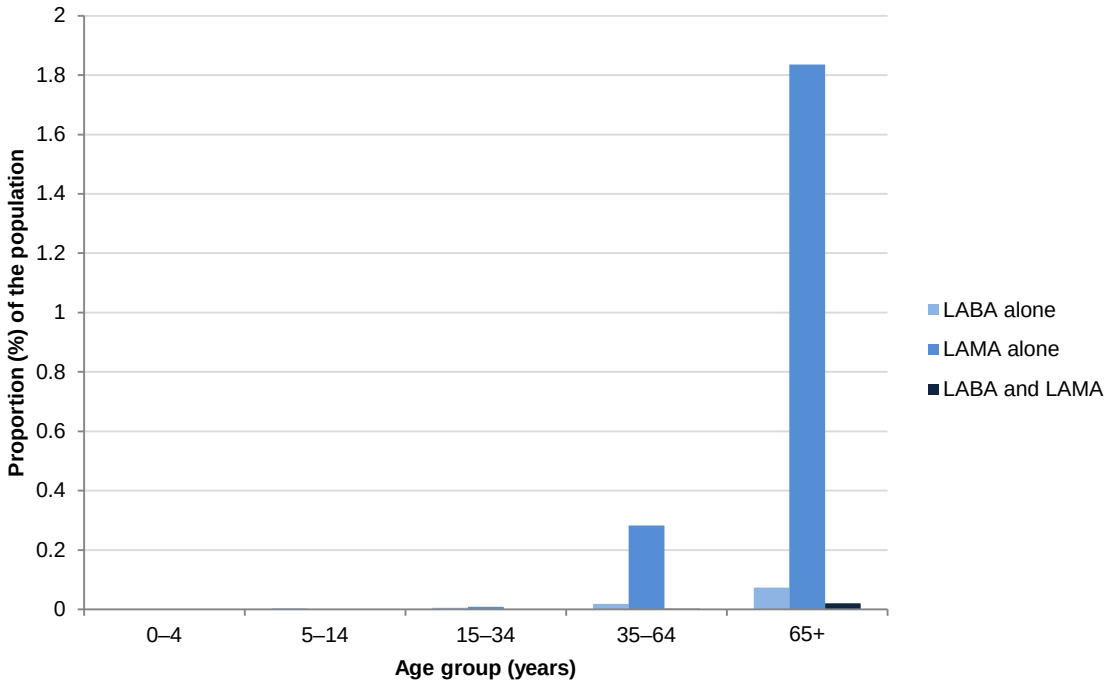
In 2013, the proportion of the Australian population dispensed LAMA was 1.2%, while 0.4% received LAMA and no ICS during the year.

LAMA are currently indicated in Australia only for COPD, where they can be prescribed for mild to moderate COPD as an alternative to, or in addition to, LABA, or in addition to ICS/LABA combinations for severe COPD. Data from a population-based lung function survey conducted in Australia show that the prevalence of mild to moderate COPD (GOLD stage II) among people aged 40 years and over was 6.6%, and that of severe COPD (GOLD stage III or IV) was 0.9% (Toelle et al. 2013).

In 2013, we found that LAMA inhalers were dispensed to 1.2% of Australians, with only one-third of these received by patients who did not receive any ICS in the same year. Among older patients, 1.8% of Australians aged 65 years and over were dispensed LAMA inhalers and 0.07% were dispensed LABA inhalers in 2013. The total use of LABA or LAMA estimated in this report (1.87% of Australians aged 65 years and over) is probably inappropriately low in older adults given that they are recommended either separately or together as first line treatment for COPD in the COPD-X guidelines.

The proportion dispensed both LABA and LAMA during the year but with no ICS during the same period was 0.004%.

The proportion of the population dispensed LABA and/or LAMA without ICS increased with age (Figure 3.14). In 2013, among people aged 65 years and over, 1.8% were dispensed LAMA without ICS, and 0.07% were dispensed LABA without ICS. In this age group 0.02% were dispensed both LABA and LAMA but no ICS in 2013 (Figure 3.14). Of the 1,150 people aged less than 35 years who were dispensed any LABA-only inhalers in 2013 (presumably for asthma, given their age), 484 (42%) were not dispensed any ICS in the same year (118 aged 0–14 years and 366 aged 15–34 years). If these young adults and children have asthma, they would be at high risk of serious asthma outcomes, including asthma-related hospitalisation or death.

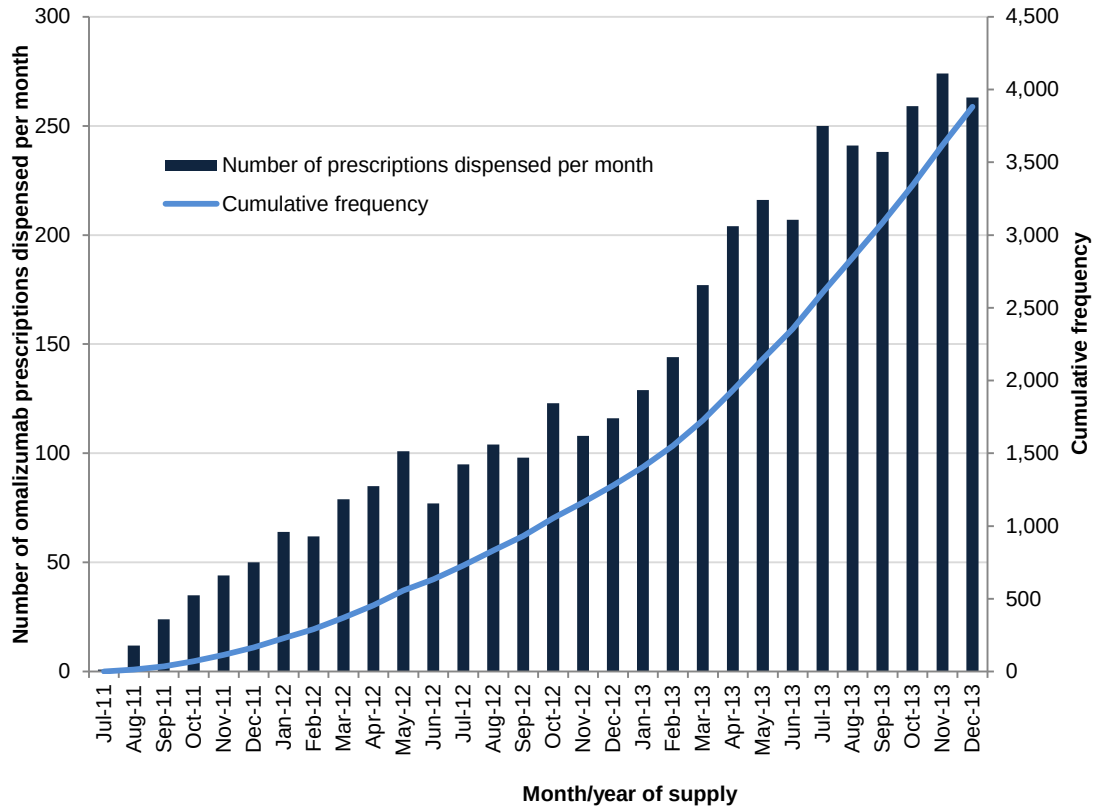


Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Figure 3.14: Proportion of the population dispensed LABA, LAMA or both LABA and LAMA, without any ICS within the same year, by age, Australia, 2013

Anti-immunoglobulin E therapy (omalizumab)

Between July 2011 and December 2013 there were 3,880 prescriptions for omalizumab dispensed to 358 patients by 144 prescribers. Prescriptions dispensed for omalizumab have steadily increased since it became listed on the PBS in July 2011 (Figure 3.15), but the use of this new medication is quite rare in Australia with only 298 people (0.001% of the population) accessing the drug in 2013.

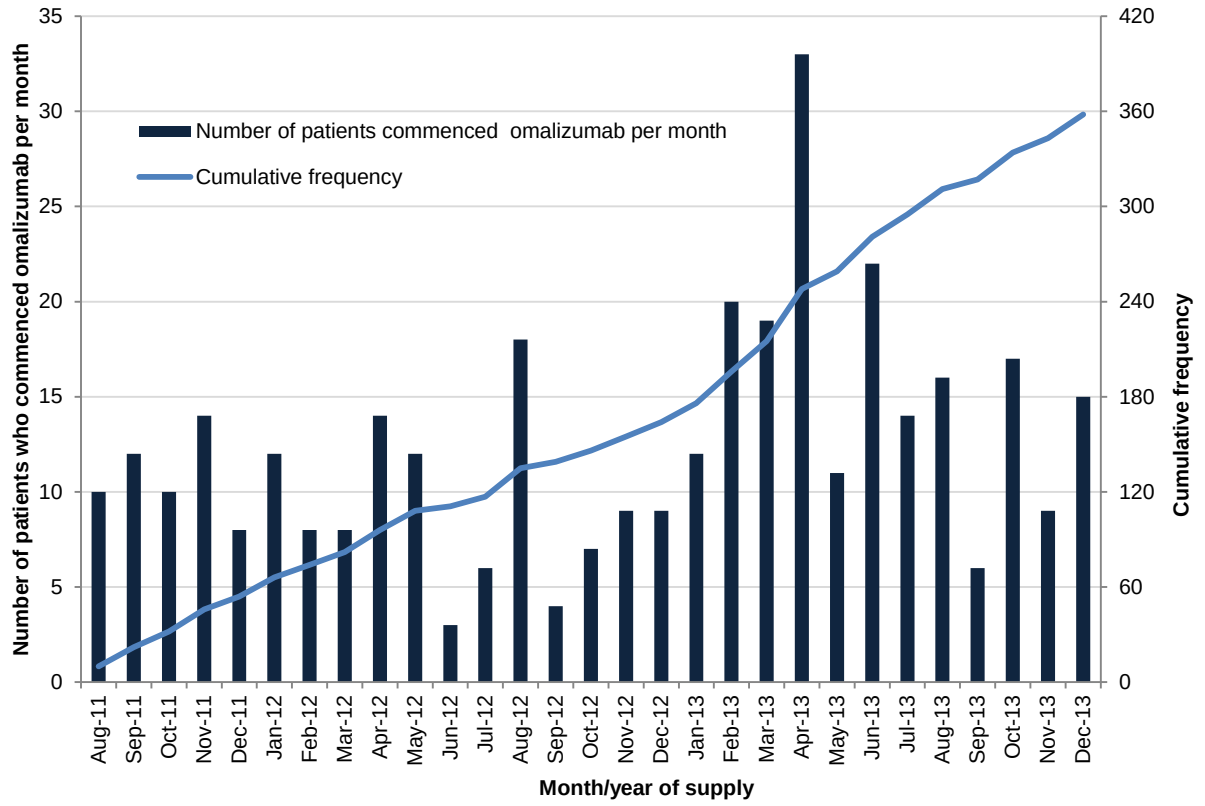


Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.15: Number of PBS prescriptions for omalizumab dispensed since its PBS listing, by month, Australia, July 2011 to December 2013.

The number of patients commencing treatment with omalizumab has varied, with a range of 3–33 new patients per month starting treatment with the drug between July 2011 and December 2013 (Figure 3.16).

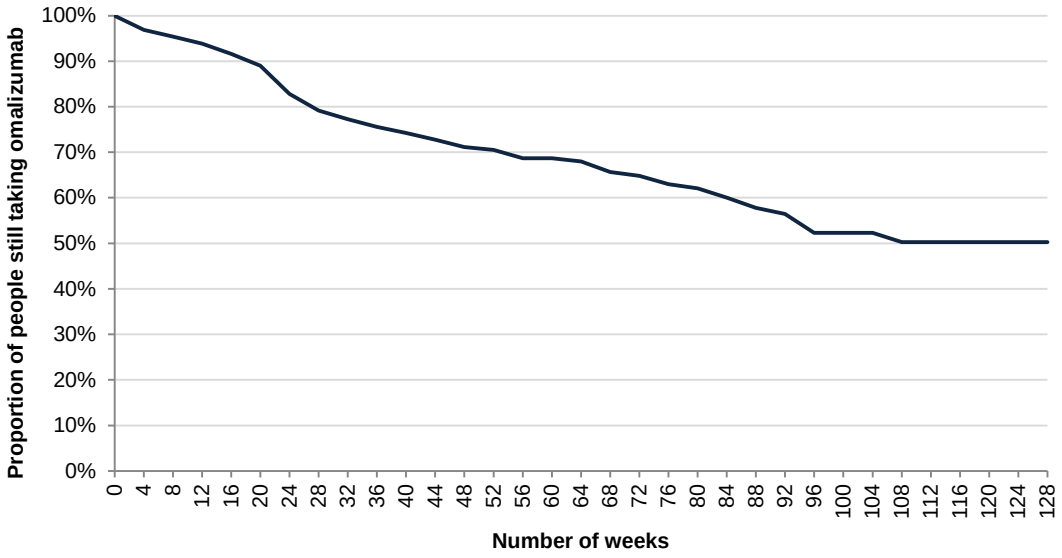
Of patients dispensed omalizumab between July 2011 and December 2013, 60.8% were female, consistent with asthma and severe asthma being more common among women than men. Most omalizumab prescriptions (67.8%) were for people aged 35–64 years, while 12.3% were dispensed to people aged 15–34 years.



Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.16: Number of new patients commencing PBS-subsidised omalizumab by month, Australia, August 2011 to December 2013

There was a steady decline in the number of patients taking omalizumab each month after their initial prescription. Of the 358 patients who received therapy between July 2011 and December 2013, 20.8% had discontinued the drug before they had received 28 weeks of treatment. This would include patients whose treatment was stopped early by either the physician or the patient, as well as those patients who did not meet the PBS criteria for continuation of treatment.



Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.17: Proportion of people dispensed PBS-subsidised omalizumab, by number of weeks since their initial dispensing, Australia, July 2011 to December 2013

The treatment involves injections every 2–4 weeks. This is an expensive medication (the cost to Government is approximately $1,071 per script) and eligibility criteria for the PBS subsidy are stringent. Eligibility for continuing treatment is assessed every 6 months.

We found that by 108 weeks, over one-half of patients initially prescribed omalizumab had discontinued treatment (Figure 3.17). This may have been because of side effects, the burden of attending for injections every 2–4 weeks or failure to respond to the treatment. Some patients recorded as having commenced therapy with omalizumab in 2011 had actually been receiving it outside the PBS prior to July 2011. For those individuals, this estimate of duration of therapy will be an underestimate.

Further information about omalizumab usage has been published by the Drug Utilisation Sub-Committee (DUSC), who assessed predicted versus actual usage of the drug based on analysis of the Department of Human Services (DHS) Authority Approvals Database (DUSC 2014). In the first year of listing (1 July 2011 to 30 June 2012) 148 patients received an authority approval for omalizumab, and in the second year of listing 156 new patients received an authority approval. This gives a total of 304 patients in the first 2 years of listing, compared with 282 patients from our PBS analysis. The difference of 22 patients may be due to a lag between obtaining authority approval and having the drug dispensed, a decision to not proceed with treatment, or incomplete public hospital records (from where most of this drug would have been dispensed) prior to the introduction of a mandatory online system for PBS claims in July 2013.

The DUSC report also indicates that 81% of patients who had received an initial authority prescription for omalizumab on or before 30 June 2013 received an authority approval for continuation of treatment with the drug. In order for treatment to continue, patients must have shown evidence of clinical improvement before week 24. This supports our finding that only 20.8% of patients who initiated omalizumab treatment discontinued it before 28 weeks (when the initial supply would have been completed).

Leukotriene receptor antagonists

There were 44,453 children aged 0–14 (1.05% of all children in Australia) who were dispensed LTRA in 2013 (Table 3.7).

Among these, a high proportion were also dispensed ICS during that year. There were 15,489 children who were dispensed LTRA as well as ICS in 2013, representing 0.4% of all children in Australia and 34.8% of children who were dispensed LTRA.

More boys (1.2%) than girls (0.9%) were dispensed LTRA. The proportion of children dispensed LTRA was highest among those with higher socioeconomic status and was least common in *Remote/Very remote* areas.

Table 3.7: Proportion of children dispensed leukotriene receptor antagonists, by demographic characteristics, 2013

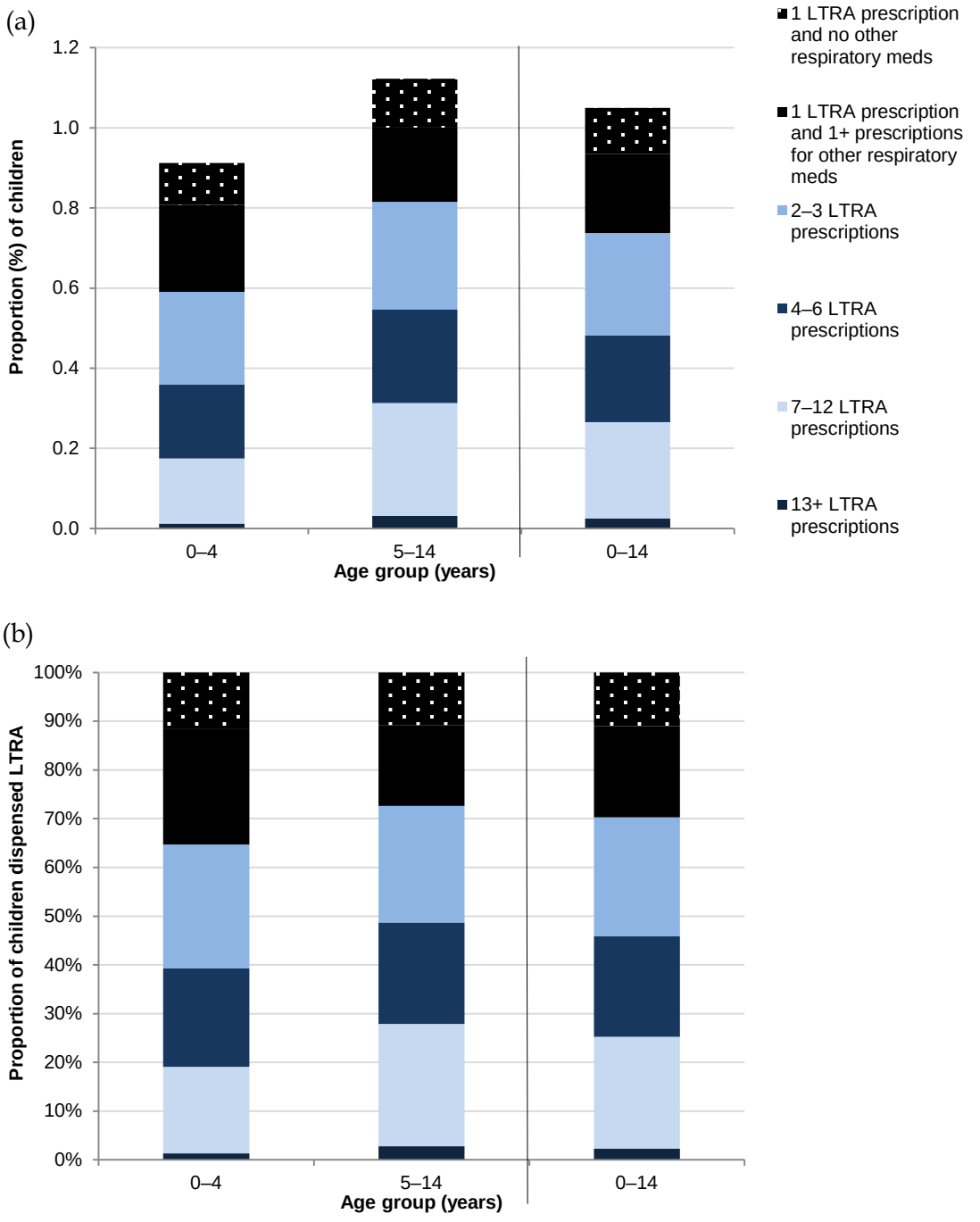
	Children (aged 0–14)	
Demographic characteristics	**Number**	**Per cent**
Sex		
Male	26,656	1.23
Female	17,797	0.86
Age group		
0–4 years	13,304	0.91
5–14 years	31,149	1.12
Socioeconomic status		
SES 1 (Lowest)	7,919	0.89
2	8,415	1.00
3	9,132	1.12
4	8,644	1.01
SES 5 (Highest)	9,939	1.22
Remoteness category		
Major cities	29,762	1.03
Inner regional	9,753	1.21
Outer regional	3,915	1.00
Remote/Very remote	654	0.57
State/Territory		
NSW	16,382	1.20
Vic	8,407	0.83
Qld	9,986	1.12
WA	4,485	1.00
SA	2,992	1.03
Tas	1,126	1.17
ACT	896	1.34
NT	162	0.31
All children	**44,453**	**1.05**

Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Of children aged 0–14 years in Australia, just over 1% were supplied one or more LTRA prescriptions in 2013 (Figure 3.18a). This proportion was slightly lower among children aged 0–4 and slightly higher among those aged 5–14.

As we found with inhaled medications, approximately 30% of children receiving any LTRA were only dispensed 1 script in any given year (Figure 3.18b). This proportion was slightly higher among children aged 0–4 (35.3%) and slightly lower among those aged 5–14 (27.4%). Just over half of children receiving any LTRA were dispensed 1–3 prescriptions in a year. In

2013, around 27% of children receiving any LTRA had received 7 or more prescriptions for the drug in that year.

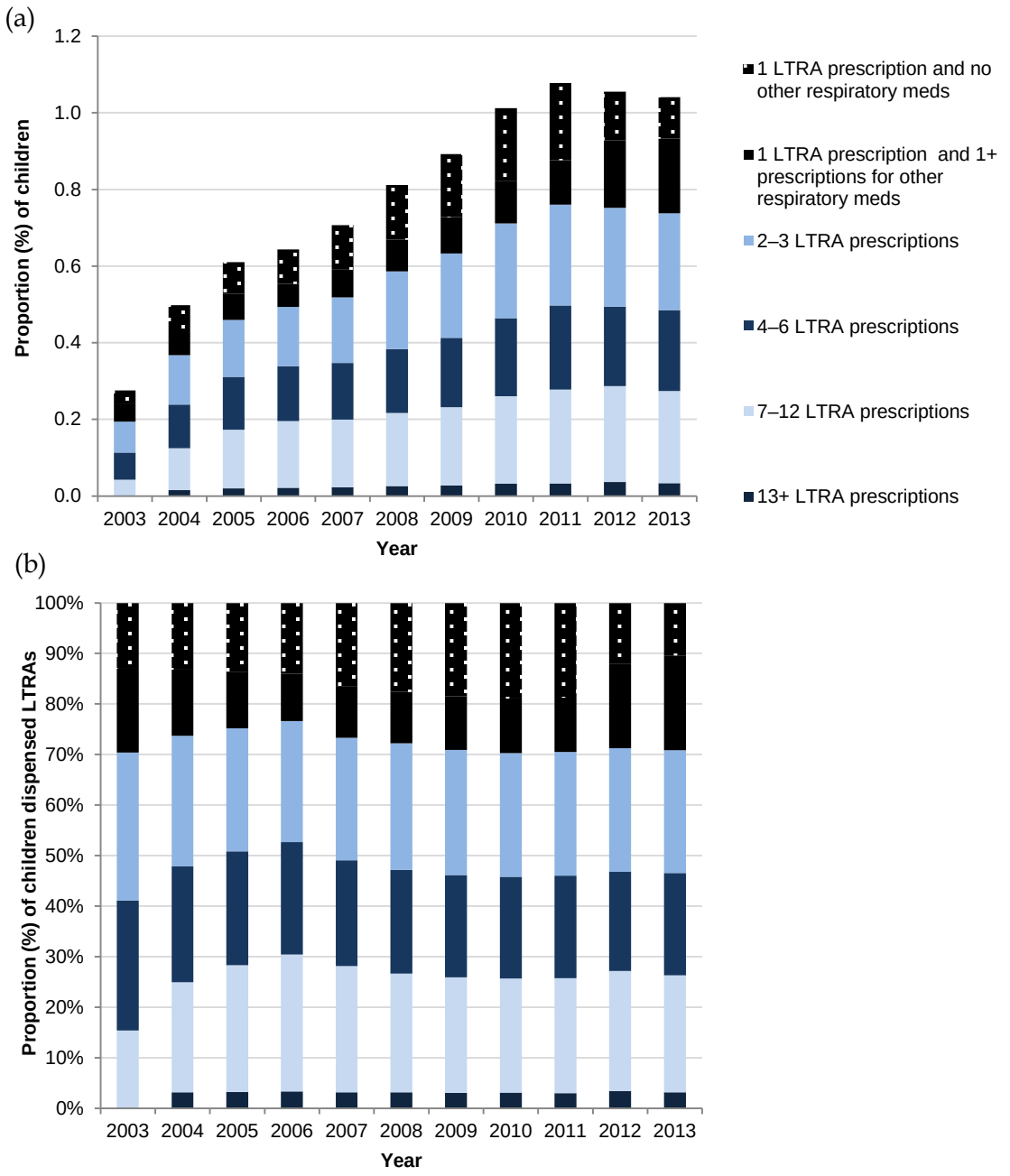


Source: Pharmaceutical Benefits Scheme Database, Department of Health.

Figure 3.18: Children aged 0–14 dispensed leukotriene receptor antagonists (LTRA) as a proportion of (a) all children in Australia and (b) those dispensed LTRA, by number of LTRA prescriptions dispensed per child in a year and age, Australia, 2013

The proportion of children aged 0–14 years who were dispensed LTRAs increased from 2004 to 2011 and then decreased slightly in 2012 and 2013 (Figure 3.19).

LTRA are occasionally used in adults with asthma, for example as an add-on treatment for patients with severe asthma; this use is not subsidised by the PBS so there are no data available on this type of LTRA use by adults.



Sources: Pharmaceutical Benefits Scheme Database, Department of Health; Estimated Resident Population, Australian Bureau of Statistics.

Figure 3.19: Children aged 0–14 dispensed leukotriene receptor antagonists (LTRA) as a proportion of (a) all children in Australia and (b) those who were dispensed LTRA, by number of prescriptions dispensed per child and year, Australia, 2003–2013

Use of asthma medication in children (LSAC data)

Analysis of data from the 2012 follow-up of children from the Longitudinal Study of Australian Children (LSAC) showed that 53.0% of children aged 8–9 years with parent-reported doctor diagnosis of asthma at any LSAC interview ('ever-diagnosed asthma') had reportedly used asthma medications in the last 12 months (Table 3.8). Among these children, 25.4% had a PBS record of any preventer medication (ICS, cromones and/or LTRA) having been dispensed at least once in the preceding two years. Among older children aged 12–13 years ever diagnosed with asthma, 42.1% of parents reported that their child had used asthma medication(s) in the last 12 months, while only 21.8% of these children had a PBS record of preventer medications being dispensed since the previous interview.

For both age groups, the reported use of asthma medications was much higher than the proportion dispensed medications indicated for the treatment of asthma through the PBS. The difference could be due to the purchase of medications over the counter (SABA) or due to the cost of the medications prescribed being below the general co-payment (for example, SABA or low-dose ICS), neither of which would have been captured in the PBS database in the relevant time period. It is also possible that parents may have incorrectly recalled their child's use of medications for asthma or overstated or understated the presence of asthma.

Table 3.8: Prevalence of asthma medication use among children from the Longitudinal Study of Australian Children (LSAC), with parent-reported ('ever-diagnosed') asthma, 2012

Type of asthma medication dispensed[a]	Age 8–9 years		Age 12–13 years	
	Number of children (n=1,123)	Prevalence per 100 children at risk[b] (95% CI)	Number of children (n=1,353)	Prevalence per 100 children at risk[c] (95% CI)
Any ICS	239	20.8 (18.3–23.2)	270	19.4 (17.2–21.5)
ICS-only inhaler	104	9.9 (8.0–11.7)	65	5.0 (3.7–6.4)
ICS in combination with long-acting beta agonists (LABA)	155	13.1 (11.0–15.2)	221	15.7 (13.7–17.6)
Cromones	7	0.9 (0.1–1.6)	9	0.8 (0.2–1.4)
LTRA	87	7.2 (5.6–8.8)	46	3.4 (2.4–4.4)
Any of the above medications	292	25.4 (22.7–28.0)	302	21.8 (19.6–24.1)
Parent-reported use of medication for child with asthma in last 12 months[d]	596	53.0 (49.6–56.3)	592	42.1 (39.3–45.0)

(a) Information collected from PBS-linked data for medications dispensed between LSAC Wave 4 (2010–2011) and Wave 5 (March 2012 to May 2013). Does not include over-the-counter items and items that cost less than the general patient co-payment, in particular short-acting beta agonists (such as Ventolin) and OCS (such as Prednisone).

(b) Weighted to the Australian population aged 8–9 years as at March 2012.

(c) Weighted to the Australian population aged 12–13 years as at March 2012.

(d) Information collected at 8-year follow-up from questionnaire (2012/LSAC Wave 5).

Note: Some children may have received more than one type of ICS within the study period, therefore, the sum of 'any ICS' does not necessarily equal the sum of 'ICS-only inhaler' and 'ICS in combination with LABAs'.

Source: Growing up in Australia: the Longitudinal Study of Australian Children (LSAC).

It is difficult to diagnose asthma with certainty among infants, as wheezing with respiratory infections is common in infancy. The longer the duration of an individual wheezing episode, the more likely it is that the child will turn out to have asthma, so we also investigated the use of asthma medication among those who had an illness with wheezing in the chest that lasted for a week or more in the last 12 months.

Among children whose parents had reported they had an illness with wheezing in the chest that lasted for a week or more in the last 12 months, 60.0% of those aged 8–9 years and 63.4% of those aged 12–13 years had used medication for their asthma. According to PBS records of dispensed medication in these children in the previous 2 years, 26.9% of those aged 8–9 and 31.3% of those aged 12–13 years were dispensed ICS, while 7.2% of the younger cohort and 4.4% of the older cohort had been dispensed LTRA. More of the younger children had been dispensed ICS inhalers (12.1% in those aged 8–9 compared to 8.8% among those aged 12–13 years) while a higher proportion of the older cohort were dispensed ICS/LABA inhalers (25.0% in those aged 12–13 and 17.7% in those aged 8–9 years) (Table 3.9).

Table 3.9: Prevalence of asthma medication use among children from the Longitudinal Study of Australian Children (LSAC) with one or more parent-reported wheezing episodes lasting a week or more in the last 12 months, 2012

	Age 8–9 years		Age 12–13 years	
Type of asthma medication dispensed[(a)]	**Number of children (n=499)**	**Prevalence per 100 children with wheezing**[(b)] **(95% CI)**	**Number of children (n=380)**	**Prevalence per 100 children with wheezing**[(c)] **(95% CI)**
Any ICS	143	26.9 (22.9–30.9)	125	31.3 (26.1–36.4)
ICS-only inhaler	62	12.1 (9.2–15.0)	33	8.8 (5.7–11.9)
ICS in combination with long-acting beta$_2$-agonists (LABA)	94	17.7 (14.3–21.1)	102	25.0 (20.3–29.8)
Cromones	4	1.0 (0.0–2.0)	5	1.3 (0.2–2.5)
Leukotriene Receptor Antagonists	39	7.2 (4.7–9.6)	22	4.4 (2.5–6.3)
Any of the above medications	161	30.4 (26.3–34.5)	137	33.6 (28.3–39.0)
Parent-reported use of medication for asthma in child with recent wheeze in last 12 months[(d)]	300	60.0 (55.1–65.0)	238	63.4 (58.1–68.6)

(a) Information collected from PBS-linked data for medications dispensed between LSAC Wave 4 (2010–2011) and Wave 5 (March 2012 to May 2013). Does not include over-the-counter items and items that cost less than the general patient co-payment, in particular short-acting beta2-agonists (such as Ventolin), some ICS alone (particularly low doses) and OCS (such as Prednisone).

(b) Weighted to the Australian population aged 8–9 years as at March 2012.

(c) Weighted to the Australian population aged 12–13 years as at March 2012.

(d) Information collected at 8 year follow-up from questionnaire (2012/LSAC Wave 5, interviews conducted between March 2012 and May 2013). Positive answer to the question 'In the last 12 months has <study child> had an illness with wheezing in the chest which lasted for a week or more?'.

Note: Some children may have received more than one type of ICS within the study period, therefore, the sum of 'any ICS' does not necessarily equal the sum of 'ICS-only inhaler' and 'ICS in combination with LABA'.

Source: Growing up in Australia: the Longitudinal Study of Australian Children (LSAC).

4 Discussion and implications

This report presents evidence suggesting significant gaps in the quality of use of medications for treatment of asthma and COPD in Australia. The problems we have highlighted include evidence of substantial over- and under-use of certain classes of medications when compared to Australian guidelines for the appropriate use of these medications. These findings are important, both in terms of the missed opportunities for improved disease control and the additional cost burden and risk of adverse effects that they impose.

It is likely, based on the analysis presented in this report, that a substantial number of prescriptions for ICS/LABA and for the most potent formulations of ICS are dispensed to people for whom treatment with less potent formulations of ICS alone would be effective. This practice leads to substantial extra and unnecessary costs to governments and patients, and may expose patients to unnecessary risks of adverse effects. The challenge, for both policy and monitoring, is to identify those who require the addition of LABA and/or more potent formulations of ICS, and those who do not.

The data presented in this report also show that many people are dispensed ICS-containing medications sporadically. This is not consistent with any existing guidelines for use of this class of medication, and is also not consistent with evidence about their effective use. This sporadic dispensing appears to arise from two causes:

1. Inappropriate one-off dispensing of ICS-containing medications for acute respiratory illness, for which there is no evidence of benefit. We previously estimated that the potential cost to government of inappropriate one-off prescriptions for ICS-containing medications was almost $3 million (for concession card holders alone in one year) (Poulos et al. 2013).
2. Failure to prescribe, or to adhere to prescriptions for, regular ICS-containing medications for people with obstructive airways disease. This is the group of people with persistent asthma and/or severe COPD with flare-ups who are likely to benefit from regular use of this class of medications (but not from sporadic use).

Newer 'biological' drugs have transformed the management of certain cancers and immunological diseases, such as rheumatoid arthritis, psoriasis and Crohn's Disease. Biological drugs are also now available for the treatment of severe asthma. As asthma is a very common disease, these drugs have important potential cost implications for the PBS. The first of these drugs, omalizumab (Xolair), which is used for anti-IgE immunotherapy in people with severe asthma, is now available through the PBS Highly Specialised Drugs Program. This is an expensive medication; the cost to Government is approximately $1,071 per script and patients require 13 to 26 scripts per year. We have shown that, currently, this drug is rarely dispensed in Australia. It will be important for this drug, and for future biological drugs for asthma, that policy and monitoring systems are in place to ensure appropriate targeting of these expensive medications to those who require and will benefit from them.

These findings indicate problems and, in the case of biological drugs, potential problems both with prescribing by health professionals and with medication usage by patients, and highlight the potential both for better outcomes and for cost savings to patients and governments by better targeting of treatment for asthma and COPD. In order to improve the

quality use of medications in Australia, prescribing practices and medication usage by patients must be targeted, but different interventions are likely to be needed.

Our findings highlight the need to link PBS data to sources of clinical data—for example hospitalisations and deaths—in order to more adequately assess the appropriateness and outcomes of current use of medications to treat asthma and COPD. The current lack of information about diagnosis in the PBS data limits our ability to interpret some findings. For example, treatment with LABA alone (without ICS) is contraindicated for asthma, but recommended for patients with mild to moderate COPD. Information about diagnosis is needed in order to distinguish between appropriate and inappropriate use of this treatment.

Without this information we have needed to rely on inferences from dispensing histories about the clinical characteristics of patients receiving respiratory medications; and about the clinical impact and health outcomes of different treatment regimens.

In other countries, the availability of data linkage has facilitated clinically important conclusions to be drawn about the impact of different patterns of medication use on clinical outcomes and healthcare costs. For example, in Canada, researchers have been able to link databases containing information about medication claims, hospital admissions, emergency department visits and outpatient services. This has led to clinically important findings such as that, in contrast with current guidelines, initial treatment of COPD with ICS-LABA combination therapy was associated with a lower risk of death or COPD hospitalisation than with LABA alone (Gershon et al. 2014).

Similar kinds of data linkage are now possible in Australia, as governments have increasingly invested in relevant data collections and tools, and implemented data linkage policies. Data linkage studies generally involve careful scrutiny by ethics committees, and meeting the requirements of each collection's data access protocols. There are often significant costs associated with data access, security and the linkage process itself. Further exploration of these approaches is an important next step in determining the best options to more fully investigate the prevalence, management, impact and outcomes for people of obstructive airways disease and other chronic diseases in Australia. Extending from this current report, a study involving data linkage could generate information to inform Quality Use of Medicine initiatives that would improve prescribing appropriateness to those with asthma and COPD.

Appendix 1: PBS items included in the analyses for this report

Table A1.1: PBS items included in the analyses for this report

Class	ATC code	Data included
Respiratory System (ATC code R)		
Alpha- and beta-adrenoreceptor agonists	R03AA	All data.
Non-selective beta-adrenoreceptor agonists	R03AB	All data.
Selective beta$_2$-adrenoceptor agonists	R03AC	All data.
Adrenergics and other drugs for obstructive airway diseases	R03AK	All data.
Glucocorticoids	R03BA	All data.
Anticholinergics	R03BB	All data.
Antiallergic agents, excluding corticosteroids	R03BC	All data.
Xanthines	R03DA	All data.
Leukotriene receptor antagonists	R03DC	All data.
Other systemic drugs for obstructive airway diseases	R03DX	All data.
Endocrine System (ATC code H)		
Glucocorticoids	H02AB	Only included for individuals who were also dispensed any medications from Respiratory System ATC code R (listed above) at least once during the study period.

Table A1.2: ICS/LABA combinations included in this report

Brand Name	Formulation
Seretide Accuhaler 100/50	Fluticasone propionate 100 mcg/actuation + Salmeterol 50 mcg/actuation inhalation powder
Seretide Accuhaler 250/50	Fluticasone propionate 250 mcg/actuation + Salmeterol 50 mcg/actuation inhalation powder
Seretide Accuhaler 500/50	Fluticasone propionate 500 mcg/actuation + Salmeterol 50 mcg/actuation inhalation powder
Seretide MDI 50/25	Fluticasone propionate 50 mcg/actuation + Salmeterol 25 mcg/actuation inhalation powder
Seretide MDI 125/25	Fluticasone propionate 125 mcg/actuation + Salmeterol 25 mcg/actuation inhalation powder
Seretide MDI 250/25	Fluticasone propionate 250 mcg/actuation + Salmeterol 25 mcg/actuation inhalation powder
Symbicort Turbuhaler 200/6	Budesonide 200 mcg/actuation + eformoterol fumarate dihydrate 6 mcg/ actuation inhalation powder
Symbicort Turbuhaler 400/12	Budesonide 400 mcg/actuation + eformoterol fumarate dihydrate 12 mcg/actuation inhalation powder
Symbicort Turbuhaler 100/6	Budesonide 100 mcg/actuation + eformoterol fumarate dihydrate 6 mcg/actuation inhalation powder
Symbicort Rapihaler 200/6	Budesonide 200 mcg/actuation + eformoterol fumarate dihydrate 6 mcg/actuation inhalation: pressurised
Symbicort Rapihaler 50/3	Budesonide 50 mcg/actuation + eformoterol fumarate dihydrate 3 mcg/actuation inhalation: pressurised
Symbicort Rapihaler 100/3	Budesonide 100 mcg/actuation + eformoterol fumarate dihydrate 3 mcg/actuation inhalation: pressurised
Flutiform 125/5	Fluticasone propionate 125 mcg/actuation + eformoterol fumarate dihydrate 5 mcg/actuation inhalation: pressurised
Flutiform 250/10	Fluticasone propionate 250 mcg/actuation + eformoterol fumarate dihydrate 10 mcg/actuation inhalation: pressurised

Appendix 2: PBS data processing

Figure A2.1: PBS data processing

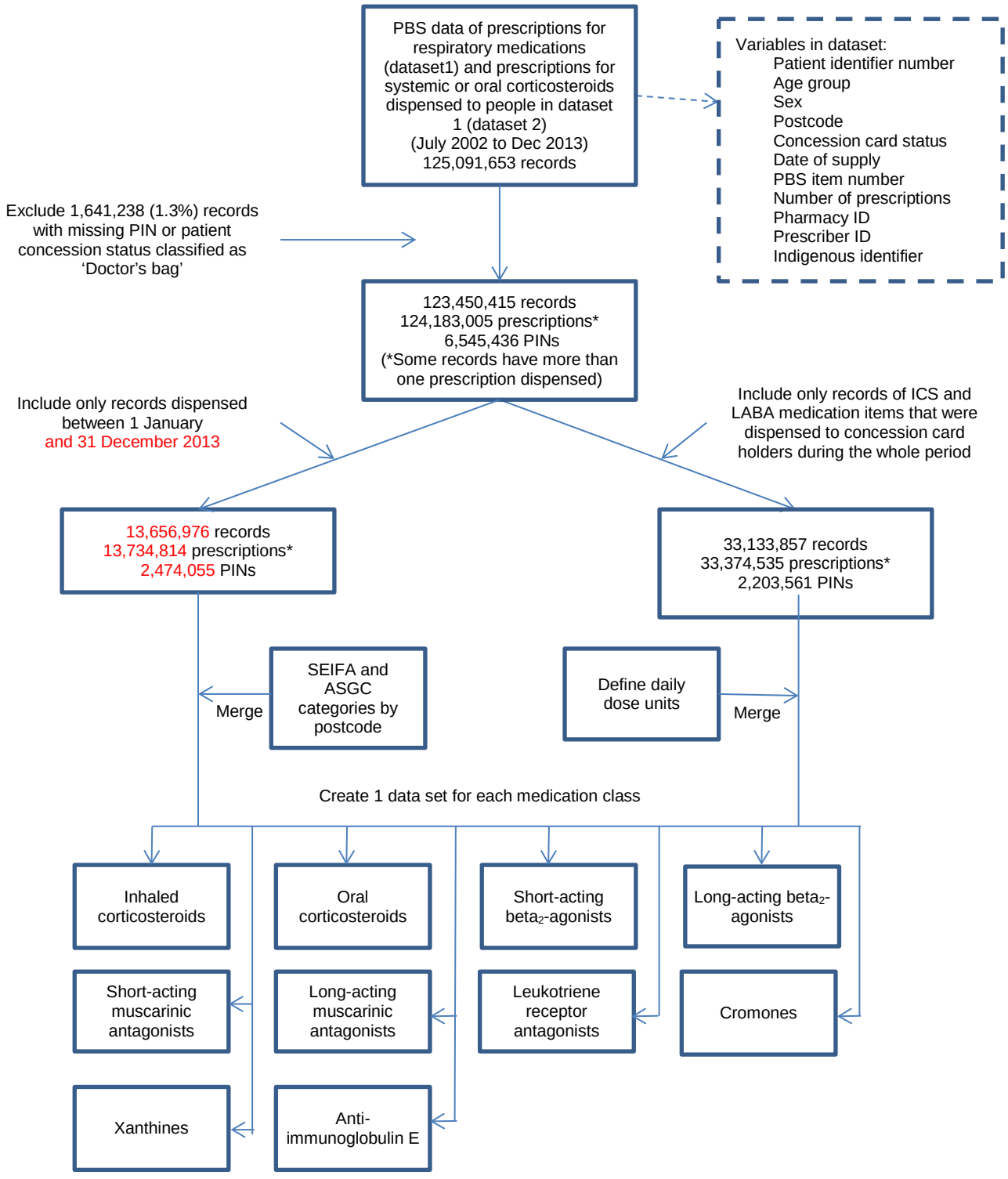


Table A2.1: Number of records and Patient Identification Numbers (PINs) by medication class in PBS data analyses used in this report

Medication class	1 July 2002 to 31 December 2013				01 January to 31 December 2013			
	All patients		Concession card holders only		All patients		Concession card holders only	
	Records	PINs	Records	PINs	Records	PINs	Records	PINs
Short-acting beta-agonists	33,960,874	3,409,782	31,196,655	2,721,974	3,606,522	1,152,703	2,808,263	740,740
Short-acting muscarinic antagonists	4,784,855	541,420	4,264,582	406,526	253,628	66,556	221,652	52,407
Inhaled corticosteroids	50,610,984	4,007,289	31,960,960	2,189,162	5,482,338	1,447,128	3,419,484	755,721
Oral corticosteroids	14,098,369	2,441,368	12,530,511	1,926,730	1,870,849	802,137	1,196,286	436,627
Systemic corticosteroids	599,516	233,184	436,279	205,789	48,850	30,845	35,553	22,656
Long-acting beta-agonists	43,937,378	3,254,185	27,710,658	1,759,453	4,956,158	1,206,725	3,207,545	659,306
Long-acting muscarinic antagonists	14,726,067	636,168	13,106,956	544,766	1,924,320	277,343	1,702,299	240,308
Anti-Immunoglobulin E therapy	3,789	350	1,683	175	2,534	313	1,121	151
Leukotriene receptor antagonists	1,655,132	172,613	686,267	73,102	209,759	46,635	86,605	18,997
Cromones	1,256,200	333,381	715,714	139,439	76,556	30,700	46,488	14,117
Xanthines	630,217	86,763	595,280	81,474	47,113	13,889	38,246	10,922

Note: Records of prescriptions include those who were categorised as 'Doctor's bag' or patient ID = 0. PINs are only for those who have been assigned IDs or for whom patient category is not 'Doctor's bag'.

Appendix 3: Inhaled corticosteroid potency classification

Table A3.1: Potency categories for ICS and ICS/LABA formulations used in this report

(Brand / Manufacturer's name)	Description	PBS Item Code
ICS POTENCY CATEGORY = LEAST POTENT		
ICS		
Pulmicort Turbuhaler	Budesonide 100 mcg/actuation inhalation powder	02070Y
Pulmicort Turbuhaler (↓)	Budesonide 200 mcg/actuation inhalation powder	02071B
Flixotide Junior pMDI	Fluticasone propionate 50 mcg/actuation pressurised inhalation	08516F
Flixotide Junior Accuhaler	Fluticasone propionate 100 mcg/actuation inhalation powder	08147T
Qvar 50 pMDI	Beclomethasone dipropionate 50 mcg/actuation pressurised inhalation	08406K
Qvar 50 pMDI Autohaler	Beclomethasone dipropionate oral pressurised inhalation in breath actuated device 50 mcg per dose	08408M
Alvesco 80 pMDI	Ciclesonide 80 mcg/actuation pressurised inhalation	08853Y
ICS/LABA		
Seretide pMDI 50/25	Fluticasone propionate 50 mcg/actuation + salmeterol 25 mcg/actuation pressurised inhalation	08517G
Seretide Accuhaler 100/50	Fluticasone propionate 100mcg/actuation + salmeterol 50 mcg/actuation inhalation powder	08430Q
Symbicort Rapihaler 50/3 (NEW)	Budesonide 50 mcg/actuation + eformoterol fumarate dihydrate 3 mcg/actuation pressurised inhalation	02867X
Symbicort Turbuhaler 100/6	Budesonide 100 mcg/actuation + eformoterol fumarate dihydrate 6 mcg/actuation inhalation powder	08796Y
Symbicort Rapihaler 100/3 (NEW)	Budesonide 100 mcg/actuation + eformoterol fumarate dihydrate 3 mcg/actuation pressurised inhalation	02938P
Symbicort Turbuhaler 200/6 (↓)	Budesonide 200 mcg/1 actuation + eformoterol 4.92 mcg/ 1 actuation inhalation powder	08625Y
ICS POTENCY CATEGORY = INTERMEDIATE POTENCY		
ICS		
Pulmicort Respules	Budesonide 500 mcg/2 ml inhalation for nebuliser	02065Q
Pulmicort Turbuhaler (↓)	Budesonide 400 mcg/actuation inhalation powder	02072C
Flixotide pMDI	Fluticasone propionate 125 mcg/actuation pressurised inhalation	08345F
Flixotide Accuhaler	Fluticasone propionate 250 mcg/actuation inhalation powder	08148W
Qvar 100 pMDI	Beclomethasone dipropionate 100 mcg/actuation pressurised inhalation	08407L
Qvar 100 pMDI Autohaler	Beclomethasone dipropionate oral pressurised inhalation in breath actuated device 100 mcg per dose	08409N
Alvesco 160 pMDI	Ciclesonide 160 mcg pressurised inhalation	08854B
ICS/LABA		
Seretide 125/25 pMDI	Fluticasone propionate 125 mcg/actuation + salmeterol 25 mcg/actuation pressurised inhalation	08518H
Seretide 250/50 Accuhaler	Fluticasone propionate 250 mcg/actuation + salmeterol 50 mcg/actuation inhalation powder	08431R

Flutiform 125/5 pMDI (NEW)	Fluticasone propionate 125 mcg/actuation + eformoterol fumarate dihydrate 5 mcg/actuation pressurised inhalation	10007Q
Symbicort Rapihaler 200/6 (NEW)	Budesonide 200 mcg/actuation + eformoterol fumarate dihydrate 6 mcg/actuation pressurised inhalation	02866W
Symbicort Turbuhaler 400/12 (↓)	Budesonide 400 mcg/actuation + eformoterol fumarate dihydrate 12 mcg/actuation inhalation powder	08750M
ICS POTENCY CATEGORY = MOST POTENT		
ICS		
Pulmicort Respules	Budesonide 1 mg/2 ml inhalation for nebuliser	02066R
Flixotide 250 pMDI	Fluticasone propionate 250 mcg/actuation pressurised inhalation	08346G
Flixotide 500 Accuhaler	Fluticasone propionate 500 mcg/actuation inhalation powder	08149X
ICS/LABA		
Seretide 250/25 pMDI	Fluticasone propionate 250 mcg/actuation + Salmeterol 25 mcg/actuation pressurised inhalation	08519J
Seretide 500/50 Accuhaler	Fluticasone propionate 500 mcg/actuation + Salmeterol 50 mcg/actuation inhalation powder	08432T
Flutiform 250/10 pMDI (NEW)	Fluticasone propionate 250 mcg/actuation + eformoterol fumarate dihydrate 10 mcg/actuation pressurised inhalation	10008R

(↓) In previous analyses by ACAM this drug was classed as a higher level potency.

(NEW) Indicates drugs that have come onto the market since the last ACAM analysis of PBS data.

Note: For all medications delivered by pressurised inhalation, the potency classification assumes that the medication has been prescribed at the approved frequency of 2 actuations per dose, and for those delivered by dry powder inhaler, that the medication has been prescribed at 1 actuation per dose.

Glossary

Adherence (and non-adherence): The extent to which patients take medications as prescribed by their health care providers. Examples of non-adherence include not taking prescribed medications at all and taking them less often or more often than prescribed. Primary non-adherence refers to patients having a prescription from a doctor, but not obtaining the medication from a pharmaceutical outlet.

Adult: Throughout this document, a person is classified as an adult from the age of 15 years, rather than strictly according to the legal age of 18 years.

Anti-IgE: Anti-immunoglobulin E monoclonal antibody: a new class of synthetic biological agent available through the Highly Specialised Drugs Program of the PBS for the management of severe allergic asthma that is not responsive to other medications. Currently there is one approved medication in this class: omalizumab.

Asthma: A common chronic inflammatory condition of the airways which can be controlled but not cured. People with asthma experience episodes of wheezing, shortness of breath, cough and chest tightness due to widespread narrowing of the airways. The symptoms of asthma vary over time and may be present or absent at any point in time (NACA 2015). Asthma affects people of all ages and has a substantial impact on the community

Asthma control: Is the extent to which the manifestations of asthma have been reduced or removed by treatment. The aim is to achieve good asthma control. The assessment of asthma control includes assessment of the patient's current status (symptoms, reliever use, lung function), and their risk of future adverse outcomes (exacerbations, decreasing lung function, medication side-effects) (Reddel H K et al. 2009).

Australian Asthma Handbook: The *Australian Asthma Handbook* is Australia's national guidelines for asthma management. This clinically-focussed online resource provides practical, evidence-based guidance for health professionals, for diagnosing and managing asthma in adults and children in primary care.

The current version 1.1, published by the National Asthma Council Australia in April 2015, is available at <www.asthmahandbook.org.au>.

Australian Centre for Airways disease Monitoring (ACAM): Formerly the Australian Centre for Asthma Monitoring (ACAM)—the name was changed in 2014 in recognition of the broadened scope of the monitoring activities being conducted by the Centre.

Australian Statistical Geographical Standard (ASGS): Common framework defined by the Australian Bureau of Statistics for collection and dissemination of geographically classified statistics. The ASGS replaced the Australian Standard Geographical Classification (ASGC) in July 2011. See also **Remoteness classification.**

Bronchitis: Inflammation of the main air passages (the bronchi). May be acute (because of infection) or chronic (most often because of tobacco smoking).

Bronchodilator: A type of medication that dilates the airways, hence, increasing airflow to and from the lungs. Bronchodilators can be either short-acting or long-acting; short-acting bronchodilators are often referred to as 'relievers'. See also **Long-acting beta-agonist**, **Short-acting beta-agonist**, **Reliever**.

Chronic obstructive pulmonary disease (COPD): A serious long-term lung disease that mainly affects older people, but also affects people of working age. It is characterised by airflow limitation that is not fully reversible with bronchodilator medications. The main cause of COPD is smoking. In everyday language, the terms COPD, emphysema and chronic bronchitis tend to be used interchangeably.

Combination therapy: Medications that contains more than one type of drug. In this report, 'combination therapy' includes inhalers which contain, for example, ICS and LABA. See also **Long-acting beta-agonists (LABA)**, and **Inhaled corticosteroids (ICS)**.

Concession card holder: Individuals who possess a government-issued health card (including repatriation health care cards) that entitles them to additional subsidy from the PBS.

Co-payment: The maximum amount payed by an individual for a dispensed medication that is subsidised by the PBS. The PBS pays the balance of the total cost to the pharmacist, if this is more than the co-payment amount.

COPD-X: Acronym for the key goals of COPD Management and used as the title for the current Australian COPD management guidelines: **C**onfirm diagnosis; **O**ptimise function; **P**revent deterioration; **D**evelop support; manage e**X**acerbations

Cromones: A class of medications (which include nedocromil sodium and sodium cromoglycate) that are administered by inhalation and used as prophylactic treatment of obstructive lung disease. Cromones must be taken regularly to produce optimal effect but they will not relieve acute symptoms. Although the mechanism of action of these drugs is not fully understood, they are thought to block allergen-induced bronchoconstriction, and may be useful in asthma associated with allergic factors. They may also be used to prevent exercise-induced bronchoconstriction.

Current asthma: People who have been diagnosed with asthma by a doctor AND have had symptoms of asthma or have taken medications for their asthma in the last 12 months.

Data linkage: The bringing together (linking) of information from 2 or more different data sources that are believed to relate to the same entity, for example, the same individual or the same institution. This can provide more information about the entity and, in certain cases, provide a time sequence, helping to 'tell a story', show 'pathways' and perhaps unravel cause and effect. The term is used synonymously with 'record linkage' and 'data integration'.

Dispense: This term is used to refer to a prescription medication being dispensed through a pharmacy. When this occurs under the Pharmaceutical Benefits Scheme a record of this dispense is added to the PBS database.

Doctor's bag medications: Drugs which can be obtained by prescribers from PBS without charge, for administration to patients in the case of an emergency.

Emphysema: A chronic lung disease with destruction of lung tissue, leading to shortness of breath, reduced oxygen absorption and other problems. See also **Chronic obstructive pulmonary disease (COPD)**.

Estimated resident population: The official Australian Bureau of Statistics estimate of the Australian population derived from the 5-yearly Census counts. It is based on the usual residence of the person.

Exacerbation: See **Flare-up**.

Flare-up: Worsening of asthma control (increase in asthma symptoms) (NACA 2015). See also **Flare-up (mild)**, **Flare-up (moderate)** and **Flare-up (severe)**. Other terms that have been used in the past to refer to these events include 'attack', 'exacerbation', 'acute asthma' and 'episode', but the preferred terminology in the 2014 Australian Asthma Handbook is 'flare-up', as described above.

Flare-up (mild): Worsening of asthma control that is only just outside the normal range of variation for the individual (documented when patient is well).

Flare-up (moderate): Worsening asthma that is troublesome or distressing to the patient and requires a change in treatment, but is not life-threatening and does not require hospitalisation.

Flare-up (severe): Event that requires urgent action by the patient (or carers) and health professionals to prevent a serious outcome such as hospitalisation or death from asthma.

General patient: Individuals who are dispensed medications subsidised by the PBS who are not categorised as concession card holders.

Health outcome: A change in the health of an individual or population due wholly or partly to preventive or clinical intervention.

Inhaled corticosteroids (ICS): A class of anti-inflammatory respiratory medication that is typically used as a preventer to control asthma symptoms and reduce the risk of flare-ups.

Leukotriene receptor antagonists (LTRA): A class of medication recommended for children with asthma that provides an oral non-steroid alternative to ICS.

Long-acting beta-agonists (LABA) : A class of long-acting medications that reverse bronchoconstriction and, hence, help to control obstructive airways disease symptoms. Their use can result in reduced doses of ICS being required. See also **Short-acting beta-agonist** and **Bronchodilator**.

Long-acting muscarinic antagonists (LAMA): A class of long-acting medications that reverse bronchoconstriction and, hence, help to control obstructive airways disease symptoms. Recommended only for people with COPD and may reduce the use of ICS.

Longitudinal Study of Australian Children (LSAC): A cohort study focusing on health and educational outcomes involving a representative sample of approximately 10,000 Australian children.

Maintenance treatment: See **Preventer**.

Medicare: A national, government-funded scheme that subsidises the cost of personal medical services for all Australians and aims to help them afford medical care.

Medication class: A categorisation of several drugs or PBS items under a common mechanism of action.

Mucolytics: Mucolytic agents are sometimes used to loosen and clear mucus from the airways. They are available over the counter in tablet and liquid formulations.

New South Wales Health Survey (NSWHS): This is an ongoing computer-assisted telephone survey conducted by the NSW Ministry of Health through continuous sampling of NSW residents to collect health and related information. See also **Health survey**.

Obstructive airways disease: This encompasses asthma and chronic obstructive pulmonary disease (COPD) as well as other, poorly defined, but related, conditions.

Oral corticosteroids (OCS): A class of medication used for a wide range of conditions. When used for obstructive airways disease, it is usually to manage flare-ups by reducing acute airway inflammation. Administered orally for short periods to regain control of the disease during acute phases.

Patient identification number (PIN): A numeric variable that anonymously identifies records for the same individual in the PBS dataset.

PBS Item : A specified drug at a given strength classified on the Pharmaceutical Benefits Scheme (PBS) by a unique code.

Pharmaceutical Benefits Scheme (PBS): A national, government-funded scheme that subsidises the cost of a wide range of pharmaceutical drugs for all Australian citizens and residents to help them afford standard medications.

Population health survey: A research method in which health information is collected from a representative sample of the population, usually at a point in time. This typically involves administering questionnaires to the participants. The questionnaire may be completed on a computer (either by the respondent or the interviewer) or on paper, and can be done in person, over the phone or by post.

Prescriber: A health professional, usually a medical practitioner, licensed to order that medications be dispensed to a patient in their care through a pharmaceutical outlet. See also **Prescription**.

Prescription: A written order from a medical officer for a medication to be dispensed to an individual. See also **Prescriber**.

Preventer : Preventer medications are those used regularly on an ongoing basis to control symptoms and prevent exacerbations. In international asthma literature, these medications are sometimes called 'controller' medications. As these medications need to be used every day, the term 'maintenance treatment' is also sometimes used, and this is the preferred term in relation to COPD.

Proportion: A proportion is a fraction in which the numerator contains a subset of the individuals contained in the denominator. Its value ranges between 0 and 1. For example, the proportion of males in the population is calculated as the number of males divided by the number of persons (that is, males + females).

Reliever: Relievers are bronchodilator medicines used for rapid reversal of bronchoconstriction in asthma or COPD. They can also be used pre-emptively to prevent exercise-induced bronchoconstriction. See also **Short-acting beta-agonists** and **Bronchodilator**.

Remoteness classification: Each state and territory is divided into several regions based on their relative accessibility to goods and services (such as general practitioners, hospitals and specialist care) as measured by road distance. These regions are based on the Accessibility/Remoteness Index of Australia (ARIA) and defined as Remoteness Areas by either the Australian Standard Geographical Classification (ASGC) (before 2011) or the Australian Statistical Geographical Standard (ASGS) (from 2011 onwards) in each Census year.

Respiratory medication: A drug that is commonly used to treat obstructive lung disease.

Safety net: A pre-set threshold of total co-payment expenses incurred from the patient or family in one calendar year. Once this threshold has been reached, the co-payment reduces for the remainder of the year. The safety net differs for general and concessional patients.

Short-acting beta-agonist (SABA): A class of medications that are taken as needed by people with obstructive airways disease to rapidly reverse bronchoconstriction and, hence, relieve symptoms. These medications are usually inhaled, either by metered dose inhaler or nebuliser and are sometimes referred to as 'reliever' medications. See also **Reliever** and **Bronchodilator**.

Short-acting muscarinic antagonists (SAMA): A class of medication also known as short-acting anticholinergics, used to relieve symptoms, with a slower onset but longer duration of effect than SABA.

Socio-Economic Indexes for Areas (SEIFA): A set of indexes, created from Census data, that aim to represent the socioeconomic status of Australian communities and identify areas of advantage and disadvantage. The index value reflects the overall or average level of disadvantage of the population of an area; it does not show how individuals living in the same area differ from each other in their socioeconomic status. This report uses the Index of Relative Socioeconomic Disadvantage, which provides a summary score for a range of key socioeconomic variables that are related to health status, including household income and resources, education, occupation, fluency in English, and Indigenous status. See also **Socioeconomic status**.

Socioeconomic status: An indication of how 'well off' a person or group is. In this report, socioeconomic status is reported using the Socio-Economic Indexes for Areas (SEIFA), typically for 5 groups, from the most disadvantaged (worst off) to the least disadvantaged (best off). See also **Socio-Economic Indexes for Areas**.

Symptom controller: This term was previously used in Australian asthma guidelines (NACA 2006) to refer to the class of long-acting beta$_2$-agonists. Because of confusion with the international usage of the term 'controller' (see **Preventer**), this term is not recommended in the 2014 **Australian Asthma Handbook**.

Xanthines: A class of medications (which include theophylline) that are bronchodilators administered orally and have a highly variable half-life of approximately 8 hours in adults and 4 hours in children.

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Related publications

This report, *Respiratory medication use in Australia 2003–2013: treatment of asthma and COPD*, can be downloaded for free from the AIHW website <www.aihw.gov.au>. The website also includes information on ordering printed copies.

The following AIHW publications relating to asthma, COPD and medication use might also be of interest:

- ACAM (Australian Centre for Asthma Monitoring) 2007. Patterns of asthma medication use in Australia. Cat. no. ACM 11. Canberra: AIHW.
- ACAM 2008. Asthma in Australia 2008. Asthma series no. 3. Cat. no. ACM 14. Canberra: AIHW.
- ACAM 2011. Asthma in Australia: with a focus chapter on chronic obstructive pulmonary disease 2011. Asthma series no. 4. Cat. no. ACM 22. Canberra: AIHW.
- AIHW ACAM 2012. Medications prescribed for people with obstructive airways disease: antibiotics and inhaled corticosteroids. Cat. no. ACM 24. Canberra: AIHW.

This report describes patterns of dispensing of respiratory medications in Australia through detailed analyses of Pharmaceutical Benefits Scheme (PBS) data, as well as other sources, to draw inferences about respiratory medication use among patients with asthma and COPD. It provides a valuable update and new information about the use of medicines for asthma and COPD, thus improving our knowledge and understanding about how these diseases are managed in Australia.