

RESEARCH PAPER

Inappropriate prescribing of inhaled corticosteroids: are they being prescribed for respiratory tract infections? A retrospective cohort study

Leanne M Poulos¹, Rosario D Ampon¹, Guy B Marks^{1,2}, *Helen K Reddel¹

¹ Woolcock Institute of Medical Research, University of Sydney, New South Wales, Australia

² Department of Respiratory Medicine, Liverpool Hospital, Liverpool, New South Wales, Australia

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Abstract

Background: Guidelines recommend regular use of inhaled corticosteroid (ICS)-containing medications for all patients with persistent asthma and those with moderate to severe chronic obstructive pulmonary disease. It is important to identify indicators of inappropriate prescribing.

Aims: To test the hypothesis that ICS are prescribed for the management of respiratory infections in some patients lacking evidence of chronic airways disease.

Methods: Medication dispensing data were obtained from the Australian national Pharmaceutical Benefits Scheme (PBS) for concessional patients dispensed any respiratory medications during 2008. We identified people dispensed only one ICS-containing medication and no other respiratory medications in a year, who were therefore unlikely to have chronic airways disease, and calculated the proportion who were co-dispensed oral antibiotics.

Results: In 2008, 43.6% of the 115,763 patients who were dispensed one-off ICS were co-dispensed oral antibiotics. Co-dispensing was seasonal, with a large peak in winter months. The most commonly co-dispensed ICS among adults were moderate/high doses of combination therapy, while lower doses of ICS alone were co-dispensed among children. In this cohort, one-off ICS co-dispensed with oral antibiotics cost the government \$2.7 million in 2008.

Conclusions: In Australia, many people who receive one-off prescriptions for ICS-containing medications do not appear to have airways disease. In this context, the high rate of co-dispensing with antibiotics suggests that ICS are often inappropriately prescribed for the management of symptoms of respiratory infection. Interventions are required to improve the quality of prescribing of ICS and the management of respiratory infections in clinical practice.

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Introduction

Inhaled corticosteroids (ICS), either alone or in combination with long-acting β_2 -agonists (LABA), are very effective for preventing many of the adverse outcomes of chronic airways disease, reducing mortality and morbidity in persistent asthma,^{1,3} and reducing the incidence of exacerbations in people who have chronic obstructive pulmonary disease (COPD) with a history of frequent exacerbations.^{4,5} For these reasons, regular treatment with ICS is recommended in international and national guidelines⁶⁻⁹ for many patients with asthma and for some patients with COPD. These medications are commonly prescribed for

chronic airways disease in many countries, including Australia, the UK, and the USA.

Medications prescribed by general practitioners are often subsidised by the government. For example, in the UK many patients are exempt from the cost of prescription medications through the National Health Service; in 2010, prescriptions provided free of charge represented approximately 94% of all items dispensed in England.¹⁰ In Australia the Pharmaceutical Benefits Scheme (PBS) currently subsidises some or all of the cost of approximately 80% of prescription medications dispensed.¹¹ Since

* **Corresponding author:** Professor Helen K Reddel, Woolcock Institute of Medical Research, P O Box M77, Missenden Road, Camperdown, New South Wales 2050, Australia. Tel: +61 2 9114 0437 Fax: +61 2 9114 0014 E-mail: helen.reddel@sydney.edu.au

both asthma and COPD are common diseases and ICS are reimbursed for these conditions, medications prescribed for chronic airways disease represent a substantial cost to the government. In 2010-11, salmeterol/fluticasone was listed as the sixth highest drug by cost to the Australian government.¹² Prescription pharmaceuticals account for a large proportion of total health expenditure and, in Australia, this accounted for 59% of the total health expenditure for asthma.¹³ Furthermore, adverse effects of ICS have been reported.^{14,15} It is therefore important that appropriate prescribing is encouraged and indicators of inappropriate prescribing are identified.

We have recently shown that, in Australia, most people who are dispensed ICS are only dispensed one ICS-containing medication in any given year.¹³ However, there is no evidence that a short course of this therapy is effective for any specific condition (other than for chronic cough due to eosinophilic bronchitis¹⁶), and guidelines for the use of ICS in asthma and COPD recommend that ICS – where indicated – should be used regularly.^{8,9} While some of the observed irregular dispensing may be due to poor adherence by patients who were prescribed this class of medication for regular use, anecdotal reports from pharmacists and patients suggest that ICS are sometimes being co-prescribed with antibiotics for treatment of respiratory tract infections.

The primary aim of our study was to investigate whether ICS are being prescribed for the treatment of respiratory tract infections in people without evidence of chronic airways disease. A second aim was to identify risk factors for this apparently inappropriate use of ICS.

Methods

The study was conducted using anonymous linkage within the Australian Pharmaceutical Benefits Scheme dataset. Ethical approval to conduct the project was obtained from the University of Sydney Human Research Ethics Committee.

The study cohort was defined within the PBS dataset for the 2008 calendar year based on the use of specific medications and beneficiary status of the patient. The PBS dataset includes the medication name and dose, dispensing date and beneficiary status (general or concession), and 5-year age group, sex, and residential postcode. Medication records are linked to individuals using an encrypted patient identification number.

The study cohort for this analysis was limited to holders of concession cards to ensure that a complete medication record was available. Until very recently, data were only recorded on the PBS database for eligible items for which the cost exceeded a specified co-payment threshold and a subsidy was provided. Since the co-payment threshold for general beneficiaries exceeded the cost of some respiratory medications and antibiotics, these classes of medications were only fully captured for concessional beneficiaries. Concession cards are available to people receiving government benefits such as unemployment and sickness benefits, and for repatriation (veterans') benefits.

The study cohort comprised all concession card holders who, in 2008, were dispensed any respiratory medication – that is, ICS (either alone or in combination with LABA), LABA (either alone or in

combination with ICS), short-acting β_2 -agonists, long-acting or short-acting anticholinergic drugs, leukotriene receptor antagonists, methyl xanthines including theophylline, or cromones. In general, one dispensing of these medications will provide sufficient medication for one month's treatment at standard doses.

We identified a sub-group who had a single episode of dispensing of ICS-containing medication in the 2008 calendar year and no other respiratory medications dispensed within ± 6 months of this date except within ± 7 days of the incident date (hereafter called 'one-off' dispensing of ICS). The exception of ± 7 days of the incident date was allowed as other dispensing of respiratory medications within this short time window may have been for the same clinical event. Co-dispensing of antibiotics was defined as dispensing of oral antibiotics within ± 7 days of the date of one-off dispensing of ICS. Antibiotics dispensed with six months' supply were assumed to be for long-term use and were excluded.

Data analysis

The number of people dispensed one-off ICS was calculated, together with the number and proportion of these who were co-dispensed antibiotics. The weekly incidence of co-dispensing was displayed by age groups for adults and children to describe seasonal patterns. Co-dispensing rates were reported for the whole cohort and for sub-

Figure 1. Derivation of the co-dispensing cohort among Australian concession card holders dispensed any respiratory medication during 2008. ICS=inhaled corticosteroids

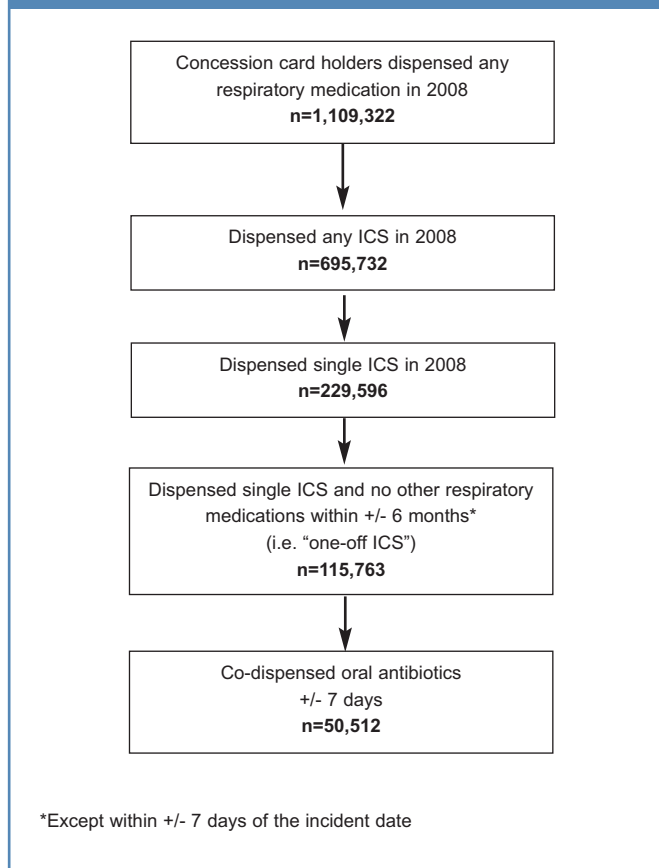


Figure 2. Timing of co-dispensing of one-off ICS and oral antibiotics (AB) for concession card holders in 2008

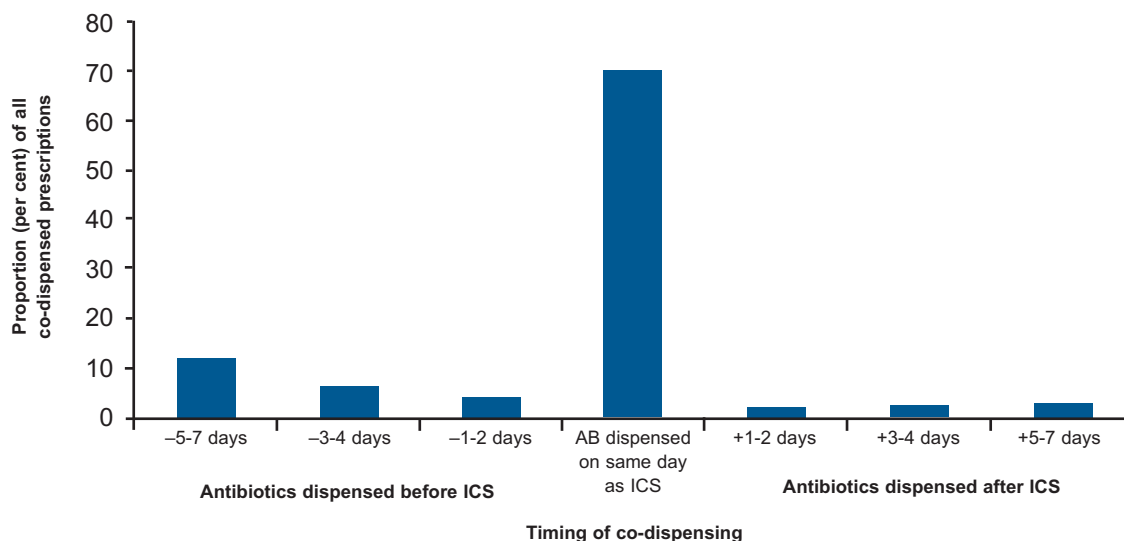


Table 1. Proportion of concession card holders dispensed one-off ICS* who were co-dispensed oral antibiotics during 2008, by demographic variables

Demographic variable	Proportion co-dispensed oral antibiotics	Relative risk (95% CI)
Overall (n=115,763)	50,512 (43.6%)	
Sex		
Males	18,705 (41.5%)	1.0
Females	31,781 (45.0%)	1.08 (1.07 to 1.10)
Age group (years)		
0-4	1,944 (39.0%)	1.03 (0.99 to 1.07)
5-14	7,032 (37.8%)	1.0
15-34	10,303 (46.0%)	1.22 (1.19 to 1.25)
35-64	16,003 (46.2%)	1.22 (1.20 to 1.25)
≥65	15,204 (43.3%)	1.15 (1.12 to 1.17)
Socio-economic status (SES) quintile		
SES 1 (low SES)	10,876 (43.7%)	0.98 (0.96 to 1.00)
SES 2	10,569 (42.8%)	0.96 (0.94 to 0.98)
SES 3	10,610 (43.2%)	0.97 (0.95 to 0.99)
SES 4	9,428 (44.4%)	0.99 (0.97 to 1.02)
SES 5 (high SES)	8,726 (44.6%)	1.0
Remoteness category		
Major cities	35,875 (45.2%)	1.0
Inner regional areas	9,757 (40.5%)	0.90 (0.88 to 0.91)
Outer regional areas	4,139 (40.0%)	0.89 (0.86 to 0.91)
Remote/very remote	529 (36.3%)	0.80 (0.75 to 0.86)

Note: The relative risk indicates the effect of the respective demographic factors on the co-dispensing of oral antibiotics.

Socio-economic status based on Socioeconomic Index For Areas (SEIFA).

Remoteness category based on Australian Standard Geographical Classification (ASGC).

*'One-off' ICS is defined as a single dispensing of ICS with no other respiratory medications within ±6 months, except within the immediate period of ±7 days.

Co-dispensing is defined as dispensing of oral antibiotics within ±7 days of the one-off ICS.

groups classified according to age, sex, socio-economic status (based on the Index of Relative Socioeconomic Disadvantage, one of the Socio-Economic Indexes for Areas (SEIFA)¹⁷), and geographical location (based on the Australian Standard Geographical Classification (ASGC)¹⁸).

The relationship between antibiotic use and demographic factors including age, sex, socioeconomic status, and remoteness of residence was described using rate ratios (RR). These were estimated using a generalised linear model with a binomial distribution in SAS Proc Genmod (SAS v9.2).

The cost to the Australian government of one-off ICS when co-dispensed with antibiotics was calculated by subtracting the concessional co-payment by the patient (\$5.00 in 2008) from the total cost of each of the ICS drugs as listed in the 2008 PBS schedule and multiplying by the number of one-off prescriptions dispensed for each of the ICS drugs.

Results

In 2008 approximately 64% of Australians receiving respiratory medications through the PBS received them at the concessional rate. In that year, 695,732 patients with a concession card were dispensed any ICS medication (Figure 1). Of these, 33% were dispensed a single prescription for ICS, and 50.4% of these (115,763) were dispensed no other respiratory medication during the six months before or after

this date ('one-off' ICS). Of the concession card holders who had only one ICS prescription in 2008 and no other respiratory medication, 50,512 (43.6%) were co-dispensed oral antibiotics (i.e. were dispensed an oral antibiotic within ± 7 days of the one-off ICS).

The medications were dispensed on the same day for most (70%) individuals who were co-dispensed one-off ICS and oral antibiotics while, for 22.5%, the antibiotic was dispensed 1–7 days before the one-off ICS (Figure 2). The remaining 7.5% were dispensed oral antibiotics 1–7 days after the one-off ICS.

Among people dispensed one-off ICS in 2008, slightly more females (45.0%) than males (41.5%) were co-dispensed oral antibiotics (relative risk 1.08, 95% CI 1.07 to 1.10). Co-dispensing of oral antibiotics was more common in adults than children and in people living in major cities than in people living in other areas, but did not differ according to socioeconomic status (Table 1).

Co-dispensing of one-off ICS and oral antibiotics was seen throughout the year, but was primarily a late winter/early spring phenomenon in people aged ≥ 5 years. In young children (aged 0–4 years) the incidence of co-dispensing peaked earlier, in June (Figure 3).

The most common Anatomical Therapeutic Chemical (ATC) classes of oral antibiotics co-dispensed with one-off ICS were beta-lactam antibacterials/penicillins (44%, including 25.7% for amoxicillin) and macrolides/lincosamides and streptogramins (34%, including 22% for roxithromycin). These antibiotics are commonly

Figure 3. Co-dispensing of oral antibiotics by week among (A) children and (B) adult concession card holders dispensed one-off ICS by age group in 2008

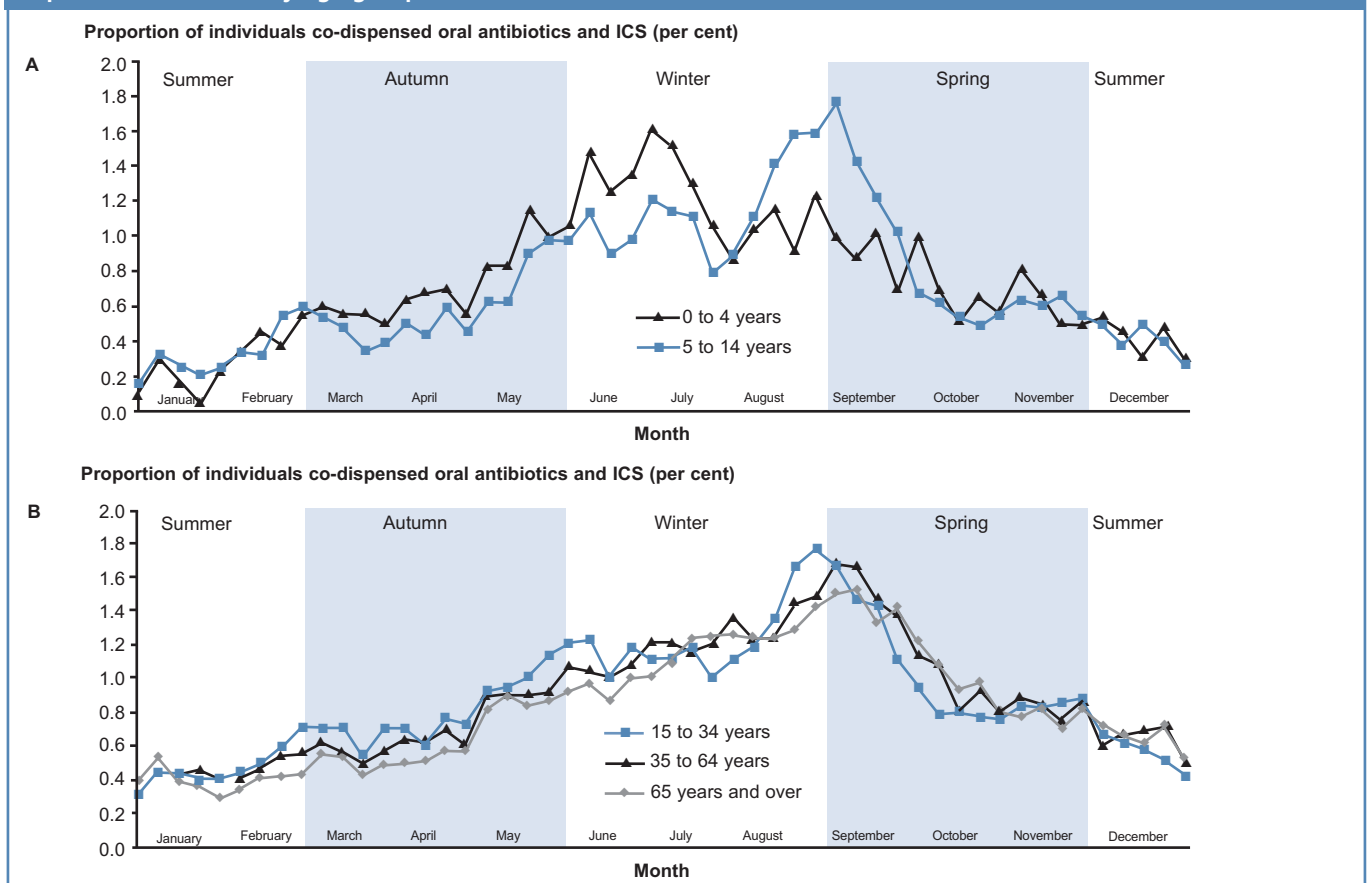


Table 2. Formulation, dose and cost of ICS dispensed as one-off prescriptions with co-dispensing of oral antibiotics for concession card holders of all ages in 2008

ICS formulation (% of one-off ICS scripts)	Dose	No (%) of prescriptions dispensed	Total cost to government (\$)
ICS alone (23%)	Low	3,221 (6.4%)	\$41,911.72
	Moderate	4,885 (9.7%)	\$135,972.02
	High	3,717 (7.4%)	\$158,248.73
ICS/LABA combination (77%)	Low	3,187(6.3%)	\$139,845.74
	Moderate	21,290 (42.1%)	\$1,139,548.98
	High	14,212 (28.1%)	\$1,069,451.38
Total ICS prescriptions co-dispensed with antibiotics		50,512	\$2,684,978.57

Notes: Low dose includes Qvar 50, Qvar 50 Autohaler, Pulmicort Turbuhaler 100, Alvesco 80, Flixotide Jnr Accuhaler 100, Flixotide Jnr 50, Seretide Accuhaler 100/50, Seretide 50/25, Symbicort Turbuhaler 100/6. Moderate dose includes Qvar 100, Qvar 100 Autohaler, Pulmicort respules 500 mcg, Pulmicort turbuhaler 200, Alvesco 160, Flixotide Accuhaler 250, Flixotide 125, Seretide Accuhaler 250/50, Seretide 125/25, Symbicort Turbuhaler 200/6. High dose includes Pulmicort Respules 1 g, Pulmicort Turbuhaler 400, Flixotide Accuhaler 500, Flixotide 250, Seretide Accuhaler 500/50, Seretide 250/25, Symbicort Turbuhaler 400/12.

The cost to the government does not include the cost of the prescription paid by the patient.

Table 3. Type and cost of ICS dispensed as one-off prescriptions with co-dispensing of oral antibiotics to concession card holders in 2008

Name of medication	No (%) of one-off prescriptions co-dispensed with antibiotics	Total cost to government
Fluticasone propionate/salmeterol xinafoate	20,296 (40.2%)	\$1,274,023.98
Budesonide/eformoterol fumarate dihydrate	18,393 (36.4%)	\$1,074,822.12
Beclomethasone dipropionate	1,068 (2.1%)	\$28,788.28
Budesonide	3,321 (6.6%)	\$108,922.61
Fluticasone propionate	6,552 (13.0%)	\$169,504.44
Ciclesonide	882 (1.7%)	\$28,917.14
Total	50,512 (100%)	\$2,684,978.57

Note: The cost to the government does not include the cost of the patient co-payment (\$5 per prescription for concession card holders in 2008).

used for the treatment of respiratory tract infections.

The majority (77%) of one-off ICS prescriptions co-dispensed with oral antibiotics were dispensed as combination ICS/LABA therapy. Furthermore, moderate- or high-dose combination ICS/LABA formulations accounted for 70.3% of all one-off co-dispensed ICS prescriptions (Table 2). Children were most commonly co-dispensed ICS at lower doses and as ICS alone, particularly those aged 0–4 years. One-off ICS dispensed as ICS alone accounted for 69% of ICS prescriptions dispensed in children aged 0–4 years (of which 88% were the lowest doses) and 38% of those in children aged 5–14 years (of which 60% were the lowest doses). For adult concession card holders, most (around 80%) of the one-off ICS were dispensed as combined formulations of ICS/LABA. Adults were most commonly dispensed the moderate/high-dose formulations of ICS (data not shown).

The cost to the Australian government of ICS dispensed as one-off prescriptions to concessional beneficiaries, when accompanied by co-dispensing of oral antibiotics, was approximately \$2.7 million (Table 2). Prescriptions for salmeterol/fluticasone accounted for almost half of this cost (20,296 prescriptions; \$1,274,023.98), followed by budesonide/eformoterol (18,393 prescriptions;

\$1,074,822.12) (Table 3). More than half (52.9%) of the one-off salmeterol/fluticasone prescriptions co-dispensed with oral antibiotics were the highest doses available compared with 18.9% for budesonide/eformoterol (data not shown). These costs exclude the cost to patients of the co-payment and the cost of the antibiotic itself.

Discussion

Main findings

Despite the known effectiveness of ICS medications in chronic airways disease, particularly in asthma, there is increasing awareness that ICS dispensing is substantially less than is consistent with regular daily usage. To date, attention has primarily focused on poor adherence by patients. However, the findings of this study suggest that ICS are also being prescribed in Australia for people without chronic airways disease, as indicated by the lack of dispensing of any other respiratory medications – not even short-acting β_2 -agonist reliever – within 12 months. This pattern was seen for half of the concession card holders who had a single ICS prescription in 2008. The finding that 44% of these patients were co-dispensed their single ICS with an oral antibiotic suggests that the ICS were being prescribed inappropriately

as treatment for symptoms of respiratory tract infection.

Several findings in the analysis support this theory. First, the co-prescribing phenomenon was strongly seasonal, with a late winter peak. This is the time of year when respiratory viruses are most frequently isolated¹⁹ and respiratory tract infections²⁰ are most frequently observed. For example, in data from an influenza surveillance programme and from patients hospitalised with a respiratory illness in Victoria, Australia in 2002 and 2003, winter peaks were seen in respiratory syncytial virus, influenza A and B, parainfluenza and metapneumovirus, with late autumn and winter peaks in picornavirus (including rhinovirus).¹⁹ Second, the antibiotics most commonly co-dispensed with one-off ICS – amoxicillin and roxithromycin – are commonly prescribed for respiratory infections.²¹ Third, 70% of co-dispensed ICS and oral antibiotics were dispensed on the same day, supporting the hypothesis that they were dispensed for treatment of the same clinical event. In 22.5% of cases the antibiotics were dispensed up to a week before the ICS, suggesting that these ICS were dispensed for respiratory symptoms that had failed to respond to antibiotics; however, the prescribing date itself was not available from the PBS dataset.

Strengths and limitations of this study

This analysis was conducted on a national administrative dataset recorded electronically at the point of dispensing. The estimate of the extent of inappropriate prescribing of ICS is conservative. In order to ensure close to complete dispensing data for each individual, the study cohort was limited to concession card holders since many respiratory medications and oral antibiotics were only captured in the Australian PBS dataset for persons receiving medications at the concessional rate. This excluded around one-third of people dispensed respiratory medications in 2008. Furthermore, the study population was limited to those with only one ICS prescription in 12 months and no other respiratory medicines. People who were co-dispensed ICS and antibiotics on more than one occasion in a year would not therefore be included in the present analysis. Lastly, we used ± 7 days as the cut-off to define co-prescription of one-off ICS and oral antibiotics; this is substantially shorter than the typical duration of lower respiratory tract infections (median 18 days, mean 24 days)²² so, if anything, the extent of co-prescribing of one-off ICS with antibiotics for a single clinical event would have been underestimated. Hence, the cost to the Australian government for the inappropriate use of ICS as treatment of respiratory tract infections is likely to be far greater than \$2.7million per year. No comment can be made about the appropriateness of the antibiotic prescriptions themselves since no diagnostic information is available in the Australian PBS dataset. However, other studies have shown that antibiotics are over-prescribed for upper respiratory tract infections in general populations in primary care.²³

Interpretation of findings in relation to previously published work

Single dispensing of ICS prescribed for regular use in asthma and COPD, as a manifestation of poor adherence by patients, is well recognised,^{24,25} and antibiotics are commonly used in the management of exacerbations of both COPD²⁶ and asthma²⁷ despite the lack of evidence to support the latter. However, we are not aware

of any other reports of co-prescribing of ICS and antibiotics in patients without evidence of chronic respiratory disease.

Short-term treatment of respiratory tract infections with ICS and antibiotics in patients with no other evidence of chronic airways disease is neither supported by evidence nor recommended in guidelines. A short period of treatment with ICS is rarely indicated, except as a therapeutic trial in a patient with a history and lung function consistent with mild asthma. However, such patients would be expected also to have used a short-acting β_2 -agonist, and the appropriate trial would be with low-dose ICS rather than moderate or high-dose ICS/LABA plus an antibiotic. For patients with chronic cough (>8 weeks in adults), guidelines recommend an empirical trial of a short course of ICS (without LABA) if eosinophilic bronchitis is considered, or extended treatment with antibiotics if the patient has persistent purulent bronchitis.¹⁶ However, again, prescribing of ICS, LABA, and antibiotics at the same time makes it unlikely that either of these was the presumed diagnosis.

Co-prescribing of ICS and antibiotics may instead reflect a lack of certainty by general practitioners about diagnosing respiratory conditions,²⁸ or a perception that a combined anti-bacterial/anti-inflammatory approach would obviate the need for diagnostic investigations by simultaneously addressing several common potential causes of respiratory symptoms such as post-viral cough. The prominent peak in co-dispensing in the winter months may reflect the seasonality of bacterial illness (e.g. community-acquired pneumonia). Clinicians may be less likely to trust a sore throat or productive cough to resolve on its own during winter. Alternatively, they may be too busy during the winter months to risk the patient requiring a return visit (e.g. for management of post-viral cough). With regard to general practitioner decision-making, it is very interesting to note the absence of a summer (February) peak in co-dispensing of oral antibiotics and ICS in children, in contrast with the well-recognised rise in hospital admissions for asthma in children after return to school from summer holidays, which is also seen in Canada, England, Sweden, and Scotland.^{29,30} This back-to-school epidemic is thought to be related to children being exposed to multiple new rhinoviruses (including in the absence of clinical colds), coinciding with time-dependent factors such as allergen exposure, traffic pollution and stress, on a background of poor adherence with preventer medications during the vacation.³¹⁻³³ The fact that we found no increase in co-dispensing of one-off ICS and antibiotics in children in February suggests that the clinical features leading to this pattern of prescribing differ from those seen in back-to-school asthma exacerbations.

Implications for future research, policy and practice

The finding that 50% of the patients who were dispensed only one month's supply of ICS in 2008 had no other respiratory medications dispensed – not even short-acting β_2 -agonists – within a 12-month period suggests that these patients were unlikely to have chronic airways disease. Co-dispensing of ICS and antibiotic may instead flag clinical episodes of respiratory tract infection.

Upper and lower respiratory tract infections are the third and tenth most commonly managed problems, respectively, in Australian primary care, together accounting for 8.7 of every 100 general

practitioner consultations,²¹ and acute upper respiratory tract infections represent the most frequently managed problem for children in general practice.³⁴

The use of ICS for the treatment of respiratory infections – particularly at high or moderate doses and in combination with LABA and an antibiotic – increases the risk of adverse events and adds substantially to the cost of managing what are common and usually self-limiting conditions. Prescribing of ICS for purposes beyond which they are intended comes at a cost to the Australian government which amounts to around \$8million over three years and an increased risk to patients of adverse events. Our results indicate that interventions may be required to improve the quality use of ICS by targeting potentially inappropriate prescribing of short-course ICS.

The large number of patients co-dispensed ICS and antibiotics and the broad spread across geographical and socio-economic areas indicates that this prescribing pattern is not isolated to a small number of clinicians. While this study was conducted using Australian dispensing data, it will be interesting to compare the present findings with prescribing patterns for ICS in other health systems.

Further research is needed to understand the clinical rationale behind this prescribing pattern in order to plan interventions that are targeted to meet the clinical need. For example, in patients with no history of chronic respiratory symptoms, is this combination being used primarily for people with acute bronchitis or prolonged post-viral cough and/or with particular symptoms/signs? Armed with this information, a range of interventions could be designed to assist in changing prescribing behaviour – for example, decision aids for differential diagnosis of acute versus chronic respiratory symptoms;³⁵ biomarker-based protocols to reduce the use of antibiotics;³⁶ or prompts for general practitioners and patients about non-pharmacological strategies for respiratory infections such as those currently directed at reducing inappropriate antibiotic prescribing.³⁷

Conclusions

Around half of the people who receive one-off prescriptions for ICS-containing medications in Australia do not appear to have chronic airways disease and often appear to be inappropriately prescribed this medication for the management of symptoms of respiratory infections, with associated risks to patients and costs to the community. While considerable attention has already been paid to reducing inappropriate prescribing of antibiotics for respiratory tract infections, our findings demonstrate that there is also a need for interventions to improve the quality of prescribing of ICS, including in the context of clinical respiratory infections. It is not known whether the pattern of prescribing reported here also occurs in other countries.

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Statistical review Gopal Netuveli

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Conflicts of interest HKR has participated on advisory committees for AstraZeneca, GlaxoSmithKline, and Novartis; is participating on a joint data

monitoring committee for AstraZeneca, GlaxoSmithKline, Merck, and Novartis; has provided consultancy services for GlaxoSmithKline; has spoken about asthma and COPD guidelines at symposia funded by AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, and Merck; and has received research funding from AstraZeneca and GlaxoSmithKline. GBM has served on advisory boards for Novartis; has given lectures at symposia funded by Boehringer Ingelheim and AstraZeneca; and has received research funding from AstraZeneca.

Contributorship HKR and GBM conceived the study. RDA performed the statistical analysis. LMP drafted the initial version of the manuscript. All authors contributed to the manuscript and have read and approved the final manuscript.

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