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Understanding reliever overuse in patients purchasing over-the-counter short-acting beta$_2$ agonists: an Australian community pharmacy-based survey

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ABSTRACT

Objectives Overuse of asthma relievers is associated with significant adverse consequences. This study aimed to better understand the population purchasing and using short-acting beta agonists (SABA) over the counter (OTC); and compare the demographic, clinical and behavioural characteristics of those who overuse SABA with those who do not.

Design and setting Real-world cross-sectional observational study in community pharmacy.

Participants Of 412 participants ≥16 years requesting SABA OTC, 289 were SABA overusers (used SABA more than twice per week in the past 4 weeks).

Main outcome measure Reliever use, Global Initiative for Asthma-defined control, healthcare utilisation, patterns of preventer use.

Results 70.1% of participants were classified as SABA overusers, that is, reporting SABA use more than twice a week within the last 4 weeks, 73.6% reported not using a preventer daily and only 81.6% reported a doctor diagnosis of asthma. SABA overusers were more likely to have moderate-severe nasal symptoms (80.8% vs 63.0%, p<0.001) and a diagnosis of depression (11.1% vs 5.7%, p<0.001), when compared with SABA non-overusers. A higher proportion of SABA overusers had uncontrolled asthma (59.0% vs 15.4%, p<0.001), were more likely to use oral corticosteroids to manage worsening asthma symptoms (26.2% vs 13.5%, p<0.01) and visit the doctor for their asthma in the past 12 months (74.5% vs 62.5%, p<0.01), when compared to SABA non-overusers.

Conclusions This study uncovers a hidden population of people who can only be identified in pharmacy with suboptimal asthma, coexisting rhinitis, poor preventer adherence and, in some cases, no asthma diagnosis.

Strengths and limitations of this study

- Real-life patient cohort of over-the-counter short-acting beta agonist users obtained in community pharmacy.
- Use of validated tools allowed for comparison with other studies.
- Patient diagnosis of asthma and healthcare utilisation could not be confirmed objectively.

INTRODUCTION

Asthma currently affects an estimated 385 million individuals worldwide.[1 2] Despite advances in disease understanding, the development of asthma management guidelines and the availability of effective treatment,[2–5] poor asthma control remains a major problem with approximately 50% of people living with suboptimally controlled disease.[6 7] Poor asthma control is associated with an increased risk of exacerbations, poor quality of life, reduced productivity for individuals and increased healthcare utilisation.[7 8] Common risk factors for poor asthma control include suboptimal medication use including poor inhaler technique, suboptimal adherence, reliever overuse, as well as poorly controlled comorbidities such as rhinitis.[9] These risk factors or modifiable elements that impact symptoms and prognosis can be successfully targeted with optimal treatment to improve disease control.[10] Therefore, the identification of these factors is critical.

Inhaled medications are the cornerstone of pharmacological treatment of asthma, and are a fundamental element of disease management and self-management. Due to the nature of the medications and the important distinction in which medications are used to treat asthma (ie, reliever vs preventer treatments), patients' self-management with their medications can give us insights into both disease status and modifiable factors.

Research has identified that inappropriate use of asthma medications is a significant issue from a global perspective, with the overuse of reliever medications and underuse of preventer medications.[11–13] For example, in the USA a medical expenditure panel survey found that 15% of the asthmatic population in the USA overuse short-acting beta agonists (SABA)[13] and 25% of patients used relievers as a monotherapy to manage their persistent asthma symptoms, that is, failed to use a preventer medication.[14]

In asthma, the inappropriate use of medications has significant adverse consequences.[15] Overuse of SABA therapy is associated with poor asthma control,[16] increased airway hyper-responsiveness,[17] increased asthma-related mortality[18] and increased healthcare utilisation due to asthma.[19] Excessive use of SABA medication has been associated with epidemics of asthma deaths, and dispensing of more than 12 SABA inhalers to one individual over a 12-month period is associated with increased risk of asthma-related death.[20] It is therefore critical and a fundamental principle of asthma medication management that, as the guidelines articulate, SABA use be exclusively restricted to use on an '*as needed*' basis.[21]

One healthcare environment, which can provide a unique perspective on the use of asthma medications, is the community pharmacy. Community pharmacy provides an opportunity to explore people with asthma based on their medication purchasing behaviour and to provide insights into the way in which they more broadly use their asthma medicines. Patients access pharmacies worldwide to purchase medications, where they determine which medication to purchase, whether it be a reliever medication or preventer. The Australian context provides us with a unique opportunity, that is, it enables us to explore the true self-management behaviours of people with asthma, through the use of SABA medicines, within a less restricted prescribing environment. In Australia, SABA medication can be purchased in community pharmacy directly from a pharmacist over the counter (OTC) without the need for a prescription. While a minority of patients will purchase an SABA with a prescription, more than 60% of SABA purchases are made OTC.[22] Research has confirmed that OTC supply of SABA has been linked to undertreatment of asthma[22] and this is of particular importance as SABA medications are often used by patients without regular medical supervision.[23] Therefore, making it a truly unique environment, that in an abundance of healthcare availabilities, patients are still overusing SABA for symptom relief. The implications of such research are of value and relevance globally.

Therefore, the specific objectives of this study were to describe the use of SABA in the Australian community pharmacy setting, and to identify and compare the demographic, clinical and behavioural characteristics of people with asthma who overuse SABA compared with those who do not.

METHODS

Study design

This study took the form of a real-world cross-sectional observational study conducted on a sample of pharmacy customers purchasing OTC SABA medication from community pharmacies between October 2017 and October 2018. No prior assumptions of asthma history were made, but focused on patient behaviour, that is, SABA purchase.

Pharmacists employed in different community pharmacies across various geographical and sociodemographic regions of New South Wales who had previously expressed an interest in being involved in research were invited to participate. In total, pharmacists across 18 different pharmacies invited customers to complete a structured survey following the purchase of SABA medication. The pharmacist distributed the patient survey in their pharmacy within their usual course of working hours. No funding was available and pharmacists' efforts were voluntary.

Pharmacy customers were invited to participate if they fulfilled the following inclusion criteria: individuals aged 16 years and over, purchased OTC SABA medication for themselves from community pharmacy and were able to communicate in English. All participants provided informed consent. There were no exclusion criteria to participation.

Data were collected using a structured self-administered questionnaire (online supplementary appendix 1), which took approximately 15 min to complete in the pharmacy setting. The questionnaire was divided into two sections and captured data relating to patient demographics and clinical characteristics, asthma symptoms, rhinitis symptoms, action plan ownership, SABA use, medication adherence, attitudes towards asthma and asthma medications, medication side effects, inhaler device use, occurrence of exacerbations and healthcare utilisation (online supplementary appendix 1). The questionnaire was developed based on empirical evidence and quantitative research, and collected domains relating to treatable traits of airway diseases.[6 7 10 24]

Participants who were not diagnosed with asthma were excluded from answering the second part of the questionnaire, that is, asthma-specific questions concerning asthma control, healthcare utilisation and preventer medication usage, as the structure of the questionnaire prompted them to stop at the asthma-specific questions (online supplementary appendix 1).

Participants were asked in the 'last week how many times they used their reliever' medication, and categorised as overusing their SABA if 'Three or more times a week' was selected. Participant responses were cross-checked against the Global Initiative for Asthma (GINA) criteria, 'reliever needed for symptoms more than twice a week', participants were categorised into two groups based on the reported frequency of SABA use for symptom relief in the past 4 weeks into *SABA overuse* (more than twice per week in the past 4 weeks) and *no SABA overuse* (less than twice per week in the past 4 weeks).[2]

Patterns of preventer medication use were evaluated with a single question adapted from the Recognise Asthma and Link to Symptoms and Experience study,[6 25 26] in which participants were asked to select a statement that best described how they take their preventer therapy. Participants were able to make multiple selections identifying the reasons for suboptimal adherence as per Price *et al*.[25]

Asthma control was assessed using GINA-defined control; asthma status was labelled as controlled, partially controlled or uncontrolled depending on selected responses.[2]

Healthcare utilisation was identified by the following patient-reported outcomes: hospital admission or emergency attendance related to asthma, and a visit to the physician due to asthma in the last 12 months.

Asthma exacerbations were identified by patients' use of a course of oral steroids for worsening asthma in the last 12 months.

Self-reported rhinitis symptoms were assessed with a two-part question derived from the Allergic Rhinitis and Its Impact on Asthma and the International Primary Care Respiratory Group definition of rhinitis,[27 28] as per Bosnic-Anticevich *et al*.[24]

The questionnaire was designed to facilitate quick and easy self-administration and reviewed by an expert panel of clinical pharmacists, general practitioners and respiratory specialists. All responses were anonymised and participants were deidentified.

Data analysis

Data were analysed using SPSS V.23 (SPSS-IBM). Descriptive statistics were used to summarise patient characteristics.

Based on a 2015 survey stating that 2.5 million people in Australia are living with asthma,[29] the minimum sample size would be 385 responses, to give a confidence level of 95% with a 5% margin of error with an SD of 0.5.

Data were compared between participants who overused SABA medication and those who did not. Continuous variables that were normally distributed were compared using Student's t-test, and the Mann-Whitney U test was used for continuous variables that were not normally distributed. Categorical variables were compared using Pearson χ^2 test. A significance level of p<0.05 was used for all statistical procedures.

Patient and public involvement

This research was conducted without patient input in the study design, patient-relevant outcomes or result interpretation. Patients were asked to complete the questionnaire which was based on current global asthma management guidelines and published patient data.

RESULTS

A total of 412 SABA users completed the questionnaire, of whom 81.6% (336/412) reported a doctor diagnosis of asthma and 70.1% (n=289/412) were classified as SABA overusers, that is, reporting SABA use more than twice a week in the last 4 weeks. Patient demographics are summarised in table 1. SABA overusers were more likely to be older, have an asthma diagnosis and have a positive smoking history than SABA non-overusers (table 1). SABA overusers were also more likely to have a coexisting diagnosis of depression than non-overusers (11.1% vs 5.7%, p<0.001) (table 1).

Reported history of asthma

Not all participants reported an asthma diagnosis (n=76/412 (18.4%)). SABA overusers were more likely to report having a doctor diagnosis of asthma than SABA non-overusers (85.8% vs 71.5%, p<0.001) (table 1). Sixteen participants (n=16/412 (3.9%)) were unsure of whether they had an asthma diagnosis: all of these participants reported having no lung function testing.

Of the 336 participants who reported a doctor diagnosis of asthma, 61.9% (n=208/336) reported having their diagnosis confirmed with a lung function test. A subset of participants (n=18/314 (6%)) self-diagnosed themselves to have asthma without healthcare professional (HCP) confirmation. Twelve per cent (n=40/336) of participants who reported having a doctor diagnosis of asthma rejected their asthma diagnosis (table 1).

Reliever medication use

The majority of participants (99%) were recommended SABA by a physician, 92.7% (382/412) were using SABA via a pressurised metered-dose inhaler and 36.9% (189/412) reported using more than four puffs of SABA a day over the previous 4 weeks. A smaller proportion of SABA overusers compared with SABA non-overusers reported a positive response to 'I only use my SABA when symptoms are present' (60.6% vs 82.1%, respectively, p<0.001) (table 2).

SABA overusers were more likely to report to have taken a maximum number of five or more puffs of SABA in 1 day in the previous 4 weeks compared with SABA non-overusers (46.0% vs 15.4%, p<0.001) (table 2). Additionally, SABA overusers owned a significantly greater number of SABA inhalers at any one time compared with SABA non-overusers (table 2).

Overall, 39.6% (n=163/412) of participants reported experiencing an SABA-associated side effect, with a higher proportion of SABA overusers experiencing side effects compared with SABA non-overusers (43.3% vs 30.9%, p<0.001) (table 2). The most commonly experienced side effect was dry mouth (table 2).

Rhinitis symptoms

Overall, 59.7% (n=246/412) of participants reported a diagnosis of comorbid allergic rhinitis (AR); however, 70.9% (n=292/412) of participants reported experiencing nasal symptoms (itchy, runny, blocked nose or sneezing when they do not have a cold), independent of whether they had a diagnosis or not. Of participants who reported

Table 1 Patient demographics, asthma diagnosis, smoking status and comorbidities

	Overall n=412	SABA overuse		P value
		No n=123	Yes n=289	
Female, n (%)	216 (52.4)	73 (59.3)	143 (49.5)	0.066
Age (years), mean (SD)	43 (17.89)	39 (18.02)	44 (17.59)	<0.001
Age range (years), n (%)				
16–29	113 (27.4)	45 (36.6)	68 (23.5)	0.023
30–49	147 (35.7)	40 (32.5)	107 (37)	
50 or more	152 (36.9)	38 (30.9)	114 (39.4)	
Asthma diagnosis, n (%)				
Physician-diagnosed asthma (self-report)	336 (81.6)	88 (71.5)	248 (85.8)	<0.001
Patient perceives they have asthma	314 (76.2)	71 (57.7)	243 (84.1)	<0.001
Comorbidities, n (%)				
Rhinitis	246 (59.7)	66 (53.7)	180 (62.3)	0.102
Eczema	80 (19.4)	23 (18.7)	57 (19.7)	0.810
Gastro-oesophageal reflux disease	69 (16.7)	16 (13)	53 (18.3)	0.185
Hypertension	69 (16.7)	14 (11.4)	55 (19)	0.128
Depression	44 (10.7)	7 (5.7)	37 (11.1)	0.032
Obstructive sleep apnoea	39 (9.5)	10 (8.1)	29 (10)	0.546
Chronic obstructive pulmonary disease	41 (10)	8 (6.5)	33 (11.4)	0.127
Smoking history, n (%)				
Never smoked	271 (65.8)	93 (75.6)	178 (61.6)	0.021
Past smoker	99 (24.1)	20 (16.3)	79 (27.3)	
Current smoker	42 (10.2)	10 (8)	32 (11)	
SEIFA, n (%)				
1 (most advantaged)	67 (16.3)	24 (19.5)	43 (14.9)	0.644
2	73 (17.7)	20 (16.3)	53 (18.3)	
3	88 (21.4)	22 (17.9)	66 (22.8)	
4	72 (17.5)	23 (18.7)	49 (17)	
5 (most disadvantaged)	112 (27.2)	34 (27.6)	78 (27)	

SABA, short-acting beta agonist; SEIFA, Socio-Economic Indexes for Areas quintiles.

experiencing rhinitis symptoms, 24.0% (70/292) were classified as having mild rhinitis and 76.0% (222/292) had moderate-severe rhinitis symptoms. In participants reporting nasal symptoms, a significantly higher proportion of SABA overusers reported moderate-severe nasal symptoms compared with SABA non-overusers (80.8% vs 63.3%, p<0.001) (figure 1A,B).

Asthma symptom control and healthcare utilisation

Participants without a doctor diagnosis of asthma were prompted to stop after section 1 of the questionnaire at asthma-specific questions (due to the structure of the questionnaire); 39 participants who were unsure of their asthma diagnosis continued to complete the questionnaire. Missing responses are excluded from this part of the analysis (37/412 (9.0%)).

Based on GINA-defined criteria, overall, 17.6% (n=66/375), 35.5% (n=133/375) and 46.9% (n=176/375) of participants had controlled, partially controlled and uncontrolled asthma, respectively (table 3); with a higher proportion of SABA overusers with uncontrolled asthma (59.0% vs 15.4%, p<0.001) compared with SABA non-overusers. SABA non-overusers were more likely to have well-controlled asthma compared with SABA overusers (48.1% vs 5.9%, p<0.001) (table 3).

Table 3 summarises the proportion of participants presenting to emergency, being hospitalised and using oral steroids for their asthma, in the last 12 months. In the year prior to the survey, 22.7% (n=85/375) reported having used at least one short-term course of oral steroids for asthma (table 3). SABA overusers were more likely to use oral corticosteroids to manage worsening asthma symptoms within the last 12 months (26.2% vs 13.5%, p<0.01), and a visit to the doctor for asthma (74.5% vs 62.5%, p<0.01) than SABA non-overusers (table 3).

Table 2 Short-acting beta agonist (SABA) medication use overall and by SABA overuse versus SABA non-overuse (n=412)

SABA medication use	Overall n=412	SABA overuse No n=123	SABA overuse Yes n=289	P value
SABA device, n (%)				
pMDI	307 (74.5)	98 (79.7)	209 (72.3)	0.363
pMDI and spacer	75 (18.2)	18 (14.6)	57 (19.7)	
Turbuhaler	28 (6.8)	6 (4.9)	22 (7.6)	
Autohaler	2 (0.5)	1 (0.8)	1 (0.3)	
Maximum number of SABA puffs in 1 day*, n (%)				
1–4	260 (63.1)	104 (84.6)	156 (54)	<0.001
5–12	128 (31.1)	17 (13.8)	111 (38.4)	
>12	24 (5.8)	2 (1.6)	22 (7.6)	
SABA used only when symptoms present, n (%)				
'Yes' response	276 (67)	101 (82.1)	175 (60.6)	<0.001
SABA side effects experienced, n (%)				
	163 (39.6)	38 (30.9)	125 (43.3)	0.019
Dry mouth	67 (16.3)	16 (13)	51 (17.6)	
Palpitations	34 (8.3)	7 (5.7)	27 (9.3)	
Tremor	26 (6.3)	10 (8.1)	16 (5.5)	
Chest tightness	12 (3)	6 (4.9)	6 (2.1)	
Muscle cramps	8 (2)	3 (2.4)	5 (1.7)	
Headache	18 (4.4)	8 (6.5)	10 (3.5)	
SABA inhalers at any one time, n (SD)	2.22 (±) 1.116	1.86 (±) 0.917	2.37 (±) 1.16	<0.001

*Maximum number of puffs used in 1 day in the last 4 weeks.
pMDI, pressurised metered-dose inhaler.

Preventer medication use

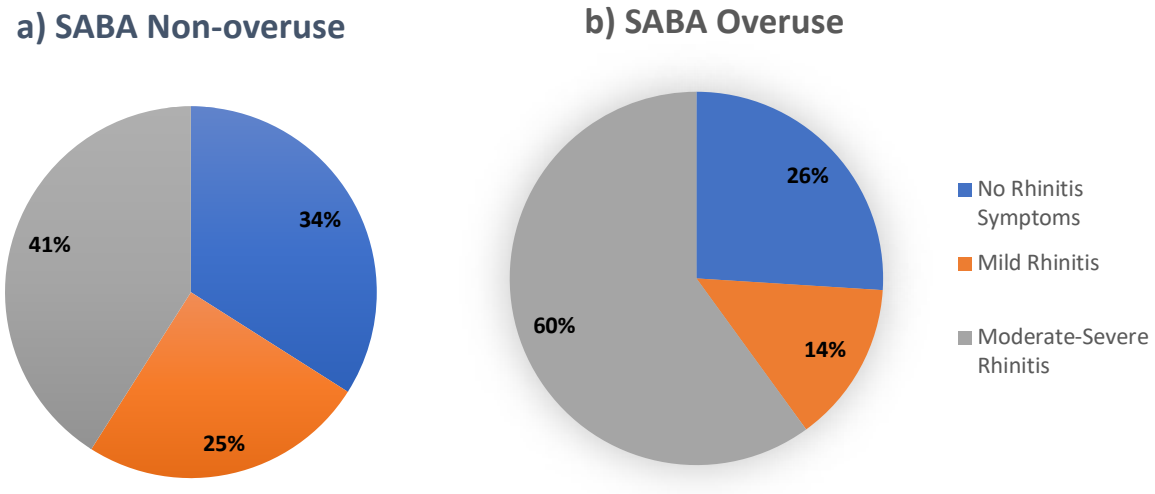
Overall, 68.0% (n=255/375) of participants reported currently having a preventer medication, 29.9% (n=112/375) and 57.1% (n=214/375) reported being instructed to use a preventer when required and every day, respectively, while 73.6% (n=276/375) reported not using a preventer every day. A significantly lower proportion of SABA overusers reported being instructed to use their preventer medication every day compared with SABA non-overusers (41.0% vs 63.0%, p<0.01) (table 4); however, there was no significant difference between the two groups with regard to reported daily use (table 4).

Overall, 25.9% (n=97/375) of participants used their preventer on an 'as needed' basis. The most common reasons reported by participants for not using a preventer medication every day was the belief that they 'did not need' to use their preventer (62.4% (n=234/375)), followed by the presence of side effects (18.1%, n=68/375) and the belief that the preventer 'does not work' (13.3%, n=50/375). There were significant differences between SABA overusers and SABA non-overusers with regard to some of the reasons behind not taking preventer medication every day (table 4).

DISCUSSION

This study provided a unique 'snapshot' of SABA reliever users presenting to Australian community pharmacies and their current asthma status. Several key findings were identified: (1) not all individuals who purchase an SABA acknowledge that they have an asthma diagnosis; (2) SABA overuse is extremely high, while preventer medication use remains low; (3) Approximately a quarter of individuals in the community experience 'controlled asthma'; (4) SABA overusers are more likely to have moderate-severe rhinitis symptoms; and (5) SABA overusers are more likely to have used a course of oral corticosteroids in the previous 12 months. Addressing these key findings in primary care is crucial to reduce the risk of asthma exacerbations and optimise asthma control.

This study revealed that a high proportion of participants overused SABA medication. Just over two-thirds of participants were using their SABA medication more than twice a week, this is a significant problem and factors warranting this overuse need to be identified and treated. In this study, participants were also asked about the maximum number of doses of SABA administered in 1 day in the past month, revealing that more



Figures 1a and 1b: Incidence of mild and moderate-severe rhinitis symptoms among Short Acting Beta Agonist (SABA) non-over users and over users.
[+]Mild Rhinitis (n=70) classified if participants experienced symptoms and symptoms were not bothersome.
[++]Moderate-Severe Rhinitis (n=222) classified if participants experienced symptoms and symptoms were bothersome.

Figure 1 (A, B) Incidence of mild and moderate-severe rhinitis symptoms among short-acting beta agonist (SABA) non-overusers and overusers. Mild rhinitis (n=70) classified if participants experienced symptoms and symptoms were not bothersome. Moderate-severe rhinitis (n=222) classified if participants experienced symptoms and symptoms were bothersome.

than a third of SABA overusers and just under one-fifth of SABA non-overusers were administering five or more puffs of their SABA medication. This finding has significant implications for the way in which we ask about SABA use (ie, the determination of SABA overuse which is currently based on greater than two times per week alone), without considering the number of doses. If, in this study, SABA use was based on both occasion and dose, overuse of SABA would have been identified in 75% (308/412) of participants. This study was not powered to explore factors associated with such high doses of SABA use, however it raises questions about patient's habitual

Table 3 Asthma control, indicators of acute exacerbations and healthcare utilisation overall and by short-acting beta agonist (SABA) overuse versus non-overuse (n=375)

		SABA overuse		
Asthma control	**Overall n=375**	**No n=104**	**Yes n=271**	**P value**
Asthma symptom control (GINA-defined)				
Well controlled	66 (17.6)	50 (48.1)	16 (5.9)	<0.001
Partly controlled	133 (35.5)	38 (36.5)	95 (35.1)	
Uncontrolled	176 (46.9)	16 (15.4)	160 (59)	
Acute exacerbations*				
Oral steroid use for worsening asthma				
≥1	85 (22.7)	14 (13.5)	71 (26.2)	0.01
Emergency presentations or hospitalisation due to asthma				
≥1	46 (12.3)	9 (8.7)	37 (13.7)	0.279
Doctor visit due to asthma				
≥1	267 (71.2)	65 (62.5)	202 (74.5)	0.01

*In the previous 12 months.
GINA, Global Initiative for Asthma-defined control.

Table 4 Preventer inhaler use overall and by short-acting beta agonist (SABA) overuse versus non-overuse (n=375)

Asthma preventermedication n (%)	Overall n=375	SABA overuse		P value
		No n=104	Yes n=271	
Preventer instruction				
Every day	214 (57.1)	43 (41.3)	171 (63.1)	P<0.001
As required	112 (29.9)	39 (37.5)	73 (26.9)	
Don't know	49 (13.1)	22 (21.2)	27 (10)	
Preventer adherence				
I take it everyday	99 (26.4)	21 (20.2)	78 (28.8)	0.322
I take it some days but others I do not	88 (23.5)	20 (19.2)	68 (25.1)	
I used to take it but now I do not	32 (8.5)	7 (6.7)	25 (9.2)	
I take it only when I have symptoms	97 (25.9)	38 (36.5)	59 (21.7)	
I never take it	59 (15.7)	18 (17.3)	41 (15.1)	
Reasons for non-adherence*				
Don't need it	234 (62.4)	65 (62.5)	169 (62.4)	0.971
Side effects experienced	68 (18.1)	12 (11.5)	56 (20.6)	0.04
Don't like it	23 (6.1)	4 (3.8)	19 (7)	0.140
Doesn't work	50 (13.3)	6 (5.8)	44 (16.2)	0.015
Forget to take it	161 (43)	27 (26)	134 (49.4)	<0.001
Too expensive	16 (4.3)	4 (3.8)	12 (4.4)	0.916

*Participants were able to select multiple answers.

behaviours,[30] the possibility of downregulation of beta receptors,[31] increased bronchial hyper-responsiveness[32] or the severity of asthma exacerbations experienced.

The diagnosis of asthma remains a fundamental problem in many cohorts impacting on disease management. Within this cohort of primary care patients, 1 in 5 participants purchase an SABA medication without having an asthma diagnosis, and 1 in 8 do not believe they had asthma despite having a doctor diagnosis. Of participants without a doctor diagnosis of asthma, over half were overusing their SABA medication. Almost all participants in the study reported that SABA medication was recommended by a doctor, irrespective of whether there was an asthma diagnosis. Further research is needed to elucidate why participants without an asthma diagnosis are using and being recommended SABA medication. Further exploration is required to ascertain whether patients are being recommended OTC SABA for undiagnosed asthma or an exacerbating comorbid condition,[2] or is it the presence of confounding comorbidities, such as AR, that can worsen asthma symptoms?

The majority of participants in this study had symptoms that warranted SABA use. A significant proportion of participants reported visiting their doctor in the past 12 months, most participants with asthma reported that they did not 'currently' have a preventer medication. This seems remarkable, as these people visit the doctor and are symptomatic, overuse SABA and yet do not have a preventer. Worldwide adherence to preventer therapy is suboptimal[33] and while those who had been prescribed a preventer acknowledged that they had been advised to take it daily, only 1 in 5 did so, while continuing to use their SABA more than two times per week. An alarming factor regarding preventer adherence was related to the participants' perception that the preventer medication 'doesn't work.' This was prevalent in half the participants who acknowledged that they were advised to take preventer medication every day. These findings are consistent with previous research reporting that patients want immediate relief from asthma symptoms[34] and that they learn that rapid symptom relief is best achieved with SABA rather than preventer medication, which has no immediate perceived benefit. This study brings to light an interesting concept surrounding patient perceived effectiveness of preventer therapy. Perhaps patient non-adherence to preventer therapy may truly identify a cohort of patients in which, as they report, their preventer medication truly 'does not work.' Could it be that a subset of these patients are in fact those patients in whom inhaled corticosteroids (ICS) are not effective, that is, patients with asthma who have neutrophilic as opposed to eosinophilic airway inflammation, or they simply perceive it non-effective due to non-adherence or incorrect inhaler technique. This could be explored further in the future, in particular as the question about asthma phenotypes continues to be a topic of great discussion at this time.

When considering the pattern of preventer use, 1 in 4 participants reported that they only take preventer

therapy when they have symptoms, that is, as needed, regardless of the medication prescribed. This is contrary to current management guidelines, which highlights that even patients with mild symptoms will benefit from daily ICS treatment. Once again, this highlights that a significant proportion of asthma morbidity and its associated costs in Australia are preventable.[7]

When it came to the asthma status of participants, a high proportion reported symptoms consistent with partially or uncontrolled asthma. This finding is consistent with findings from a number of multinational, international and local studies.[6 7 24 26] While participants of this study were recruited at the time of SABA request in the pharmacy, which may suggest they were currently experiencing symptoms/a flare-up, this is nevertheless an unacceptably high proportion of people with asthma who had poorly controlled disease. This is concerning, particularly in a developed country with an abundance of medical services and healthcare accessibility. In trying to determine the asthma severity of the participants in this study, it was noted that about a quarter of participants reported taking at least one dose of oral corticosteroids in the last 12 months to treat an acute exacerbation. This figure is lower than that identified in international data sets; where 44% of respondents in Europe reported having used oral steroids[6] and 77% in Asia[25] where SABA is available on prescription only, however it is consistent with Australian research.[24] One possible reason for this finding is an under-reporting of oral corticosteroids use in this cohort, however there is another possible explanation. What this finding potentially suggests is that perhaps the population visiting community pharmacy in Australia, to purchase OTC SABA, may be a population with milder asthma overall, though still symptomatic. There are insufficient data surrounding the treatment of patients with mild asthma due to their variability of symptoms. This potentially places community pharmacists in a unique position to be able to identify patients, with milder disease, who are experiencing poor control and not using preventer medication, by adopting the paradigm of treatable traits[35] that can be identified in a pharmacy setting. We suggest that this be taken one step further, where pharmacists can begin to identify treatable factors that warrant oral steroid use and SABA overuse.

In exploring this population, it is important to consider comorbidities, which may trigger poor asthma control and potentially lead to the overuse of SABA. The most common comorbidity among participants in this study was AR, which was experienced to a moderate-severe extent and reported to be burdensome to day-to-day living, especially among SABA overusers. While a majority of participants recognised that they had AR, either as a result of doctor diagnosis or self-diagnosis, 1 in 10 experienced symptoms that were suggestive of AR yet did not recognise them as such. As with recent global research in AR,[24] this study once again highlights the high burden of AR on individuals (whether diagnosed or not) and as in this study, on individuals with asthma and having poorly controlled disease.[36 37] This study identifies the gap in AR management in the community[24] and an opportunity for pharmacists to engage with patients around optimising AR control.

In addition to AR, a significant proportion of participants also reported having gastro-oesophageal reflux disease, cardiovascular disease and depression. In recent research these comorbidities have been identified as treatable traits.[10] It is known that extrapulmonary traits can either exacerbate asthma or mimic symptoms of asthma, making it essential for HCPs to rule out any poorly controlled conditions and ensure they are adequately managed and that asthma control is achieved and maintained. There is evidence suggesting that focusing on treatable traits can lead to improvements in patients' quality of life, and allow for the engagement of patients in a multidimensional management plan.[38] Participants with coexisting chronic obstructive pulmonary disease (COPD) are an interesting cohort, as 1 in 10 participants reported coexisting COPD and almost all overused their SABA medication, suggesting that a review of their respiratory status and treatment is required.

This study uncovered several inconsistencies, misunderstandings and disconnects between participant responses as they related to medication use, asthma control and asthma diagnosis. While it is not possible to definitely determine the causes of SABA overuse in this cohort, there are several possible explanations which need to be considered. Research suggests that patients under-report their symptoms, commonly due to their lack of perception in regard to actual level of asthma control.[6 24 25] That is, patients may tolerate their symptoms and deem them to be the 'norm' or perhaps they manage their asthma with a 'crisis-orientated' approach, that is, they only respond to symptoms when they are bad.[6 25] Therefore, it is possible in this survey that participants may be over-reporting or under-reporting of symptoms and medication use, due to patient-related factors. Participants reported differing answers when asked about medication use and adherence to preventer therapy. In this study we were unable to ascertain how many participants were prescribed and dispensed a preventer medication to elucidate their actual adherence. Participants were asked a series of questions relating to current 'ownership' of a preventer ('*Do you currently have a preventer…?*'), instruction on preventer use ('*How often does your doctor want you to take your preventer?*') and how participants take their preventer. This uncovered interesting/inconsistent results with a higher proportion of participants reporting receiving instruction on how to use a preventer than those reporting that they currently had a preventer. This could be interpreted in at least two ways: some participants were prescribed a preventer but did not currently have one, or there was a misinterpretation of the later question relating to '*How often does the doctor want you to take this (preventer) medication?*'. The lack of clarity with regard to the appropriateness of the instruction received by the doctor and its correlation with adherence is a limitation

of this line of questioning. Participant responses further varied when asked SABA use (>2 occasions per week over the last 4 weeks). We speculate that participants prefer to give socially desirable answers and this is consistent with past research.[39] This raises the question—due to inconsistencies within research data that our old approach of simply asking about asthma and asthma medication usage is problematic and control in these patients is not being achieved.[35] Future research is required to determine the extent of symptom-driven SABA use and distinguished from SABA use associated with exercise or due to HCP instruction. This is a limitation within this study as SABA overuse classification could not accurately factor in if the use was for symptoms and/or exercise, future studies will need to explore this. This raises the question surrounding clinician-used terminology; whether it be understood or correctly interpreted by the patient. Research is needed to find patient-suited terminology to enable effective, efficient and appropriate assessment and treatment of asthma and to deter the provision of socially desirable responses. Our approach in addressing asthma requires change and a multidisciplinary approach for phenotype treatment moving towards individualised patient treatment and care in a real-life setting.

While SABA medication is not available OTC in many countries, this research has global implications, healthcare relevance and should not be discounted as country specific. It identifies patient-driven medication purchasing and taking decisions and patterns of medication use/misuse. Globally, patients present to pharmacies to purchase medications of their 'choosing'.[40] In this study, while 68% of patients report that they currently have a preventer medication, only 26% report taking it every day. While there is no direct comparative evidence with Australia, there is evidence to suggest that Australians with asthma may not be dissimilar to people with asthma globally when it comes to their perceptions of their disease, in fact there is growing global evidence that people with asthma all around the world exhibit key similarities in terms of disease control and perceptions of their asthma.[7 9 25 26 39 41] The correlation between ICS adherence and the availability of SABA OTC is unknown, hence further research is necessary to determine whether the availability of OTC SABA could potentially exacerbate poor ICS adherence (ie, patient runs out of their preventer and chooses to get a reliever OTC only perhaps as a matter of convenience). In pharmacy this is a missed opportunity to rectify and begin to address this issue of patient medication choice leading to preventer underuse and SABA overuse. While most patients visit other HCPs such as physicians, it is clearly not enough to just maintain what is currently being done, as asthma control worldwide is suboptimal. We need to take a multidisciplinary approach and engage physicians and prescribers, and pharmacists, so that problems are identified at all healthcare levels and any point that patients seek treatment.

This study recruited participants in real time, making it a major strength of this study, data were collected in real time from a real-life cohort of SABA users, which is broad in nature and reach, using validated tools to provide a complete picture of SABA medication use in the community. This study explored factors surrounding participants' purchase and use of SABA medications; however, it is limited by the fact that doctor confirmation of asthma diagnosis could not be established. A further potential limitation is the potential for selection bias in the recruitment of this convenience sample. Due to the data being collected during pharmacy opening times, response rate was not captured and is unknown adding to the convenience sample bias. While the study was run over a whole year, we are unable to discount that seasonality could be a major factor in SABA overuse, this should be explored in future studies. SABA pharmacy purchases could potentially overidentify overuse of participants due to worsening symptoms on that particular day or week further adding to selection bias, longitudinal data collection is necessary to identify consistent SABA overusers.

In conclusion, this is the first research to explore the real-life use of SABA in the community pharmacy, giving insights into individuals who overuse SABA medications and those who do not. This study uncovered a hidden population who can only be uncovered in community pharmacy; a cohort with suboptimal asthma, coexisting AR, poor ICS adherence and, in some cases, no asthma diagnosis. This research uncovered major disconnects in the thinking and behaviour of people with asthma. It highlights the need to better understand people with asthma and better use the opportunity provided through the community pharmacy to identify treatable traits, patients at risk of poorly controlled disease, and to address the issues of medication management. Perhaps the most significant finding of this research is that it identified people with asthma in the community who have poorly controlled asthma and without pharmacist's intervention, may never be identified as problematic and in need of ICS treatment. We can no longer ignore the critical contribution that pharmacists have to identify problematic traits linked with poor medication use. This reinforces the importance of a multidisciplinary approach, and therefore the need for a collective effort to identify and treat these patients. Future research is needed to explore how the community pharmacist can better identify uncontrolled patients and to develop tools/strategies designed for community pharmacy to help identify these patients.

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