# Over-prescription of short-acting $\beta_2$-agonists for asthma in South Africa: Results from the SABINA III study

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**Background.** Asthma medication prescription trends, including those of short-acting $\beta_2$-agonists (SABAs), are not well documented for South Africa (SA).
**Objectives.** To describe demographics, disease characteristics and asthma prescription patterns in the SA cohort of the SABA use IN Asthma (SABINA) III study.
**Methods.** An observational, cross-sectional study conducted at 12 sites across SA. Patients with asthma (aged ≥12 years) were classified by investigator-defined asthma severity, guided by the Global Initiative for Asthma (GINA) 2017 recommendations, and practice type (primary/specialist care). Data were collected using electronic case report forms.
**Results.** Overall, 501 patients were analysed – mean (standard deviation) age, 48.4 (16.6) years; 68.3% female – of whom 70.6% and 29.4% were enrolled by primary care physicians and specialists, respectively. Most patients were classified with moderate-to-severe asthma (55.7%; GINA treatment steps 3 - 5), were overweight or obese (70.7%) and reported full healthcare reimbursement (55.5%). Asthma was partly controlled/uncontrolled in 60.3% of patients, with 46.1% experiencing ≥1 severe exacerbations in the 12 months before the study visit. Overall, 74.9% of patients were prescribed ≥3 SABA canisters in the previous 12 months (over-prescription); 56.5% were prescribed ≥10 SABA canisters. Additionally, 27.1% of patients reported purchasing SABA over-the-counter (OTC); among patients with both SABA purchase and prescriptions, 75.4% and 51.5% already received prescriptions for ≥3 and ≥10 SABA canisters, respectively, in the preceding 12 months.
**Conclusion.** SABA over-prescription and OTC purchase were common in SA, demonstrating an urgent need to align clinical practices with the latest evidence-based recommendations and regulate SABA OTC purchase to improve asthma outcomes.
**Keywords.** Asthma, exacerbations, over-prescription, SABINA, SABA, short-acting $\beta_2$-agonist, South Africa.

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**Study synopsis**
**What the study adds.** This study provides valuable insights into asthma medication prescription patterns, particularly SABAs, across SA. Collection of this real-world data in patients treated in primary and specialty care demonstrates that SABA over-prescription and SABA OTC purchase are common, even in patients with mild asthma. These findings will enable clinicians and policymakers to make targeted changes to optimise asthma outcomes across the country.
**Implications of the findings.** SABA over-prescription represents a major public health concern in SA. Healthcare providers and policymakers will need to work together to promote educational initiatives aimed at patients, pharmacists and physicians, align clinical practices with the latest evidence-based recommendations, improve access to affordable medications and regulate SABA purchase without prescription.

Asthma, a heterogeneous chronic inflammatory condition of the airways,[1] is estimated to affect 339 million people globally.[2] The traditional view of asthma being a disease of high-income countries no longer holds true as most affected individuals reside in low- and middle-income countries, where asthma remains under-recognised and poorly managed.[3] South Africa (SA)has a particularly high prevalence of asthma and is currently ranked 25th globally. Furthermore, the prevalence of asthma is increasing in both urban and rural areas.[2]

Although a substantial decline in asthma-related deaths has been reported over the past decade, mortality rates in SA remain one of the highest globally (ranked 5th), with an estimated 18.5 deaths per 100 000 asthma cases.[2] These high mortality rates are primarily due to incorrect and inadequate implementation of international and national asthma guidelines, which may be attributable to challenges within the SA healthcare system; behaviours of healthcare providers (HCPs), patients and caregivers; and socioeconomic and structural barriers that may restrict access to healthcare services.[4] Moreover, the magnitude of the burden of asthma is often underestimated in SA, partly owing to a healthcare system that is frequently overwhelmed by communicable respiratory diseases, such as pneumonia, tuberculosis and human immunodeficiency virus-associated lung diseases.[4] Consequently, despite the availability of a range of medications, asthma management in SA remains suboptimal, with many patients continuing to have poorly controlled asthma.[5]

Despite the high burden of asthma in SA,[1,4] data on trends in medication use across the country are lacking. However, an understanding of asthma medication prescribing would be of immense value as adherence to the latest evidence-based guidelines is essential to achieve and maintain asthma symptom control and prevent exacerbations.[6] Moreover, following mounting evidence that SABA overuse (≥3 canisters/year) is associated with an increased risk of exacerbations, hospitalisations and mortality,[7-9] the Global Initiative for Asthma (GINA) no longer recommends treatment with as-needed SABA without a concomitant inhaled corticosteroid (ICS) for symptom relief in patients ≥12 years of age. Instead, low-dose ICS-formoterol is now recommended as the preferred as-needed reliever for adults and adolescents with mild asthma and for those with moderate-to-severe asthma who are prescribed ICS-formoterol maintenance therapy.[6] Therefore, an overview of asthma medication prescription patterns, particularly those of SABA and its consequences in SA, will bring clinicians, researchers and healthcare policymakers to a better understanding of current treatment practices and the extent of potential SABA overuse.

The SABA use IN Asthma (SABINA) III (International) study was undertaken to describe SABA prescription patterns in 24 countries across five continents through a series of real-world observational studies using a harmonised approach to data collection, evaluation and interpretation.[10] Here, we report results from the SA cohort of the SABINA III study to provide real-world evidence on asthma treatment patterns in the country.

# Methods

## Study design

The detailed methodology for SABINA III has been described previously.[11] In brief, this was an observational, cross-sectional study conducted at 12 sites across SA, with patient recruitment from August 2019 to December 2019. The study objectives were to describe the demographic and clinical features of the asthma population and to estimate SABA and ICS prescriptions in the 12 months prior to the study visit. At each site, during a single visit, pre-specified patient data were collected by HCPs using electronic case report forms (eCRFs). The study was conducted in compliance with the study protocol, local ethics committee and the Declaration of Helsinki.

## Study population

Patients (aged ≥12 years) with a documented asthma diagnosis, ≥3 HCP consultations and medical records containing data for ≥12 months prior to the study visit were eligible for enrolment. Patients with other chronic respiratory diseases or a limiting acute or chronic condition were excluded. Signed informed consent was collected from patients or legal guardians.

## Variables and outcomes

Patients were categorised by their SABA and ICS prescriptions in the 12 months before the study visit. SABA prescriptions were categorised as 0, 1 - 2, 3 - 5, 6 - 9, 10 - 12 and ≥13 canisters/inhalers, with over-prescription defined as ≥3 SABA canister prescriptions per year.[10] ICS canister prescriptions were recorded and categorised according to the prescribed average daily dose (low, medium or high).[12]

Secondary variables included sociodemographic characteristics, practice type (primary or specialist care), investigator-classified asthma severity (guided by GINA 2017 treatment steps: steps 1 - 2, mild asthma; steps 3 - 5, moderate-to-severe asthma,[12]) time since asthma diagnosis and asthma treatment prescriptions, including SABA monotherapy, SABA in addition to maintenance therapy, ICS, fixed-dose combinations of ICS with long-acting $\beta_2$-agonists (LABAs), oral corticosteroid (OCS) burst treatment (defined as a short course of intravenous corticosteroids or OCS administered for 3 - 10 days or a single dose of an intramuscular corticosteroid to treat an exacerbation), long-term OCS (defined as any OCS treatment for >10 days) and antibiotics. In addition, SABA over-the counter (OTC) purchase data based on patient recall was obtained directly from patients at the study visit and entered in the eCRF by the investigator.

The asthma-related health outcomes assessed were asthma symptom control at the time of study visit (using the GINA 2017 assessment of asthma control[12]) and the number of severe asthma exacerbations defined according to the American Thoracic Society/ European Respiratory Society recommendations as a worsening of asthma symptoms resulting in hospitalisation, an emergency room visit, or the need for OCS burst treatment.[13]

## Statistical analyses

Descriptive analyses were used to characterise patients according to baseline demographics and clinical characteristics. Continuous variables were summarised as the number of non-missing values, mean, standard deviation (SD), median and range, while categorical variables were summarised as frequency counts and percentages.

## Results

***Patient disposition***

Of the 505 patients enrolled, four were excluded owing to an asthma duration <12 months (Supplementary Fig. 1). The majority of patients (70.6%) were treated by primary care physicians (PCPs), with 29.4% treated by specialists.

## Patient demographics and lifestyle characteristics

Patients had a mean (SD) age of 48.4 (16.6) years; the majority were female (68.3%), overweight or obese (70.7%) and had never smoked (71.7%). Overall, most patients (43.7%) had received high school education, whereas 37.1% had obtained university and/or postgraduate education. Just over half of all patients (55.5%) reported full healthcare reimbursement, while 37.7% reported no healthcare reimbursement. Across disease severities, 81.6% of patients under specialist care had full healthcare reimbursement compared with only 44.5% of patients under primary care. Notably, 73.7% of patients with mild asthma under specialist care had full healthcare reimbursement compared with only 20.7% of patients with mild asthma under primary care (Table 1).

## Disease characteristics

Just over half of all patients (55.7%) had investigator-classified moderate-to-severe asthma (GINA treatment steps 3 - 5). The mean (SD) asthma duration was 22.1 (15.9) years, with most patients at GINA treatment step 2 (37.5%) or step 4 (29.9%). Overall, 78.2% of patients had ≤2 comorbidities. Patients reported a median (min, max) of 0.0 (0.0, 6.0) severe asthma exacerbations in the 12 months preceding study initiation, with 46.1% experiencing ≥1 severe asthma exacerbation (Table 2).

The level of asthma symptom control was assessed as well-controlled in 39.7%, partly controlled in 33.5% and uncontrolled in 26.7% of patients. More patients in specialist care than those in primary care had well-controlled asthma (59.9% v. 31.4%, respectively). Furthermore, in specialist care, the percentage of patients with well-controlled mild asthma was higher compared with that of patients with well-controlled moderate-to-severe asthma (78.9% v. 57.0%, respectively; Table 2).

## Asthma treatments in the 12 months before the study visit

Altogether, 74.9% of patients were prescribed ≥3 SABA canisters, defined as over-prescription, with more than half (56.3%) prescribed 10 - 12 SABA canisters in the 12 months prior to study entry; 14.6% of patients received no SABA prescriptions (Fig. 1). A higher proportion of patients with mild asthma compared with those with moderate-to-severe asthma were prescribed ≥3 (86.9% v. 65.2%, respectively) and ≥10 (75.7% v. 41.2%, respectively) SABA canisters. More patients in primary care than those in specialist care were prescribed 10 - 12 SABA canisters (68.0% v. 28.6%, respectively) in the previous 12 months.

## SABA monotherapy

SABA monotherapy was prescribed to 6.8% of patients, with a mean (SD) of 5.0 (4.5) canisters in the preceding 12 months. Of these patients, 52.9% were prescribed ≥3 SABA canisters and 23.5% were prescribed ≥10 SABA canisters (Table 3).

In primary care, 9.3% of patients, all of whom were categorised with mild asthma, were prescribed SABA monotherapy, with a mean (SD) of 4.8 (4.4) canisters in the previous 12 months. Among these patients, 51.5% were prescribed ≥3 SABA canisters in the prior 12 months. In specialist care, only one patient was prescribed SABA monotherapy. This patient with mild asthma was prescribed 12 SABA canisters in the preceding 12 months.

## SABA in addition to maintenance therapy

The majority of patients (78.6%) were prescribed SABA in addition to maintenance therapy, with a mean (SD) of 9.9 (3.7) canisters in the previous 12 months. Of these patients, 90.6% were prescribed ≥3 SABA canisters and 69.8% were prescribed ≥10 SABA canisters (Table 3).

More patients treated in primary care were prescribed SABA in addition to maintenance therapy (84.1% v. 65.3% in specialist care). Although 90.6% of patients in both practice types were prescribed ≥3 SABA canisters, a higher proportion of patients in primary care were prescribed ≥10 SABA canisters (78.8% v. 42.7% in specialist care).

## SABA purchased OTC without a prescription

Overall, 27.1% of patients purchased SABA OTC in the preceding 12 months, of whom 45.6% purchased ≥3 SABA canisters (Table 4). SABA OTC purchase was higher in primary care than in specialist care (30.6% v. 18.4%, respectively), with 50.0% of patients in primary care purchasing ≥3 SABA canisters in the previous 12 months compared with 25.9% in specialist care.

Almost all patients (98.5%) who purchased SABA OTC also received SABA prescriptions. Among patients with both SABA purchase and prescriptions, 75.4% received prescriptions for ≥3 SABA canisters and 51.5% received prescriptions for ≥10 SABA canisters in the preceding 12 months (Fig. 2).

## Other prescriptions of asthma medication in the 12 months before the study visit

***Inhaled corticosteroids***

In the 12 months prior to study entry, 36.1% of patients were prescribed ICS, with a mean (SD) of 11.9 (3.1) canisters. Most patients were prescribed medium-dose ICS (52.0%), with 31.8% and 16.2% prescribed low- and high-dose ICS, respectively (Supplementary Table 1).

***ICS/long-acting $\beta_2$-agonist (LABA) fixed-dose combination***

ICS/LABA fixed-dose combination maintenance therapy was prescribed to 58.9% of patients. Of these patients, 51.7% were prescribed medium-dose, 33.7% were prescribed low-dose and 14.6% were prescribed high-dose ICS (Supplementary Table 1).

***Other medications***

Overall, 37.3% of patients were prescribed an OCS burst in the previous 12 months (39.9%, primary care; 31.3%, specialist care (Supplementary Table 1). An OCS burst was prescribed to more patients with moderate-to-severe asthma than those with mild asthma in both primary (44.0% v. 36.9%, respectively) and specialist care (32.8% v. 21.1%, respectively). Antibiotics for asthma were

**Table 1. Demographics and baseline clinical characteristics by investigator-classified asthma severity and practice type in the SABA use IN Asthma (SABINA) III South African cohort**

| | | Primary care | | | Specialist care | | |
|---|---|---|---|---|---|---|---|
| **Characteristics** | **All (*N*=501)** | **Investigator-classified mild asthma (*n*=203)** | **Investigator-classified moderate-to-severe asthma (*n*=150)** | **All (*n*=353)** | **Investigator-classified mild asthma (*n*=19)** | **Investigator-classified moderate-to-severe asthma (*n*=128)** | **All (*n*=147)** |
| **Age (years)** | | | | | | | |
| Mean (SD) | 48.4 (16.6) | 47.6 (16.7) | 46.2 (16.0) | 47.0 (16.4) | 55.4 (16.9) | 51.2 (16.7) | 51.8 (16.7) |
| Median (min, max) | 49.0 (12.0, 93.0) | 48.0 (13.0, 87.0) | 48.0 (12.0, 80.0) | 48.0 (12.0, 87.0) | 51.0 (21.0, 85.0) | 51.0 (16.0, 93.0) | 51.0 (16.0, 93.0) |
| **Age groups, *n* (%)** | | | | | | | |
| 12 - 17 years | 20 (4.0) | 11 (5.4) | 7 (4.7) | 18 (5.1) | 0 (0.0) | 2 (1.6) | 2 (1.4) |
| ≥18 - 54 years | 292 (58.3) | 113 (55.7) | 96 (64.0) | 209 (59.2) | 11 (57.9) | 71 (55.5) | 82 (55.8) |
| ≥55 years | 189 (37.7) | 79 (38.9) | 47 (31.3) | 126 (35.7) | 8 (42.1) | 55 (43.0) | 63 (42.9) |
| **Sex, n (%)** | | | | | | | |
| Female | 342 (68.3) | 143 (70.4) | 98 (65.3) | 241 (68.3) | 13 (68.4) | 87 (68.0) | 100 (68.0) |
| Male | 159 (31.7) | 60 (29.6) | 52 (34.7) | 112 (31.7) | 6 (31.6) | 41 (32.0) | 47 (32.0) |
| **BMI (kg/m$^2$)** | | | | | | | |
| Mean (SD) | 29.9 (8.4) | 30.3 (9.3) | 30.5 (8.3) | 30.3 (8.8) | 27.6 (7.2) | 29.0 (6.9) | 28.8 (7.0) |
| **BMI groups (kg/m$^2$), *n* (%)** | | | | | | | |
| <18.5 | 22 (4.4) | 16 (7.9) | 3 (2.0) | 19 (5.4) | 1 (5.3) | 2 (1.6) | 3 (2.0) |
| ≥18.5 - 24.9 | 125 (25.0) | 43 (21.2) | 37 (24.7) | 80 (22.7) | 7 (36.8) | 38 (29.7) | 45 (30.6) |
| ≥25 - 29.9 | 135 (26.9) | 53 (26.1) | 41 (27.3) | 94 (26.6) | 5 (26.3) | 36 (28.1) | 41 (27.9) |
| ≥30 | 219 (43.7) | 91 (44.8) | 69 (46.0) | 160 (45.3) | 6 (31.6) | 52 (40.6) | 58 (39.5) |
| **Education level, *n* (%)** | | | | | | | |
| Unknown | 1 (0.2) | 1 (0.5) | 0 (0.0) | 1 (0.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Primary school | 29 (5.8) | 22 (10.8) | 4 (2.7) | 26 (7.4) | 0 (0.0) | 3 (2.3) | 3 (2.0) |
| Secondary school | 66 (13.2) | 42 (20.7) | 18 (12.0) | 60 (17.0) | 1 (5.3) | 5 (3.9) | 6 (4.1) |
| High school | 219 (43.7) | 108 (53.2) | 42 (28.0) | 150 (42.5) | 11 (57.9) | 58 (45.3) | 69 (46.9) |
| University and/or post-graduate education | 186 (37.1) | 30 (14.8) | 86 (57.3) | 116 (32.9) | 7 (36.8) | 62 (48.4) | 69 (46.9) |
| **Healthcare insurance/medication funding, *n* (%)** | | | | | | | |
| Unknown | 2 (0.4) | 1 (0.5) | 0 (0.0) | 1 (0.3) | 0 (0.0) | 1 (0.8) | 1 (0.7) |
| Not reimbursed | 189 (37.7) | 157 (77.3) | 22 (14.7) | 179 (50.7) | 0 (0.0) | 10 (7.8) | 10 (6.8) |
| Partially reimbursed | 32 (6.4) | 3 (1.5) | 13 (8.7) | 16 (4.5) | 5 (26.3) | 11 (8.6) | 16 (10.9) |
| Fully reimbursed | 278 (55.5) | 42 (20.7) | 115 (76.7) | 157 (44.5) | 14 (73.7) | 106 (82.8) | 120 (81.6) |
| **Smoking status history, n (%)** | | | | | | | |
| Active smoker | 56 (11.2) | 35 (17.2) | 21 (14.0) | 56 (15.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Former smoker | 86 (17.2) | 32 (15.8) | 23 (15.3) | 55 (15.6) | 6 (31.6) | 25 (19.5) | 31 (21.1) |
| Never smoker | 359 (71.7) | 136 (67.0) | 106 (70.7) | 242 (68.6) | 13 (68.4) | 103 (80.5) | 116 (78.9) |

BMI = body mass index; max = maximum; min = minimum; SD = standard deviation.

prescribed to 12.9% of patients, with this occurring in a similar proportion of patients in primary and specialist care (13.7% and 11.0%, respectively).

### Asthma treatments and severe exacerbations

When stratified by treatments prescribed in the previous 12 months, most patients who were prescribed an OCS burst treatment experienced ≥1 severe asthma exacerbation (94.1%), followed by those prescribed antibiotics (84.4%), SABA monotherapy (52.9%), ICS/LABA fixed-dose combination (47.1%), SABA in addition to maintenance therapy (46.2%) and ICS (43.1%).

## Discussion

This cross-sectional study, conducted as part of SABINA III, provides valuable real-world insights into the extent of SABA prescriptions in SA. Overall, results showed that SABA over-prescription was extremely common across SA, with 74.9% of patients prescribed ≥3 SABA canisters, which is defined as over-prescription, in the 12 months prior to the study visit. This figure was considerably higher than that reported in the overall SABINA III population, where 38% of patients were prescribed ≥3 SABA canisters.[11]

In general, the overall sociodemographic and disease characteristics of SA patients were consistent with those of SABINA III patients.[11]

**Table 2. Asthma characteristics according to investigator-classified asthma severity and practice type in the SABA use IN Asthma (SABINA) III South African cohort**

| | | Primary care | | | Specialist care | | |
|---|---|---|---|---|---|---|---|
| **Asthma characteristics** | **All (*N*=501)** | **Investigator-classified mild asthma (*n*=203)** | **Investigator-classified moderate-to-severe asthma (*n*=150)** | **All (*n*=353)** | **Investigator-classified mild asthma (*n*=19)** | **Investigator-classified moderate-to-severe asthma (*n*=128)** | **All (*n*=147)** |
| **Asthma duration, years** | | | | | | | |
| Mean (SD) | 22.1 (15.9) | 21.1 (13.5) | 19.6 (13.6) | 20.5 (13.6) | 25.5 (24.7) | 26.2 (19.2) | 26.1 (19.9) |
| Median (min, max) | 20.0 (1.0, 85.0) | 19.0 (1.0, 60.0) | 17.0 (1.0, 66.0) | 18.0 (1.0, 66.0) | 19.0 (1.0, 85.0) | 24.5 (1.0, 80.0) | 23.0 (1.0, 85.0) |
| **GINA classification, *n* (%)** | | | | | | | |
| Step 1 | 34 (6.8) | 33 (16.3) | 0 (0.0) | 33 (9.3) | 1 (5.3) | 0 (0.0) | 1 (0.7) |
| Step 2 | 188 (37.5) | 170 (83.7) | 0 (0.0) | 170 (48.2) | 18 (94.7) | 0 (0.0) | 18 (12.2) |
| Step 3 | 97 (19.4) | 0 (0.0) | 40 (26.7) | 40 (11.3) | 0 (0.0) | 57 (44.5) | 57 (38.8) |
| Step 4 | 150 (29.9) | 0 (0.0) | 96 (64.0) | 96 (27.2) | 0 (0.0) | 53 (41.4) | 53 (36.1) |
| Step 5 | 32 (6.4) | 0 (0.0) | 14 (9.3) | 14 (4.0) | 0 (0.0) | 18 (14.1) | 18 (12.2) |
| **Number of comorbidities, *n* (%)** | | | | | | | |
| None | 152 (30.3) | 61 (30.0) | 56 (37.3) | 117 (33.1) | 1 (5.3) | 34 (26.6) | 35 (23.8) |
| 1 - 2 | 240 (47.9) | 100 (49.3) | 69 (46.0) | 169 (47.9) | 9 (47.4) | 61 (47.7) | 70 (47.6) |
| 3 - 4 | 88 (17.6) | 33 (16.3) | 23 (15.3) | 56 (15.9) | 7 (36.8) | 25 (19.5) | 32 (21.8) |
| ≥5 | 21 (4.2) | 9 (4.4) | 2 (1.3) | 11 (3.1) | 2 (10.5) | 8 (6.2) | 10 (6.8) |
| **Number of severe asthma exacerbations in 12 months before the study visit** | | | | | | | |
| Mean (SD) | 0.8 (1.1) | 0.8 (1.2) | 0.8 (1.1) | 0.8 (1.1) | 0.3 (0.6) | 0.6 (0.8) | 0.6 (0.8) |
| Median (min, max) | 0.0 (0.0, 6.0) | 0.0 (0.0, 6.0) | 0.0 (0.0, 5.0) | 0.0 (0.0, 6.0) | 0.0 (0.0, 2.0) | 0.0 (0.0, 5.0) | 0.0 (0.0, 5.0) |
| **Number of severe asthma exacerbations 12 months before the study visit by groups, *n* (%)** | | | | | | | |
| 0 | 270 (53.9) | 112 (55.2) | 76 (50.7) | 188 (53.3) | 14 (73.7) | 67 (52.3) | 81 (55.1) |
| 1 | 141 (28.1) | 45 (22.2) | 44 (29.3) | 89 (25.2) | 4 (21.1) | 48 (37.5) | 52 (35.4) |
| 2 | 58 (11.6) | 25 (12.3) | 22 (14.7) | 47 (13.3) | 1 (5.3) | 10 (7.8) | 11 (7.5) |
| 3 | 17 (3.4) | 13 (6.4) | 2 (1.3) | 15 (4.2) | 0 (0.0) | 2 (1.6) | 2 (1.4) |
| >3 | 15 (3.0) | 8 (3.9) | 6 (4.0) | 14 (4.0) | 0 (0.0) | 1 (0.8) | 1 (0.7) |
| **Level of asthma symptom control, *n* (%)** | | | | | | | |
| Well controlled | 199 (39.7) | 62 (30.5) | 49 (32.7) | 111 (31.4) | 15 (78.9) | 73 (57.0) | 88 (59.9) |
| Partly controlled | 168 (33.5) | 75 (36.9) | 60 (40.0) | 135 (38.2) | 2 (10.5) | 30 (23.4) | 32 (21.8) |
| Uncontrolled | 134 (26.7) | 66 (32.5) | 41 (27.3) | 107 (30.3) | 2 (10.5) | 25 (19.5) | 27 (18.4) |

GINA = Global Initiative for Asthma; max = maximum; min = minimum; SD = standard deviation.

However, patients from SA had a longer asthma duration (mean duration 22.1 years) than those from the overall SABINA III cohort (mean duration 14.9 years),[11] which may be attributed to the high prevalence of childhood asthma in SA.[3,14] The majority of patients (70.7%) were classified as overweight or obese, possibly reflecting the increasing prevalence of obesity in the southern African region,[15] especially in SA.[16] Notably, 70.6% of patients were treated in primary care, a considerably higher proportion than that observed in SABINA III (17.7%).[11] Consequently, a higher percentage of patients from SA were classified with mild asthma (44.3%) compared with those from SABINA III (23.4%),[11] where the majority of patients were classified with moderate-to-severe asthma and therefore treated by specialists. Accordingly, the current study provides a more accurate picture of how asthma of all severities is currently being managed and treated across SA.

Concerningly, a high proportion of patients from SA were prescribed SABA treatments, either as monotherapy or in addition to maintenance therapy. Although only 6.8% of patients were prescribed SABA monotherapy, 52.9% of these patients were prescribed ≥3 SABA canisters in the preceding 12 months. Furthermore, of the 78.6% of patients prescribed SABA in addition to maintenance therapy, 90.6% were prescribed ≥3 canisters in the previous 12 months. Moreover, 23.5% and 69.8% of patients were prescribed ≥10 SABA canisters as monotherapy or with maintenance treatment, respectively, in the 12 months prior. Although SABA over-prescription occurred across practice types, this trend was more apparent in primary care, wherein a greater proportion of patients received prescriptions for 10 - 12 SABA canisters (68.0% v. 28.6% in specialist care). A possible explanation for this trend is that PCPs frequently face a number of challenges, including limited time for in-depth diagnostic assessments, non-availability of diagnostic

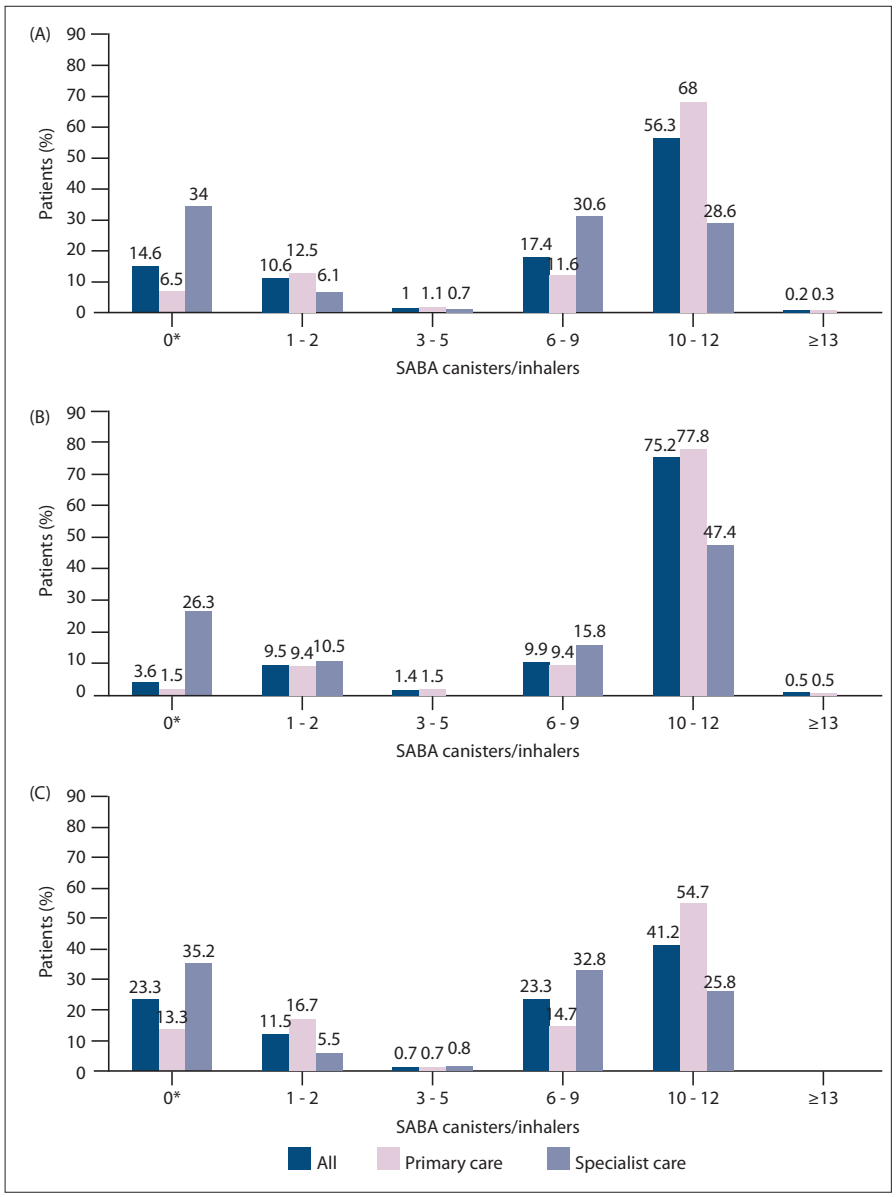


*Fig. Proportion of patients (%) receiving short-acting $\beta_2$-agonist prescriptions in the 12 months before the study visit according to investigator-classified asthma severity and practice type: (A) all patients, (B) mild asthma (C) moderate-to-severe asthma in the SABA use IN Asthma (SABINA) III South African cohort.*

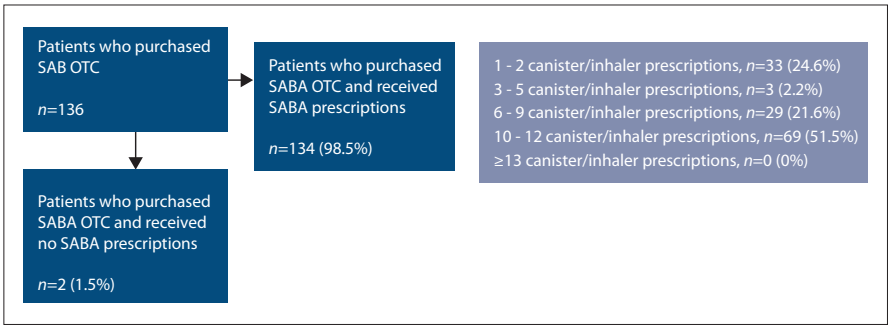


*Fig. Short-acting $\beta_2$-agonist purchases and prescriptions in the 12 months before the study visit in the SABA use IN Asthma (SABINA) III South African cohort.*

resources and a lack of specific primary care guidelines, all of which may hinder the implementation of evidence-based recommendations in the primary care setting.[17-21] However, this is worrisome since overall findings from SABINA III, which included 8 351 patients across 24 countries, indicated that ≥3 SABA prescriptions per year (v. 1 - 2 SABA prescriptions) were associated with increasingly lower odds of controlled or partly controlled asthma and higher rates of severe exacerbations across treatment steps and clinical care settings.[11]

Notably, SABA over-prescription was more common in patients with mild asthma treated in primary care. This finding suggests an underestimation of patients with milder disease or inappropriate management of patients with 'mild' asthma, resulting in suboptimal symptom control. Indeed, PCPs tend to overestimate asthma control, leading to undertreatment of asthma.[22-24] Moreover, many patients, including those with mild asthma, overestimate their level of asthma control,[17,25] resulting in sporadic use of maintenance therapy[26] and over-reliance on SABA alone for rapid symptom relief during episodes of asthma worsening.[27] In addition, many patients perceive control as the management of exacerbations, reflective of a crisis-oriented mindset.[28] While SABA prescriptions may not necessarily reflect actual usage, these findings indicate that many patients across SA are not optimally treated. Therefore, there remains an urgent need for educational initiatives targeted at both PCPs and specialists to align clinical practices with the latest evidence-based recommendations to reduce SABA over-prescription.

Crucially, over a quarter of patients obtained SABAs through unregulated sources, with 45.6% purchasing ≥3 SABA canisters OTC in the 12 months prior to the study visit. While this probably reflects the readily available access to OTC medicines in SA,[29] it is concerning as SABA OTC purchase has been associated with infrequent physician consultations; low use of prescription medication, particularly ICS; and an overall undertreatment of asthma.[30,31] Strikingly, almost all patients (98.5%) who purchased SABA OTC had already received SABA prescriptions. Moreover, 75.4% of patients with both SABA prescriptions and

**Table 3. SABA prescriptions in the 12 months before the study visit in the SABA use IN Asthma (SABINA) III South African cohort**

| | | Primary Care | | | Specialist Care | | |
|---|---|---|---|---|---|---|---|
| **Totals** | **All (*N*=501)** | **Investigator-classified mild asthma (*n*=203)** | **Investigator-classified moderate-to-severe asthma (*n*=150)** | **All (*n*=353)** | **Investigator-classified mild asthma (*n*=19)** | **Investigator-classified moderate-to-severe asthma (*n*=128)** | **All (*n*=147)** |
| **Patients prescribed SABA monotherapy, *n* (%)** | | | | | | | |
| Yes | 34 (6.8) | 33 (16.3) | 0 (0.0) | 33 (9.3) | 1 (5.3) | 0 (0.0) | 1 (0.7) |
| No | 467 (93.2) | 170 (83.7) | 150 (100.0) | 320 (90.7) | 18 (94.7) | 128 (100.0) | 146 (99.3) |
| **Number of canisters or inhalers per patient prescribed 12 months before the study visit** | | | | | | | |
| Number of patients | 34 | 33 | NA | 33 | 1 | NA | 1 |
| Mean (SD) | 5.0 (4.5) | 4.8 (4.4) | NA | 4.8 (4.4) | 12.0 (NA) | NA | 12.0 (NA) |
| Median (min, max) | 5.0 (1.0, 12.0) | 4.0 (1.0, 12.0) | NA | 4.0 (1.0, 12.0) | 12.0 (12.0, 12.0) | NA | 12.0 (12.0, 12.0) |
| **Number of canisters or inhalers (as categories) per patient prescribed 12 months before the study visit, *n* (%)** | | | | | | | |
| 1 - 2 | 16 (47.1) | 16 (48.5) | NA | 16 (48.5) | 0 (0.0) | NA | 0 (0.0) |
| 3 - 5 | 1 (2.9) | 1 (3.0) | NA | 1 (3.0) | 0 (0.0) | NA | 0 (0.0) |
| 6 - 9 | 9 (26.5) | 9 (27.3) | NA | 9 (27.3) | 0 (0.0) | NA | 0 (0.0) |
| 10 - 12 | 8 (23.5) | 7 (21.2) | NA | 7 (21.2) | 1 (100.0) | NA | 1 (100.0) |
| ≥13 | 0 (0.0) | 0 (0.0) | NA | 0 (0.0) | 0 (0.0) | NA | 0 (0.0) |
| Missing data | 0 (0.0) | 0 (0.0) | NA | 0 (0.0) | 0 (0.0) | NA | 0 (0.0) |
| **Patients prescribed SABA in addition to maintenance therapy, *n* (%)** | | | | | | | |
| Yes | 394 (78.6) | 167 (82.3) | 130 (86.7) | 297 (84.1) | 13 (68.4) | 83 (64.8) | 96 (65.3) |
| No | 107 (21.4) | 36 (17.7) | 20 (13.3) | 56 (15.9) | 6 (31.6) | 45 (35.2) | 51 (34.7) |
| **Number of canisters or inhalers per patient 12 months before the study visit** | | | | | | | |
| Number of patients | 394 | 167 | 130 | 297 | 13 | 83 | 96 |
| Mean (SD) | 9.9 (3.7) | 11.4 (2.4) | 8.8 (4.5) | 10.3 (3.7) | 9.2 (4.0) | 8.5 (3.3) | 8.6 (3.4) |
| Median (min, max) | 12.0 (1.0, 24.0) | 12.0 (1.0, 24.0) | 12.0 (1.0, 12.0) | 12.0 (1.0, 24.0) | 12.0 (1.0, 12.0) | 7.0 (1.0, 12.0) | 7.0 (1.0, 12.0) |
| **Number of canisters or inhalers (as categories) per patient prescribed 12 months before the study visit, *n* (%)** | | | | | | | |
| 1 - 2 | 37 (9.4) | 3 (1.8) | 25 (19.2) | 28 (9.4) | 2 (15.4) | 7 (8.4) | 9 (9.4) |
| 3 - 5 | 4 (1.0) | 2 (1.2) | 1 (0.8) | 3 (1.0) | 0 (0.0) | 1 (1.2) | 1 (1.0) |
| 6 - 9 | 78 (19.8) | 10 (6.0) | 22 (16.9) | 32 (10.8) | 3 (23.1) | 42 (50.6) | 45 (46.9) |
| 10 - 12 | 274 (69.5) | 151 (90.4) | 82 (63.1) | 233 (78.5) | 8 (61.5) | 33 (39.8) | 41 (42.7) |
| ≥13 | 1 (0.3) | 1 (0.6) | 0 (0.0) | 1 (0.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Missing data | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |

OTC purchase were prescribed ≥3 SABA canisters and 51.5%, ≥10 SABA canisters in the previous 12 months. SABA OTC purchase was also substantially higher in patients treated in primary care compared with those treated in specialist care (30.6% v. 18.4%, respectively) and occurred more frequently in patients with mild asthma than in those with moderate-to-severe asthma. This finding may have been further compounded by the fact that approximately only one-fifth of patients with mild asthma treated in primary care in this study reported full healthcare reimbursement. Possible explanations for this may be patients' lack of prioritising reimbursement requests from their medical aid, failure of PCPs to register their patients in the prescribed minimum benefit category or provider formulary constraints often placed on patients with low-cost medical aid plans. However, this is of concern as inadequate healthcare insurance coverage in patients with asthma is associated with poor quality of care, including a lower likelihood of receiving ICS.[32] Altogether, these findings demonstrate the need for patient educational initiatives on asthma self-management and urgent policy changes to regulate SABA OTC purchase and improve access to affordable care for all patients with asthma in SA.

Most patients were prescribed maintenance medication, either ICS or an ICS/LABA fixed-dose combination. However, more patients (58.9%) were prescribed ICS/LABA fixed-dose combinations, reflective of the greater number of patients with moderate-to-severe asthma (55.7%). Likewise, the proportion of ICS prescriptions (36.1%) was in alignment with the percentage of patients at GINA step 2 (37.5%). Although it is unknown whether patients took their medications as directed, patients were prescribed a mean of 11.9 ICS canisters in the previous 12 months. This quantity, which suggests good clinical practice as 1 canister per month is considered appropriate,[6] may be indicative of automatic repeat prescriptions. However, over half of all patients with mild asthma treated in primary care were prescribed medium-dose ICS instead of the recommended low-dose,[6] indicating that daily maintenance therapy

**Table 4. Patients who purchased SABA without a prescription in the 12 months before the study visit in the SABA use IN Asthma (SABINA) III South African cohort**

| | | Primary care | | | Specialist care | | |
|---|---|---|---|---|---|---|---|
| **Totals** | **All (*N*=501)** | **Investigator-classified mild asthma (*n*=203)** | **Investigator-classified moderate-to-severe asthma (*n*=150)** | **All (*n*=353)** | **Investigator-classified mild asthma (*n*=19)** | **Investigator-classified moderate-to-severe asthma (*n*=128)** | **All (*n*=147)** |
| Yes | 136 (27.1) | 67 (33.0) | 41 (27.3) | 108 (30.6) | 3 (15.8) | 24 (18.8) | 27 (18.4) |
| No | 363 (72.5) | 136 (67.0) | 109 (72.7) | 245 (69.4) | 16 (84.2) | 102 (79.7) | 118 (80.3) |
| **Number of canisters or inhalers (as categories) per patient purchased without a prescription, *n* (%)** | | | | | | | |
| 1 - 2 | 73 (53.7) | 34 (50.7) | 19 (46.3) | 53 (49.1) | 3 (100.0) | 17 (70.8) | 20 (74.1) |
| 3 - 5 | 47 (34.6) | 24 (35.8) | 18 (43.9) | 42 (38.9) | 0 (0.0) | 4 (16.7) | 4 (14.8) |
| 6 - 9 | 4 (2.9) | 2 (3.0) | 1 (2.4) | 3 (2.8) | 0 (0.0) | 1 (4.2) | 1 (3.7) |
| 10 - 12 | 7 (5.1) | 3 (4.5) | 2 (4.9) | 5 (4.6) | 0 (0.0) | 2 (8.3) | 2 (7.4) |
| ≥13 | 4 (2.9) | 3 (4.5) | 1 (2.4) | 4 (3.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Not applicable* | 1 (0.7) | 1 (1.5) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |

*'Not applicable' could be selected in the eCRF when patients purchased non-canister forms of SABA (e.g. oral or nebulised SABA) without a prescription.
SABA = short-acting β2-agonist; eCRF = electronic case report form.

prescriptions did not always conform to internationally recommended treatment and prevention recommendations.[6] This further emphasises the need for continuing medical education, particularly at the primary care level, and updating local guidelines in line with the latest international treatment recommendations.

OCS burst treatment was prescribed to 37.3% of patients and more frequently to patients with moderate-to-severe asthma. These prescriptions were presumably for the management of severe exacerbations because 94.1% of patients who received OCS burst/short-course prescriptions experienced ≥1 exacerbation in the previous 12 months. However, while OCS bursts are effective in the resolution of acute asthma symptoms, their benefits must be balanced against the impact of their side-effects.[33] Additionally, 12.9% of patients were prescribed antibiotics for asthma, suggesting a lack of familiarity with asthma guidelines because routine antibiotic use without strong evidence of a lung infection is not supported by GINA.[6] However, this issue may also reflect prescribing practices in SA, where inappropriate prescription of antibiotics has been reported, underscoring the need for further education to tackle antibiotic resistance.[34]

Overall, only just over one-third of patients (39.7%) had well-controlled asthma; this translated into a high disease burden, with nearly half of all patients (46.1%) experiencing at least one severe exacerbation in the preceding 12 months. However, the level of asthma control observed in the current study is in line with previous reports from SA, including audits of asthma care and patient questionnaires in relatively similar patient populations.[5,35-37] Therefore, asthma remains relatively poorly controlled across the country, suggestive of undertreatment, inappropriate treatment and/or a lack of patient and HCP education. Despite an active national education programme, and the work of the National Asthma Education Programme and professional societies that are closely involved in the development of evidence-based guidelines,[38,39] it is apparent that further educational initiatives targeting patients, pharmacists and physicians are required to improve asthma care.

The results of the current study should be viewed considering the following limitations. Data entry into the eCRF would have been subject to human error, which is probably random. SABA prescription data may not reflect actual medication use and do not provide information on treatment adherence. Furthermore, the high level of SABA prescriptions observed in this study could be a reflection of GINA 2017 recommendations (in place at the time this study was conceived and implemented) advising on SABA use. Finally, as the primary focus of the study was on SABA canister prescriptions, data on oral (tablet) or nebulised dosage forms of SABA were not captured. However, despite these limitations, this is to our knowledge the first study to describe SABA prescription patterns and SABA OTC purchase in SA. Moreover, the collection of these real-world data will enable clinicians and policymakers to make targeted changes to optimise asthma outcomes across the country.

## Conclusion

Results from the SA cohort of the SABINA III study demonstrated SABA over-prescription (≥3 canisters in the previous 12 months) in nearly three-quarters of all patients. Furthermore, over a quarter of patients purchased SABA OTC without a prescription, often in addition to SABA prescriptions. Therefore, SABA over-prescription poses a major public health concern in SA, underscoring an urgent need for HCPs and policymakers to collaborate to provide physician, pharmacist and patient education; secure access to appropriate treatments for all patients; regulate SABA purchase without prescription; and ensure that clinical practices align with the latest evidence-based recommendations to improve outcomes for all patients with asthma in SA.

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**Conflicts of interest.** CS received honoraria for talks and serves on advisory boards for numerous companies, including AstraZeneca. KL and RS are employees of AstraZeneca. MJHIB was an employee of AstraZeneca at the time this study was conducted. All other authors have no conflicts of interest to declare.


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