AVAILABILITY, PRICE AND AFFORDABILITY OF ASTHMA MEDICINES IN FIVE INDIAN STATES

A. Kotwani
Department of Pharmacology, Vallabhbhai Patel Chest Institute, University of Delhi, Delhi, India

SETTING: States of Haryana, Karnataka, Maharashtra and Rajasthan, and Chennai (capital of Tamil Nadu State), India.

OBJECTIVE: To assess the availability, price and affordability of beclomethasone and salbutamol inhalers in five Indian states using a standardised methodology.

DESIGN: Data on the availability and price of two essential medicines for asthma, beclomethasone (50 μg/dose) and salbutamol (0.1 mg/dose) inhalers, were collated from five medicine price studies on essential medicines.

RESULTS: Beclomethasone and salbutamol inhalers were available in 25% and 30% of public facilities in Rajasthan State only. The procurement price for beclomethasone and salbutamol was respectively 0.74 and 0.56 times the international reference price (IRP). The availability of beclomethasone inhalers was poor in the private sector (10–65%) in four states. The availability of salbutamol inhalers ranged from 20% to 95% as an innovator brand and 83% to 100% as the generic. The price of beclomethasone was 0.87–1.49 times the IRP, while salbutamol cost 0.82–1.12 times the IRP. Purchasing one inhaler each of salbutamol and beclomethasone cost between 1.6 and 2.3 days’ wages for the lowest paid government worker. Eighty per cent of the population earn less than this wage.

CONCLUSIONS: Essential inhalation medicines for asthma were not available in the public sector where low-income populations receive treatment. Steroid inhalers were not readily available in the private sector. Essential inhalation medicines for asthma are not affordable for the majority of the population.

KEY WORDS: access to medicines; asthma; chronic diseases; India; inhalation medicines

ASTHMA, a major chronic disease, has become a cause of global concern in terms of its increasing prevalence, morbidity and economic impact. It affects about 300 million people worldwide, and approximately 50 million asthma patients reside in India. In 2001, a survey showed that no inhalers for asthma treatment were available in public facilities managed by the Government of Delhi. Medicines are provided free in public facilities, which are the primary source of drugs for poor populations. Asthma patients were generally prescribed oral bronchodilators, xanthine derivatives, antibiotics and cough syrups at the secondary level of the public health facility in Delhi. However, as inhalation medications are the treatment of choice for asthma, the availability of inhalers in the public sector and the price, availability and affordability of inhalers at private retail outlets in other states should be investigated.
veloped by the WHO and Health Action International (WHO/HAI).\textsuperscript{18} The WHO/HAI methodology is discussed briefly later in this section. The survey methodology provides a ‘core list’ of 30 essential medicines. Beclomethasone inhaler (50 μg/dose) and salbutamol inhaler (0.1 mg/dose) are included in this ‘core list’ for treating asthma.

All the institutes involved approved the study. Data on the price and availability of the surveyed medicines at public and private facilities were collected with the consent of the officers-in-charge and owners. As these data do not include any information about human subjects, ethical clearance for human subject research was not required.

The first survey of all ‘core list’ medicines was conducted in the state of Rajasthan in 2003,\textsuperscript{7} followed by six surveys in Haryana, Karnataka, West Bengal, Maharashtra (two surveys) and Chennai, the capital city of Tamil Nadu, in 2004.\textsuperscript{8} The West Bengal survey is excluded from this analysis because the survey team did not measure prices and availability for beclomethasone. The beclomethasone inhaler was not listed in the West Bengal EML and the team believed that availability would be poor in the private sector. This analysis excludes one of the Maharashtra studies because it deviates from the WHO/HAI sampling methodology. Price and availability data for asthma medications were therefore collated from five survey sites: the states of Haryana, Karnataka, Maharashtra and Rajasthan, and the city of Chennai. The survey data were collected at public sector facilities as well as private retail pharmacies (Table 1). Data on price and availability of innovator brands (IBs) and lowest-priced generics (LPGs) found at each facility were used. As medicines are provided free of charge in public facilities, procurement prices were collected in the public sector.

**WHO/HAI survey methodology**

The WHO/HAI methodology measures the prices and availability of a basket of essential medicines. This ‘core list’ includes 30 essential medicines used in the treatment of common acute and chronic conditions that result in significant morbidity and mortality. These core medicines are usually recommended as first-line treatment, they are available in standard formulations and are used worldwide, and finally most are included in the WHO Model EML. The availability and prices for ‘core list’ medicines should be collected in at least four geographical areas in both public health facilities and private retail outlets.\textsuperscript{18}

**Sampling**

One major urban area (usually the state capital) in combination with three randomly selected administrative areas were surveyed. In each of the identified areas, at least five public facilities (including one main public facility and four secondary or primary health care facilities) were selected. Furthermore, a private sector pharmacy near the selected public health facilities was surveyed.

**Medicines**

For each medicine, data were collected for both the IB (originator brand) and LPG equivalent found at each medicine outlet. The IB is the product first authorised for worldwide marketing. Generic pharmaceutical products are manufactured without a license from the originator manufacturer and are marketed after the expiry of patent or other exclusivity rights.

**Data collection and analysis**

Trained data collectors visited enrolled facilities with a standardised form and recorded the price and availability of each medicine. The availability of each medicine was measured as the percentage of outlets where the medicine was available on the day of the survey. To facilitate international comparisons, price results were expressed as the median price ratio (MPR), calculated as follows:\textsuperscript{19}

\[
\text{MPR} = \frac{\text{Median price of each medicine across all facilities in a sector}}{\text{International reference price (IRP)}}
\]

The IRP is obtained from the Management Sciences for Health (MSH).\textsuperscript{20} The MSH IRPs were selected as the reference standard as they are recognised internationally, updated annually and are available to the public.

The WHO/HAI methodology also measures the affordability of certain selected clinical conditions that are treated with medicines on the core list. Affordability is defined as the number of days an unskilled government worker must work to purchase a standard treatment regimen for a common clinical condition.

**RESULTS**

The availability (percentage of facilities where the medicine was available on the day data were collected) and price (median price compared to IRP) of beclomethasone and salbutamol inhalers are presented below.

**Public sector**

**Availability**

Apart from Rajasthan, inhalers were not available at any public facility in the other states surveyed (Table 2).

### Table 1: Total number of districts, public and private facilities surveyed in the various Indian states

<table>
<thead>
<tr>
<th>State</th>
<th>Districts/ regions</th>
<th>Public facilities</th>
<th>Private facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chennai City</td>
<td>4</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Haryana</td>
<td>6</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Karnataka</td>
<td>8</td>
<td>24</td>
<td>40</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>12</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Rajasthan</td>
<td>4</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

\textsuperscript{18} WHO/HAI.\textsuperscript{18} WHO/HAI methodology provides a ‘core list’ of 30 essential medicines.

\textsuperscript{19} Median price ratio (MPR) = \frac{\text{Median price of each medicine across all facilities in a sector}}{\text{International reference price (IRP)}}

\textsuperscript{20} MSH IRPs were selected as the reference standard.
Generic beclomethasone was found only in Jaipur. Generic salbutamol was available only in Jaipur, the capital city of Rajasthan, and at one public facility in another Rajasthan administrative area.

**Procurement prices**

MPRs were calculated even if the inhaler was found at only one public sector facility. The MPR for the procurement price was calculated only for Rajasthan, as both inhalers were not available at any other survey site. In Rajasthan, the median price for beclomethasone and salbutamol was respectively 0.74 times and 0.56 times the IRP.

**Private sector**

**Availability**

The availability of IB beclomethasone was very poor in all of the states surveyed (Table 2). IB beclomethasone was not found in Rajasthan. In Haryana, Maharashtra and Karnataka, IB beclomethasone was available at respectively 1, 2 and 2 of a total of 30, 60 and 40 pharmacies surveyed. In Chennai, IB beclomethasone inhalers were available at 22 of 40 (55%) pharmacies surveyed.

The availability of generic beclomethasone inhalers was 10% in Haryana, 20% in Karnataka, 35% in Maharashtra, 65% in Rajasthan and 90% in Chennai (Table 2). IB salbutamol inhalers were available in all the surveyed states, although the availability ranged from 20% to 95% (Table 2). Availability of the generic version varied between 83% and 100% (Table 2).

**Retail prices**

MPRs were calculated only if the inhaler was found at a minimum of four private sector facilities. In Chennai, the median price for IB and generic beclomethasone was respectively 1.08 and 0.91 times the IRP. As IB beclomethasone was found in less than four outlets in other states, the MPR for IB beclomethasone was not calculated for other survey sites. The median price for generic equivalents of beclomethasone inhaler was in the range of 0.87 to 1.49 times the IRP in other states.

Data on prices were available for both the IB and the generic versions of salbutamol inhalers in all states. The median price of the IB salbutamol inhaler ranged from 0.86 to 1.12 times the IRP; the median price of the generic version ranged from 0.82 to 0.96 times the IRP.

**Affordability**

Affordability was measured as the number of days worked by the lowest paid unskilled government worker to purchase a standard treatment regimen for asthma. This study uses the wages of the lowest paid government worker as a measure of affordability, as this metric is universally available, reliable and can be used to make international comparisons. The daily wage of an unskilled government worker ranged from Indian rupees (INR) 130 to INR150 (~US$3.50) in the states studied. Such a worker requires approximately 2 days’ wages to purchase a month’s treatment, i.e., one inhaler each of generic beclomethasone and salbutamol (Table 3). The majority of the Indian population, nearly 77% (~836 million), works in the unorganised sector, with an average salary of below US$0.50/day, approximately seven times lower than the daily salary of the lowest paid government worker. Essential inhalation medications for asthma are thus beyond the reach of the majority of the population. This study does not measure the affordability of beclomethasone and salbutamol in the public sector, as medicines are meant to be provided free of cost at public facilities. The surveys, however, indicate that availability is generally very poor at public facilities.

### Table 2 Percentage of facilities where beclomethasone inhaler (50 μg/dose) and salbutamol inhaler (0.1 mg/dose) were available in the public and private sectors in the various Indian states

<table>
<thead>
<tr>
<th>State</th>
<th>Beclomethasone inhaler</th>
<th>Salbutamol inhaler</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Private sector</td>
<td>Public sector</td>
</tr>
<tr>
<td></td>
<td>Innovator Generic</td>
<td>Innovator Generic</td>
</tr>
<tr>
<td>Chennai City</td>
<td>55 90 0 0</td>
<td>95 98 0 0</td>
</tr>
<tr>
<td>Haryana</td>
<td>3 10 0 0</td>
<td>33 100 0 0</td>
</tr>
<tr>
<td>Karnataka</td>
<td>5 20 0 0</td>
<td>20 83 0 0</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>3 35 0 0</td>
<td>22 93 0 0</td>
</tr>
<tr>
<td>Rajasthan</td>
<td>0 65 0 25</td>
<td>45 100 0 30</td>
</tr>
</tbody>
</table>

### Table 3 Asthma treatment affordability: beclomethasone inhaler 50 μg/dose (200 doses/1 inhaler per month) plus salbutamol inhaler 0.1 mg/dose (200 doses/1 inhaler per month)

<table>
<thead>
<tr>
<th>State</th>
<th>Private, innovator brand</th>
<th>Private, lowest price generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chennai City</td>
<td>1.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Karnataka</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Maharashtra</td>
<td>2.3</td>
<td></td>
</tr>
<tr>
<td>Rajasthan</td>
<td>1.7</td>
<td></td>
</tr>
</tbody>
</table>

* Based on daily wage of lowest-paid government worker.
DISCUSSION

The results show the non-availability of beclomethasone and salbutamol inhalers at public sector facilities at all sites except for the capital of Rajasthan State. India’s Model National EML, which is prepared by the federal government, includes beclomethasone inhaler and salbutamol inhaler for asthma treatment.10 Most state governments, however, have not included these or any other inhalers in their procurement lists or EMLs. Although beclomethasone and salbutamol inhalers were listed in Rajathan’s EML,22 these could be procured only in the state capital, Jaipur. States may be omitting inhalers from their EMLs because of their high cost. Medicines are provided free of cost in public facilities, where poor populations come to receive prescribed medications. The unavailability of inhalers at public facilities therefore affects those patients who depend on these facilities for treatment and medications. Although public facilities may stock relatively inexpensive oral medications for treating asthma,16,17 patients are likely to experience unnecessary asthma-related morbidity and mortality without essential inhalation medications.23 State-level pooled procurement of bulk medications could reduce the costs of inhalation medications for public facilities, the main providers of care to poor populations.

In the private sector, salbutamol was widely available, except in Karnataka, where it was available at 83% of the surveyed retail outlets. The availability of beclomethasone, however, was found to be very poor in all the states surveyed, except Chennai, where generic beclomethasone was available at 90% of the outlets surveyed. For the period 2000–2007, national sales data for single molecule corticosteroid inhalers were obtained from IMS Health, a major provider of pharmaceutical and health care industry data, to confirm whether other steroid preparations were being substituted for beclomethasone. Beclomethasone was the most-sold single-molecule corticosteroid inhaler in 2003 and 2004 when these surveys were conducted (Table 4). The poor availability of a cost-effective corticosteroid, such as beclomethasone, hinders maintenance treatment for asthma. In the light of the high sales and wide availability of salbutamol, the poor availability of beclomethasone suggests excessive use of relief medication and underutilisation of inhaled corticosteroids. This could also indicate that patients and/or prescribers are treating acute episodes, rather than focusing on long-term asthma control.

To save time and the cost of consulting a physician, many Indian patients visit retail pharmacies to purchase medicines without a prescription.24,25 As the majority of such patients cannot afford expensive medicines, retailers dispense inexpensive over-the-counter medicines at retail pharmacies. In Chennai City, simulated clients with symptoms of mild persistent asthma visited private retail pharmacies; they were given oral bronchodilators, antibiotics, methylxanthines and oral corticosteroids rather than inhaled medications.26 Such a study implies that patients with financial constraints are generally not receiving essential medications for asthma. Moreover, a recent Indian study shows that general practitioners (GPs) have poor knowledge about preventive treatment for asthma.27 The majority of GPs surveyed in Delhi (72%) reported salbutamol as the preferred preventive medicine for asthma, while only 25% considered inhaled medicines to be their preferred preventive treatment. It is therefore likely that all categories of patients, especially those of low socio-economic status, are receiving inappropriate medication for asthma. Current sales data for India show increasing popularity of fixed-dose combination inhalers (inhaled corticosteroids + short-acting or long-acting β2-agonist, Table 5). This suggests overuse of combination products, although

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Percentage sales volume for inhalers,* by category</th>
</tr>
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<tbody>
<tr>
<td>Inhaler</td>
<td>2000</td>
</tr>
<tr>
<td>Short-acting β2 agonist</td>
<td></td>
</tr>
<tr>
<td>Salbutamol</td>
<td>100</td>
</tr>
<tr>
<td>Single-molecule corticosteroid</td>
<td></td>
</tr>
<tr>
<td>Beclomethasone</td>
<td>59</td>
</tr>
<tr>
<td>Budesonide</td>
<td>34</td>
</tr>
</tbody>
</table>

* National sales volume data obtained from IMS Health.

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Five most-sold inhalers in India*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>2004</td>
</tr>
<tr>
<td>Beclomethasone + salbutamol</td>
<td>Beclomethasone + salbutamol</td>
</tr>
<tr>
<td>Fluticasone + salmeterol</td>
<td>Fluticasone + salmeterol</td>
</tr>
<tr>
<td>Beclomethasone</td>
<td>Beclomethasone</td>
</tr>
<tr>
<td>Budesonide</td>
<td>Budesonide</td>
</tr>
<tr>
<td>Budesonide + formoterol</td>
<td>Budesonide</td>
</tr>
</tbody>
</table>

* National sales volume data obtained from IMS Health.
inhaled corticosteroid monotherapy successfully controls asthma in a significant proportion of patients.  

Add-on therapy with β2-agonists is required only in patients with moderate-to-severe persistent asthma. Moreover, commonly prescribed fixed-dose combination inhalers such as fluticasone + salmeterol (Seroflo) and budesonide + formoterol (Foracort) are almost 100% more expensive than beclomethasone inhalers.

According to this study, the lowest paid unskilled government worker requires 2 days’ wages (approximately US$7) to purchase a standard treatment regimen for asthma. Most of the Indian population works in the unorganised sector, where wages tend to be lower than government wages. The 2006 World Bank Report says that 34.7% of the Indian population earn less than US$1 per day. Therefore, even if the surveyed asthma medicines are priced slightly lower than IRP, thanks to India’s vigorous generic industry, standard asthma treatment is beyond the reach of the majority of the population.

In most industrialised countries, the rising trend in mortality due to asthma has stopped or has been reversed since 1990. This decrease in mortality, despite a rise in the prevalence of asthma, is probably linked to the widespread use of inhaled corticosteroids and adherence to standard treatment guidelines. The results of this study suggest that the high cost of essential asthma inhalation medicines, coupled with their non-availability in the public sector, increases the burden of asthma exacerbation and mortality in India. The burden of asthma can be reduced for the majority of Indian patients, primarily by increasing access to affordable essential asthma medicines in the public and private sectors. Moreover, prescriber education and patient awareness are required to amplify receptiveness to preventive treatment, the cornerstone of cost-effective asthma management.

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