

# Pediatric outpatients from a bronchopulmonary medicine service in a public hospital in Chile: assessment of the adherence and inhalation technique

## Abstract

Drugs used for inhaled therapies are based on the use of topics corticosteroids and known as “metered dose inhalers” (MDI). They are the cornerstone of the pharmacologic treatment of certain respiratory diseases. It is widely described that the success or failure of this pharmacotherapy is determined by a variety of factors, such as adherence and inhalation technique. So, the purpose of this work was to assess the adherence and inhalation technique in paediatric outpatients and/or their caregivers of Exequiel González Cortés Hospital in Chile. To evaluate the degree of knowledge and adherence, a questionnaire was developed and applied to patients and/or caregivers. The instrument had 15 questions, apart from question 11, all the questions were posed in a dichotomous way, to systematize the data register. Once the questionnaire was ready, a prospective cross-sectional study was carried out surveying 85 people. Of these, 82 interviews were correctly conducted and included in the analysis. Of the patients using inhalers, 57,3% were male, with a mean age of 6,7±4,6 years. Most of caregivers interviewed were female, and 86,3% turned out to be the mother of the patients. The adherence reported in this survey was 30,4% and 89% were declared “knowledgeable” of the inhalation technique. This work determined that patients have basic knowledge about inhalation technique, but there are still important gaps in it. Additionally, there is an adherence rate that has a wide margin for improvement.

**Keywords:** metered dose inhalers, pediatrics, respiratory tract diseases, adherence, inhalation technique

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**Abbreviations:** MDI, metered dose inhalers; BMS, bronchopulmonary service; EGCH, Exequiel González Cortés Hospital; SMHS, South Metropolitan Health Service

## Introduction

Drugs used for inhaled therapies are based on the use of topics corticosteroids and known as “metered dose inhalers” (MDI). They are the cornerstone of the pharmacologic treatment of certain diseases such as bronchial asthma,<sup>1,2</sup> chronic obstructive pulmonary disease (COPD)<sup>3</sup> or cystic fibrosis,<sup>4</sup> since they delay the inflammatory process of these pathologies at the pulmonary level, improving patient survival.<sup>5</sup> In addition, in inhaled therapies, a fixed dose of the drug is released, their topical effect is more efficient, and it has little systemic effect.<sup>6</sup>

In the literature, it is widely described that the success or failure of this pharmacotherapy is determined by a variety of factors. In first place, the adherence to treatment is essential to delay the irreversible inflammatory process of the airways, as well as the number and intensity of exacerbations,<sup>7</sup> which also affects care in hospital emergency services.<sup>8</sup>

Montes de Oca et al. have reported that poor adherence to inhaled therapies is common in COPD with non-adherence being associated with poor symptom control, higher healthcare utilization and costs and decreased health-related quality of life. Consequently, poor adherence to these therapies is associated with higher morbidity and healthcare utilization, probably because of worse and more frequent respiratory symptoms, and more frequent exacerbations.<sup>9</sup>

Related to asthma, poor adherence to inhaled controller therapy and inadequate inhalation technique during therapy are two factors that have some challenging aspects that should be considered when approaching difficult-to-control pediatric asthma in low- to middle-income countries. The failure detecting nonadherence usually results in unneeded dose increases and/or escalation of controller therapy to more costly medications, thus further increasing, in an unnecessary and potentially avoidable way, the economic burden of the disease. Also, suboptimal adherence to medications is a very complex behavior, with many family factors contributing.<sup>10</sup>

A Chilean study showed a significant increase in asthma hospitalizations in 5-15-year-old children. This increase was mainly seen in the group of 5- to 7-year-olds. Because hospitalizations for asthma in children constitute a considerable burden to children and their families and have a large impact on health care costs, it is important to determine whether there are any factors associated with this increase that may offer opportunities for interventions.<sup>11</sup>

Herrera et al. state that in Chile, there is a lack of information on treatment regimens used to manage pediatric asthma exacerbations in the different hospitals throughout the country and the associated health costs. And they propose the implementation a nationwide asthma program for this selected group of patients including controller treatment, education for patients and caregivers and close follow up, to achieve better asthma control and outcomes for these children in a more cost-effective manner.<sup>12</sup>

Another important detail is that inhalers generally require a technique of use with a series of certain steps, so it is extremely

important to use these therapies well. Its correct use optimizes the delivery of the medication to this site of action,<sup>13</sup> maximizing its effect.

According to Teixeira Rodrigues et al. despite the use of appropriate pharmacotherapy, many patients experience a sub-optimal effect of their medication. Inadequate inhaler technique is one of the main reasons for poor disease control, with negative impact on health and economic outcomes. Therefore, adherence to therapy and correct performance of inhaler technique are key factors to control the disease.<sup>14</sup>

Assessing adherence is complex and several instruments (scales, checklists, or questionnaires) have been developed. Failure to detect or effectively handle nonadherence and/or inhaler misuse in a patient with uncontrolled respiratory disease can mislead clinicians into thinking that the patient is nonresponsive to the original, less intensive, and less-costly therapy, resulting in unnecessary requests for expensive diagnostic tests to try to understand the patient's poor response to treatment.<sup>10</sup>

Patient's self-report methods accompanied with inhaler technique assessment are considered the most suitable for measuring adherence to medication in clinical practice, even though patients tend to over-estimate adherence.<sup>9</sup> This is because adherence to inhaled controller therapy is usually assessed by using subjective methods, mainly clinical judgment, and self-reporting, both of which are notoriously unreliable.<sup>10</sup>

This work has carried out in the outpatient pharmacy of the Exequiel González Cortés hospital (EGCH), the reference base hospital of paediatric patients in the south of the metropolitan region of Santiago (Chile). In the context of this work, is relevant to know the adherence to inhaled therapies, and to identify whether patients and/or caregivers know how to use these medications. Meeting both aspects will optimize the logistical and financial resources and health interventions oriented to improve this pharmacotherapy. The purpose of this research was to assess the adherence and inhalation technique in paediatric outpatients and/or their caregivers attending in Bronchopulmonary Medicine Service of Hospital Exequiel González Cortés, Santiago, Chile.

## Materials and methods

### Elaboration of the questionnaire

To assess the degree of knowledge and adherence of the patients to inhalers therapy, a questionnaire was compiled using as references the work of Aquino et al.<sup>15</sup> In addition, some topics of a survey designed in the hospital to evaluate the effectiveness of fluticasone + salmeterol (Brexotide®) v/s budesonide (data of this survey was not published) were added. Finally, questions using as model the test of Morisky-Green<sup>16</sup> were attached.

Questions 1 to 7 of questionnaire aimed to ask about the inhaled technique using MDI in the patients of EGCH. The knowledge of the patients and caregivers was evaluated quantitatively, establishing in this work, that if the patient and/or their caregiver was able to answer at least 4 of the first 7 questions correctly, they were considered "knowledgeable" of the inhalation technique. Otherwise, they were classified as "not aware" of the therapy.

Questions 8 to 10 inquired about the perception of the patients and/or caregivers about the use of inhalers. Question 11 referred to the behavior of patients and/or caregivers when the medication ran off.

Questions 12 a 15 evaluated adherence and/or therapeutic compliance.<sup>16</sup>

Except for question 11, all the questions were posed in a dichotomous way, in order to easily systematize the data.

Lastly, an open-response question was added: What difficulties do you have with the administration of medication? And a section on "suggestions, doubts or comments in this regard", to find out data that was not obtained in previous sections, mainly due to non-adherence factors or some specific difficulty when using the medication. After its design, the questionnaire was submitted to a face validity and several pharmacists made the respective corrections and suggestions, without making subsequent validations with the users or other professionals.

### Design of the study

Once the questionnaire was ready, a prospective cross-sectional study was carried out, using the survey designed in the previous point as instrument, through interviews with patients and/or caregivers in the bronchopulmonary medicine service (BMS).

#### Inclusion criteria:

- Patients and/or caregivers who agreed to answer the survey.
- Patients receiving MDI from the hospital outpatient pharmacy.
- Patients between 0 to 17 years (both ages inclusive).

#### Exclusion criteria:

- Patients and/or caregivers who do not have sufficient cognitive capacities to answer the survey.
- Patients or caregivers who refuse or do not finish to answer the survey during its application.
- Patients older than 18 years.

Patients were identified consecutively in the BMS waiting room and invited to participate. If they meet eligibility criteria and provide consent were enrolled. There was only one encounter in which the interviewer explained the purpose of the research, invited to participate, and applied the survey.

The number of patients to be interviewed was obtained with a formula for calculating samples for an infinite population and a qualitative variable,<sup>17</sup> taking a confidence level of 90%, an error of 10% and assuming the maximum prevalence mathematically possible, resulting in 68 patients to be interviewed. Taking in care a loss of 20%, the number of patients to be interviewed was 85.

#### For practical purposes, patients were classified as follows:

- Patients from 0 months to 1 year 11 months: Neonates and infants
- Patients from 2 years to 4 years 11 months: Preschool children
- Patients from 5 years to 11 years 11 months: Schoolchildren
- Patients from 12 years to 17 years 11 months: Adolescents

All questionnaire responses were collected electronically and were saved to a central database with the information coded and protected.

Categorical variables were described through frequencies and percentages. A correlation between adherence and some of the variables present in the study, such as sex, age, and caregiver educational level were explored using the chi square test.

### Ethical considerations

The Ethics Committee of the South Metropolitan Health Service (SMHS) authorized this Project (Memorandum 469/2016). All patients

provided written informed consent and their data was encrypted to avoid the individualization of the information.

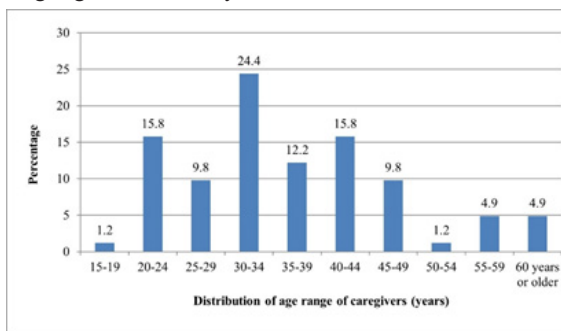
## Results

The questionnaire was executed in the BMS, where 85 interviews were conducted to patients and/or caregivers. Of these, a 3,5% (n=3) were discarded since they were not totally answered, with 96,5% (n=82) interviews correctly conducted and included in this analysis. Of the patients using MDI, 57,3% (n=47) were male, with a mean age of  $6,7 \pm 4,6$  years (Table 1).

**Table 1** Distribution by age group of patients who participated in surveys

Age group	N° patients	%
Neonates and infants	12	14,6
Preschool children	21	25,6
School children	33	40,2
Adolescents	16	19,5
Total	82	100

The 96,3% of caregivers interviewed were female, and 86,3% turned out to be the mother of the patients (Figure 1). Meanwhile 74,4% have schooling equal to or greater than 12 years, 93,3% of those interviewed stated that they reside in a district belonging to SMHS. The 73,2% indicated that their patient's diagnosis was asthma. In addition, most caregivers were between 30 and 34 years old, with an average age of  $36 \pm 11,3$  years old.



**Figure 1** Distribution (%) of caregivers by age group.

All the interviewees declared the use of the aero chamber, although 2,4% (n=2) said they did not use it with its corresponding mouthpiece. Table 2 breaks down the answers obtained in the survey carried out in BMS.

**Table 2** Number of correct answers broken down by question

	Question	Correct answers	
		n	%
Inhalation technique	1. Do you shake the inhaler before use?	82	100
	2. Position of inhaler	79	96,3
	3. Does the patient bite the mouthpiece?	80	97,6
	4. Do you exhale air before puff?	38	46,3
	5. Do you hold your breath after the puff?	33	40,2
	6.a. Do you wait between two puffs?	76	92,6
	6.b. Waiting time between puffs	48	63,1
	7. Do you rinse your mouth after the puff?	50	61,0
	8.a. Someone explained you how to use the inhaler?	74	90,2
	9. Did you understand that explanation?	72	97,6
Users' perception	10. Did you perceive the use of the inhaler as easy?	79	96,3

Regarding question 11, which refers to what the first thing is the caregiver does when the medicine runs out, 81,7% (n=67) go to the hospital outpatient pharmacy. A 3,7% (n=3) indicated that they preferred to buy it, and 14,6% prefer to acquire it through other means, such clinics or other care centers, or that they have a "inhalers hoarding". The adherence reported in this survey, was 30,4% (n=25).

In the comments section, the interviewees expressed their concerns, the most common being:

- The caregivers don't wake up the child while he sleeps.
- The caregivers have problems picking up the inhaler in the pharmacy, either for work or other reasons.
- The patient becomes restless when aero chamber is placed.
- Doubts about adverse effects of the inhaled therapy.
- They would like an inhaler with dose counter.

Considering questions 1 to 7, the number of correct questions on average was  $5 \pm 1,1$  questions correctly answered, and 89% (n=73) answered correctly at least 4 of these questions and were declared "knowledgeable" of the inhalation technique.

## Discussion

Among the strengths of this work is the fact that it was able to analyze in detail the knowledge about the inhalation technique in pediatric patients and their caregivers indirectly and investigated the adherence in paediatric patients who attend the BMS in EGCH.

From the results of the survey, it was first determined that most of the patients surveyed were male, reside in districts that have the hospital as a reference health service, and are school-age children. As for the caregivers, the vast majority are the mother of the patients. This fact possibly has a social and historical connotation, since women always have been related to the care of children and sick people,<sup>18</sup> with all the implications that this responsibility entails.

When evaluating knowledge about the inhalation technique, it was observed that about 9 of 10 of the interviewees was considered "knowledgeable" of the inhalation technique. However, the result could also indicate gaps in the knowledge about this technique, so health interventions aimed at improving this aspect could be required.

Among the most frequent errors, it was observed that patients did not exhale the air before a puff, and they did not hold their breath after the puffs. Although there is no clear explanation for the shortcomings that occurred in these steps, it must be considered that among our patients there are neonates and preschool patients, who, as result of their age, do not have the mechanical or psychomotor skills to conscientiously execute these steps, which it would explain why there are so many errors specifically in these two cases.

Nava et al.,<sup>19</sup> evaluated the technique of using inhalers in asthmatic patients older than 10 years, finding 45% of patients with poor inhalation technique, while Chan et al.,<sup>20</sup> evaluated the technique of utilization of MDIs with a spacer in pediatric patients, finding 86,4% of patients with adequate technique. However, in the work of Aquino et al.,<sup>15</sup> all the caregivers of children had a technique defined as "regular".

Sleath et al.,<sup>21</sup> studied the use of different inhalers in pediatrics, finding that 8,1% (n=22) of the patients carried out all the steps correctly. A similar analysis developed by Reznik et al.,<sup>22</sup> in caregivers of patients using inhalers with a spacer, showed that 1 patient (n=169) executed all the steps out of a total of 10.

The differences between the previous work and this study lies in the way in which the knowledge of the inhalation technique was evaluated. Sleath et al.,<sup>21</sup> directly evaluated the execution of the inhalation technique by children. While Reznik et al.,<sup>22</sup> applied a ten-steps checklist together with a practical demonstration using a toy. Our study did not ask to patients or their caregivers to demonstrate how they proceed with inhalers. It should be noted that interviewees perceived that execution of the inhalation technique was easy. However, it is complex to dilucidate whether this perception is real, or the participants did not want to give a negative answer.

Regarding the analysis of the adherence differences were found between our results and those found in the literature. Keemink et al.,<sup>7</sup> Chan et al.,<sup>20</sup> and Berg et al.,<sup>23</sup> studied adherence electronically in pediatric patients with asthma, and found 84, 30 and 64% respectively, while Koster et al.,<sup>24</sup> found 57% of adherence in pediatric patients. Blais et al.,<sup>25</sup> in their study, by analyzing inhaled corticosteroid prescriptions found adherence of 33,9%.

Although the adherence determined in this study was within the results mentioned in the literature, there is a high rate of non-adherent patients, so interventions are required to improve this aspect. Of the questions referring to adherence, it was found that the most common cause for non-adherence, was that caregivers or parents forgot to administer the therapy. This coincided with some comments mentioned by the interviewees in the survey, where they stated that they did not want to wake up the children at night to give them their medication, which could partly explain the lack of adherence.

In addition, some variables under study were assessed to find out if there was any correlation with the adherence of our patients.

There is evidence suggesting that easier is to use the inhaler, the greater adherence.<sup>26, 27</sup> However, in this study no correlation could be found between these variables. Lawani et al.,<sup>26</sup> carried out their study in patients older than 12 years, while Foster et al.,<sup>27</sup> did it with patients older than 14 years. On the other hand, this study includes patients between 0 and 17 years of age, so although the literature explains the phenomenon in children over 12 years of age, it may be that in younger patients this correlation does not exist, due the evident difficulty of administering these drugs in young children.

In relation to adherence and patient sex, no correlation was found between these variables. In the case of Apter et al.,<sup>28</sup> they studied adherence in patients older than 16 years, and Jessop & Rutter<sup>29</sup> in adult patients. As for Chan et al.,<sup>30</sup> they studied adherence through electronic medication monitoring, in patients whose ages ranged between 6 to 15 years.

The correlation between adherence and age of patients was also analyzed. Koster et al.,<sup>24</sup> found greater adherence in children under 6 years of age, while our study found no correlation. In the case of the aforementioned study, a cohort of 527 patients was used, while the present study included a broader age and a smaller group of patients, which could partially explain the differences.

Regarding the adherence and education of the caregivers, Xu et al.,<sup>31</sup> found less adherence to higher education to the mother, while Koster et al.,<sup>24</sup> correlated better adherence in those parents with an educational level of more than 12 years. In this study, no association was found between caregiver education and adherence. The main reason that would explain the differences between the results is the cohort used by each author. In this study, 82 patients were interviewed, while the cited authors interviewed 665 and 527 patients respectively.

Our results and those of the literature present discrepancies. One reason could be that each result corresponds to local reality of the places where the studies were carried out, not necessarily be applicable to the patients of EGCH. In many cases, the cohorts (sizes and age ranges) of this study and those of the literature also differ. Finally, the percentages of adherence, and methodologies to determine it in this research, could also influence the results.

As the main limitations of this study, in first place, the adherence was assessed by self-reported measures and important steps of the inhalation technique could be omitted during the interview, so its evaluation may be incomplete or giving an over estimated value of adherence. In second place, it is noted that the statistical validation of the survey was not carried out.

Promoting the rational and cost-effective use of this therapy could help to optimize the limited health resources in many countries in which the inappropriate and unnecessary use of costly medications on the one hand and the inadequate provision of primary care services on the other perpetuate the inequality. Although recognizing poor adherence and inhaler misuse does not automatically lead to their improvement, it is usually an essential first step in effectively targeting adherence behavior, especially if the reasons for low or erratic compliance are explored.<sup>10</sup>

## Conclusion

This work determined that paediatric outpatients and/or caregivers have basic knowledge about inhalation technique, but there are still important gaps in it. Additionally, there is an adherence rate that has a wide margin for improvement, which is the reason why health interventions aimed for getting better these aspects are required. The identification of the factors that specifically influence the adherence of the patients of EGCH, would help to program efficient pharmaceutical interventions to optimize pharmacotherapy. These solutions will benefit the pharmacy service, since they would optimize financial resources associated with the administrative management of these medications, could reduce the people who go to the pharmacy, lower waiting times for the dispensing of the medication, and reduce the workload of pharmacy staff.

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## Conflicts of interest

Authors declare having no conflicts of interest.

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