

Inhalation treatment: Errors in application and difficulties in acceptance of the devices are frequent in wheezy infants and young children

Marguet C, Couderc L, Le Roux P, Jeannot E, Lefay V, Mallet E.
Inhalation treatment: Errors in application and difficulties in acceptance of the devices are frequent in wheezy infants and young children.
Pediatr Allergy Immunol 2001; 12: 224–230. © Munksgaard 2001

The recent availability of small-volume spacers has facilitated the general use of inhaled treatment in infants. The purpose of this study was to evaluate any errors made by parents when using this new inhalation technique and the child's behavior during the inhalation. Ninety-four young children (61% boys) under 5 years of age were enrolled in the study. Inhalation treatment was recommended either by a general practitioner or by a pediatrician. Data concerning treatment regimens, the ability of parents to use the spacer and metered-dose inhalers (MDIs), and the acceptance of the devices, were collected by means of a demonstration and questionnaire. Unexpectedly, the doses, administration times, and duration of the treatments varied from one child to the next. No explanation or training in administering the treatment via the spacers was given to 12% and 47% of the parents, respectively. Fourteen per cent of parents did not shake the MDIs, 12% did not monitor the valves, and 22% allowed too short a time for inhalation. The lack of explanation increased the occurrence of errors in manipulation of the devices. The procedure was judged to be easy to follow by 78% of the parents, but the face mask was accepted with difficulty by 22% of the children. Repeated crying during administration of the treatment was observed in 38% of the patients, particularly the youngest. Crying influenced the acceptance of the face mask, reduced parental compliance, and made the use of the devices more difficult. Errors altering the efficiency of inhalation treatment in infants are frequent. Most of these errors could be avoided by spending more time to inform the parents about correct usage. Furthermore, repeated crying during inhalation is common in young children and this problem should to be taken into consideration in the evaluation of treatment.

**C. Marguet¹, L. Couderc¹,
P. Le Roux², E. Jeannot³, V. Lefay¹
and E. Mallet¹**

¹Paediatric Respiratory Disease Unit, Rouen University Hospital Charles Nicolle, Rouen, France, ²Paediatric Respiratory Disease Unit, Le Havre General Hospital, Le Havre, France, ³Paediatric Department, Dieppe General Hospital, Dieppe, France

Key words: inhalation treatment; infantile wheeze; education; behavior

Dr Christophe Marguet, Paediatric Respiratory Disease Unit, Rouen University Hospital Charles Nicolle, 76031 Rouen Cedex, France
Tel.: +33 2 32 88 82 16
Fax: +33 2 32 88 81 88
E-mail: christophe.marguet@chu-rouen.fr

Accepted 19 February 2001

Inhalation therapy has been recommended for children with asthma (1) and proven to be effective in infants (2,3) and premature babies (4). Several studies have demonstrated the clinical or functional benefit of inhaled steroids in infants by using either large-volume spacer devices (5–7) or nebulizers (8,9). The recent availability of smaller-volume spacer devices (Babyhaler[®], GSK Pharmaceuticals, Marly le Roy, France; and Nebuchamber[®], Astra Draco Pharmaceuticals, Rueil-Malmaison, France), specifically designed for infants, have facilitated the administration of

inhalation treatment and are thought to improve the airway delivery of the drugs (10,11). These spacers have a low volume (350 and 250 ml, respectively) and are fitted with low-pressure inspiratory and expiratory valves and an adjustable face mask. The visible valves permit the effective monitoring of infant breathing (at least five breaths are recommended) through the device (12). The use of these spacers was expected to be easy (13–15). However, to our knowledge, the ability of parents to administer inhalation treatment has not been evaluated in clinical practice. In

one clinical trial, none of 77 infants would accept a face mask (6), and in a second trial only 17% of 24 infants (7) would accept a face mask attached to a large-volume spacer. This type of data, when obtained in a clinical trial and then associated with careful instructions, could be optimized (16). By conducting a prospective survey, we attempted to establish the efficacy of inhalation treatment that the family practitioner recommended in infants and young children and whether errors occurred in the administration of this treatment that consequently altered its efficiency.

Patients and methods

This prospective study was conducted from December to March 1997 in the Pulmonology Clinic (Rouen, Le Havre, Dieppe). Infants and young children under 5 years of age and with the following inclusion criteria, were enrolled:

- attending the pulmonology clinic for the first time;
- inhalation treatment for recurrent symptoms recommended to be administered through a Babyhaler or Nebuchamber. (In France, parents have to purchase these spacers at a pharmacy, approximate cost £30.);
- treatment prescribed at the primary care level by a general practitioner or general pediatrician;
- treatment given by the parents; and
- acceptance of the parents to meet the nurse educator.

The progress of the survey was conducted in two stages. The parents demonstrated to an asthma-trained nurse educator how they administered the inhalation treatment. The assessment of their skills was based on the instruction booklet provided with each of the devices studied (Appendix I). In these booklets, the handling of the spacer and the use of the metered-dose inhalers (MDIs) are accurately explained and illustrated, as well as the monitoring of the valves and the number of breaths (5–10) from the device that are recommended. The behavior of the child was also observed (does he cry?). Then, a questionnaire was given to the parents by a practitioner (one of the authors) who did not prescribe and explain the treatment. The questions (Appendix II) are those usually asked in an educational training program. The aim of the questionnaire was mainly to evaluate:

- whether the parents were given any explanation or demonstration in using both the spacers and the metered-dose aerosols;
- whether or not the parents were familiar with the manipulation of these delivery systems; and

- the acceptance of this type of treatment by the parents and the children.

The data were considered reliable when the skills assessed during the demonstration corresponded to the responses obtained from the questionnaire (questions 8 to 10). In addition, the recommended treatment prescribed at the primary care level was checked: administration times/day of bronchodilators or steroids, and duration of the treatment. The parents met the nurse again for complementary education after the medical consultation.

Statistical analysis

Qualitative differences between the groups were determined by using the Pearson chi-square test and, when applicable, the Fisher Exact test. A p-value of less than 0.05 was considered statistically significant.

Results

The average age of the 94 children (61% boys) included in this study was 21.7 months (range: 1 month to 5 years). Thirty-nine per cent of the children were younger than 12 months of age, 35% ranged between 13 and 24 months, and the remaining 26% were older than 2 years. The medical diagnoses leading to the inhalation treatment were, in all cases, recurrent symptoms such as infantile wheeze (84%), asthma (2%), chronic cough (5%), and recurrent bronchitis (8%).

Analysis of the recommended treatment regimens

Sixty-one per cent and 39% of the treatments were, respectively, prescribed by a general practitioner or a general pediatrician. The spacers were Babyhaler (n=88) and Nebuchamber, which has recently become available in France (n=6). Consequently, the administered drugs, which should be adapted to the spacer, were primarily salbutamol 100 µg and beclomethasone 250 µg per puff and, with the latter device, terbutaline 250 µg and budesonide 200 µg per puff. In one subject, the treatment was not given by the parents although they bought the spacer device and the drugs. Two other infants were not treated because they refused to accept the face mask. The recommended regular treatments varied considerably between infants (Table 1) and comprised β₂-mimetics or steroids alone in 17% and 5% of the patients, respectively. Accounting for the duration of action of these drugs, the frequency of administration times of bronchodilators and steroids were not appropriate in 43% and 39%,

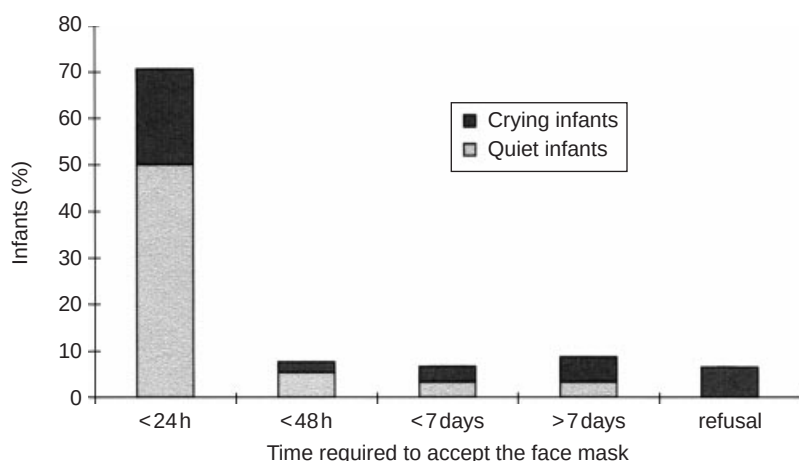


Fig. 1. Estimation of the necessary time required by the parents to make the facemask of two small-volume spacer devices (Babyhaler[®], n=87, Nebuchamber[®], n=6) acceptable by the infants, regarding the child's behavior. Among those accepting the facemask immediately, crying infants were fewer than among those who later became accustomed to the mask (see the text for details). Six children never accepted the facemask, but four nevertheless were continued to be treated with a spacer.

respectively, of the infants. The duration of the treatments also varied widely (Table 1). Assessment of the clinical status at the time of the medical consultation revealed that 57% of the children still had symptoms either at rest (46%) or only on exercise (11%).

Analysis of the errors in inhalation technique and administration of the drugs, and influence of the explanations provided

The errors are listed in Table 1. All the parents stated that they had read the instructions provided with the spacer. A supplementary explanation was given to parents either by the general practitioner (76%) or by the pharmacist (48%). Twelve per cent of the parents had no information on either the use of the spacer or MDIs. Providing explanations on the way to use the spacer enhanced the skills of the parents: the parents who had no explanations were less likely to monitor the shift of the valves (63.6% vs. 92.5%, $p=0.016$), and more frequently forgot to shake the MDIs (50% vs. 9.7%, $p=0.004$). The other errors listed in Table 1 were not dependent on having received an explanation or demonstration. In summary, 42% of the parents made at least one error in the administration of an inhalation treatment by a spacer device: four, three, two, and one errors were committed in administration of the treatment of to one, three, 12, and 22 children, respectively.

Evaluation of the acceptance, by the infants, of the spacers with facemask

Acceptance of the spacers by the infants, based on the opinion of parents, is shown in Fig. 1. On the other hand, 38% of the infants cried repeatedly during the observed administration of the treatment. These infants were younger than those who did not cry, with a respective median [25th–75th

quartiles] age of 14 months (7–19 months) compared with 21 months (10–36 months), $p=0.005$. Crying was half as likely in those who accepted the facemask during the first 48 h than in those who later adapted to the mask (29% vs. 70%, $p=0.002$). Six infants did not accept the device: the parents of four children continued treatment and those of the two others stated that the manipulation of the spacer was categorically impossible.

Evaluation of the acceptance of the treatment by the parents and influence of the behavior of their infants

The handling and the use of these devices were found to be either easy or very easy by most of the parents (78%) and either difficult or very difficult by the remaining 20%. The ease of handling was related to the reaction of the infant to the face mask (chi-square=15.8, $p<0.0001$). Seventy-seven per cent of the parents said that they complied with regular administration of the drugs, 11% indicated an oversight at least once a week, and 8% omitted the treatment at least once a day. Parental adherence to the treatment was not related to the difficulty in manipulating devices (chi-square=0.017, $p=0.76$) or to the delay in acceptance of the face mask (chi-square=1.68, $p=0.13$). However, the percentage of crying children was higher in the groups of parents either admitting an altered observance of the treatment regimens or who had found the manipulation of the devices difficult, than in the respective groups of those who did not, i.e. 57% vs. 32%, $p=0.04$ and 65% vs. 31%, $p=0.008$.

Discussion

The introduction of pediatric spacers with a face mask has provided the practitioner with an easy means for administering inhaled bronchodilators

Table 1. Recommended treatment regimens (n=94) and errors in handling devices in infants (n=91)*

Recommended duration of the treatment	
<1 week	21%
1 week to 1 month	45%
1–3 months	18%
3–12 months	8%
Unknown	7%
Administration times/day of bronchodilators	
Once a day	6%
Twice a day	37%
Three times a day	55%
Four times a day	2%
Administration times/day of steroids	
Once a day	8%
Twice a day	61%
Three times a day	31%
Parents having no information on handling the spacer and administering the treatment	12%
Parents having no demonstration in handling the spacer and administering the treatment	47%
pMDI is placed correctly into the spacer	100%
pMDIs are shaken	86%
Bronchodilators are actuated before steroids	85%
Handling the spacer in the horizontal position	87%
Face mask is correctly applied before actuating pMDIs	100%
Child inhales more than five breaths	78%
Monitoring of the valve shift	88%
*Three children were not treated (see the text).	
MDI, metered-dose inhalers.	

or steroids to children, which have fewer side-effects than the oral drugs (1). Although the aim of this study was to evaluate the errors in the inhalation technique to avoid treatment failure, the study also highlighted the various unexpected patterns of inhalation treatment that were prescribed to children, 50% of whom were still symptomatic at the time of the clinical examination. The doses, the number and distribution of puffs, and the duration of the treatment, varied considerably from child to child. Bronchodilators and high doses of inhaled steroids ($>500 \mu\text{g}$ per day) were commonly prescribed, but the recommendations in the administration times were frequently not adapted to the duration of action of the drugs. Two-thirds of these children with recurrent symptoms were treated for less than 1 month, although the efficacy of a short duration of treatment with inhaled steroids has not been demonstrated (17,18). These results emphasize the difficulty in prescribing anti-inflammatory drugs in young children with chronic bronchial diseases and the need to ensure a better application of the recommendations (1).

In previous reports, handling of small-volume spacers has been assessed as easy by 80–91% (13,15) of parents and were usually preferred to the devices previously used (14). Although confirming these results, our study further attempted to analyze the difficulties encountered by the parents in the application of the face mask to their children. Regarding the delay of acceptance estimated by the parents, one-quarter of the families found that the delay was longer than 48 h. Furthermore, 11 families had great difficulty in delivering the treatment. This was consistent with the report of Noble et al. (7) but contrasted with another study (6). Because the concept of acceptance could vary from one parent to other, we evaluated whether the children cried during the inhalation and questioned the parents on the frequency of this reaction. All but one child who cried during the demonstration, was designated as crying often or very often during the inhalation. Thus, more than one-third of the infants cried repeatedly through the spacer when the face mask was applied. The frequency and age distribution showed that the children who cried were the youngest in the study group. This observation highlights the recent findings of Janssens et al. (19), who demonstrated that the within-subject variability of aerosol delivery through similar spacer devices was not only high but also inversely correlated with age in children younger than 5 years old. Moreover, our study showed that crying influenced the parental compliance to the treatment regimens. Therefore, an unexplained poor parental adherence was previously reported in preschool children (20) but the child's behavior was not analyzed. On the other hand, two-thirds of the crying children studied were considered by the parents as completely accepting the face mask. Therefore, in contrast to the sentiments of the parents, the medical practitioner should expect to follow-up infants who do not get into the habit of inhaling through a face mask. This factor could alter either the compliance of the parents or the lung deposition of the drug, and therefore the efficacy of the treatment.

To our knowledge, few studies are available regarding the errors committed by using both spacer devices and MDIs in infants. In children, the remaining problem is the difficulty in hand-to-mouth co-ordination, leading to inefficient inhalation of the drugs (21,22). However, Pedersen et al. (23) found that the three most common errors were the lack of breathing out, not shaking the MDI before actuating it, and too short a breath when inhaling. Despite the use of a spacer device, the two latter errors were observed, suggesting a reduction in the efficacy of the

drugs. Thus, one out every seven treated children did not inhale the expected amount of effective compounds, because the MDI had never been shaken. A similar ratio of infants had no monitoring of the valves, which resulted in an uncertain intake of drugs. Moreover, one-fifth of the infants breathed for too short a time through the spacer, reducing the chance of inhaling an optimal dose. Although the spacers studied are believed to improve lung deposition (11), these errors and the others previously mentioned contribute, with the crying, to alter the already small amount of inhaled drugs (19,24).

All the information specified in the instruction booklet given with each of the spacers studied was believed to be sufficiently specific and detailed, as only 7% of the parents required additional information on how to use the Babyhaler device (14). However, we observed that an oversight of information reduced skills in inhalation technique in a higher proportion of cases. This underlines the need of accompanying the prescription with at least an oral explanation, which could be offered either by the practitioner or the pharmacist (25). However, the practitioner, pediatrician or pharmacist's knowledge, as well as their ability to use the inhalation devices, were not evaluated in this study. They were previously suggested to be deficient where new skills were required for a new device (26–28).

Conclusion

Although the availability of new small-volume spacer devices has permitted the generalization of inhalation treatment in young children, results of the present study suggest that several factors could influence an apparently poor response. The prescription of treatment regimens appeared to be more dependent on the practitioner than on the underlying bronchial disease. The practitioners should not only be aware of the skills required by the parents when prescribing inhaled treatment for children under 5 years of age but also of the influence of children's resistance to face masks. Quiet breathing appeared inconstant in infants and should be taken into account in subsequent evaluations of the efficiency of inhalation treatment.

Acknowledgments

The authors are indebted to Mrs Blasquez and Mrs Lorey, the nurse educators of the pulmonology clinics, and to Mr Richard Medeiros for his advice in editing the manuscript.

References

1. WARNER JO, NASPITZ CK, CROPP CGA. Third international pediatric consensus statement on the management of childhood asthma. *Pediatr Pulmonol* 1998; 25: 1–17.
2. MALLOL J, BARRUETO L, GIRARDI G, TORO O. Bronchodilator effect of fenoterol and ipratropium bromide in infants with acute wheezing: Use of MDI spacer device. *Pediatr Pulmonol* 1987; 3: 352–6.
3. O'CALLAGHAN C, MILNER AD, SWARBRICK A. Spacer device with face mask attachment for giving bronchodilators to infants with asthma. *BMJ* 1989; 298: 160–1.
4. YUKSEL B, GREENOUGH A, MACONOCHE I. Effective bronchodilator treatment by a simple spacer device for wheezy premature infants. *Arch Dis Child* 1990; 65: 782–5.
5. FREIGANG B. New method of beclomethasone aerosol administration to children under 4 years of age. *Can Med Assoc J* 1977; 117: 1308–9.
6. BISGAARD H, MUNCK SI, NIELSEN JP, PETERSEN W, OHLSSON SV. Inhaled budesonide for treatment of recurrent wheezing in early childhood. *Lancet* 1990; 336: 649–51.
7. NOBLE V, RUGGINS NR, EVERARD ML, MILNER AD. Inhaled budesonide for chronic wheezing under 18 months of age. *Arch Dis Child* 1992; 67: 285–8.
8. CARLSEN KH, LEEGAARD J, LARSEN S, ORSTAVIK I. Nebulised beclomethasone dipropionate in recurrent obstructive episodes after acute bronchiolitis. *Arch Dis Child* 1988; 63: 1428–33.
9. DE BLIC J, DELACOURT C, LE BOURGEOIS M, et al. Efficacy of nebulized budesonide in treatment of severe infantile asthma: a double-blind study. *J Allergy Clin Immunol* 1996; 98: 14–20.
10. KRAEMER R, FREY U, SOMMER CW, RUSSI E. Short term effect of albuterol, delivered via a new auxiliary device, in wheezy infants. *Am Rev Respir Dis* 1991; 144: 347–51.
11. BISGAARD H, ANHOJ J, KLUG B, BERG E. A non-electrostatic spacer for aerosol delivery. *Arch Dis Child* 1995; 73: 226–30.
12. CLARKE JR, ASTON H, SILVERMAN M. Delivery of salbutamol by metered dose inhaler and valved spacer to wheezy infants: effect on bronchial responsiveness. *Arch Dis Child* 1993; 69: 125–9.
13. MARGUET C, LUMBROMSKA B, KOHEN L, MALLET E. Salbutamol and beclomethasone treatment through a new spacer Babyhaler® in infants with chronic asthma: a prospective study. *Eur Resp J* 1995; 8: 469s. (Abstr.)
14. HENDRICKS HJ, OVERBERG PC, BRACKEL HJ, VERMUE NA. Handling of a spacer (Babyhaler) for inhalation therapy in 0 to 3-year-old children. *J Asthma* 1998; 35: 297–304.
15. PRICE M, MAHAJAN P, MADEN C, THWAITES R. Parental preference for the babyhaler inhalation device and its ease of use in the administration of inhaled asthma medication to pre-school children. *Eur Resp J* 1997; 10: 81s. (Abstr.)
16. REISER J, WARNER JO. Value of participating in an asthma trial. *Lancet* 1985; i: 206–7.
17. RICHTER H, SEDDON P. Early nebulized budesonide in the treatment of bronchiolitis and the prevention of post-bronchiolitic wheezing. *J Pediatr* 1998; 132: 849–53.
18. VOLOVITZ B, SOFERMAN R, BLAU H, NUSSINOVITCH M, VARSANO L. Rapid induction of clinical response with a short-term high dose starting schedule of budesonide nebulizing suspension in young children with recurrent wheezing episodes. *J Allergy Clin Immunol* 1998; 101: 464–9.
19. JANSSENS HM, DEVADASON SG, HOP WCJ, LESOUËF PN, DE JONGSTE JC, TIDDENS HAWM. Variability of aerosol

- delivery via spacer devices in young asthmatic children in daily life. *Eur Respir J* 1999; 13: 787–91.
20. GIBSON NA, FERGUSON AE, AITCHINSON TC, PATON JY. Compliance with inhaled asthma medication in pre-school children. *Thorax* 1995; 50: 1274–9.
 21. DE BLIC J, LE BOURGEOIS M, BRAINE C, DEBALEVAERE C, SCHEINMANN P, PAUPE J. Techniques d'utilisation des aerosols doseurs chez l'enfant. *Press Med* 1987; 16: 1007.
 22. HUGHES DM, McLEOD M, GARNER B, GOLDBLOOM RB. Controlled trial at a home and ambulatory program for asthmatic children. *Pediatrics* 1991; 87: 54–61.
 23. PEDERSEN S, FROST L, ARNFRED T. Errors in inhalation technique and efficiency of inhaler use in asthmatic children. *Allergy* 1986; 41: 118–24.
 24. TAL A, GOLAN H, GRAUER N, AVIRAM M, ALBIN D, QUASTEL MR. Deposition pattern of radiolabeled salbutamol inhaled from a metered-dose inhaler by means of a spacer with mask in young children with airway obstruction. *J Pediatr* 1996; 128: 479–84.
 25. CHARLTON I, ANTONIOU AG, ATKINSON J, et al. Asthma at the interface: bridging the gap between general practice and a district general hospital. *Arch Dis Child* 1994; 70: 313–8.
 26. KESTEN S, ZIVE K, CHAPMAN KR. Pharmacist knowledge and ability to use inhaled medication delivery systems. *Chest* 1993; 104: 1737–42.
 27. AMIRAV I, AVNER G, PAUWLOWSKI NA. What do paediatricians in training about the correct use of inhalers and spacer devices. *J Allergy Clin Immunol* 1994; 94: 669–75.
 28. HANANIA NA, WITTMAN R, KESTEN S, CHAPMAN KR. Medical personnel's knowledge of and ability to use inhaling devices. Metered-dose inhalers, spacing chambers, and breath- actuated dry powder inhalers. *Chest* 1994; 105: 111–6.

Appendix I

Assessment of the handling of the devices and the administration of the inhalation treatment by the parents

1. Handling of the spacer device is in the horizontal position	Yes	No
2. The face mask is correctly applied on the mouth and nose	Yes	No
3. The face mask is applied before actuating pMDIs	Yes	No
4. pMDIs are shaken	Yes	No
5. pMDIs are correctly placed into the spacer	Yes	No
6. The valves are monitoring by the parents during the inhalation	Yes	No
7. The child inhales more than five breaths	Yes	No
8. Do the parents monitor the time of inhalation?	Yes	No
If yes:		
With the number of breaths	Yes	No
By controlling the time	Yes	No
9. Does the child accept the face mask during the administration of the treatment?	Yes	No
If not:		
Does the child cry?	Yes	No

Appendix II

Questionnaire

1. Do you know why an inhalation treatment is given to your child?	Yes	No
If yes:		
Wheeze	Yes	No
Cough	Yes	No
Asthma	Yes	No
Other	Yes	No
2. Did the symptoms occur for at least 1 week per month during the last 3 months	Yes	No
3. Have you had any explanation on the handling of the spacer?	Yes	No
4. Have you had any explanation on the handling of the pMDIs?	Yes	No
5. Have you had any demonstration of the handling of the spacer?	Yes	No
6. Have you had any demonstration of the actuating of the pMDIs?	Yes	No
7. Did you read the instruction provided with the spacer device?	Yes	No
8. Do you know that:		
The spacer must be handling in the horizontal position	Yes	No
The face mask should cover the mouth and nose	Yes	No
The face mask should be applied before actuating the pMDIs	Yes	No
9. Do you know that pMDIs		
Should be shaken	Yes	No
Should be administered in a defined order	Yes	No
10. Did you monitor the time of inhalation?	Yes	No
If yes:		
With the number of breaths (If yes, how many?)	Yes	No
By controlling the time (If yes, how long?)	Yes	No
11. Do you find that the handling of the spacer and pMDIs devices are		
Very easy	Yes	No
Easy	Yes	No
Difficult	Yes	No
Very difficult	Yes	No
12. Do you feel that the face mask has been accepted by your child?	Yes	No
If yes, estimate the delay:		
The first day	Yes	No
<48 h	Yes	No
<7 days	Yes	No
>7 days	Yes	No
If not, do you continue the treatment?	Yes	No
13. Did your child cry during the inhalation?	Yes	No
If yes:		
Every day (or very often)	Yes	No
Sometimes (or rarely)	Yes	No
14. Do you feel that you have omitted to give the treatment?	Yes	No
If yes:		
At least once a day	Yes	No
Once a week	Yes	No
Never given	Yes	No
15. Why did you not administer the treatment?		
The spacer was not bought	Yes	No
Too difficult to use	Yes	No
Not accepted by your child	Yes	No
Adverse effect of the drugs	Yes	No