

Evaluation of Inhaler Device Technique in Caregivers of Young Children with Asthma

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Inhalation therapy has become the primary treatment mode for most pediatric pulmonary diseases. Errors in inhalation technique can decrease intrapulmonary drug deposition, which may lead to a decrease in therapeutic response. This study examined the ability of caregivers of young children with asthma, after being provided careful and standardized instruction, to correctly demonstrate how to use 1 of 2 different inhaler delivery systems. Caregivers of children aged 1–6 years, who were being prescribed an inhaler device for the first time, were trained by a staff asthma educator using a standardized educational checklist. One week later, the caregiver was required to demonstrate the correct preparation, use, and maintenance of their prescribed device to a different staff asthma educator, who rated their performance using the same standardized educational checklist. Errors (total and major) in carrying out the individual steps for each delivery device were recorded, and a Performance Mastery Score (measure of ability to do device steps correctly) was calculated. The total and major error rates were 24.8% and 15.6%, respectively, for the metered-dose inhalers (MDIs) with spacer, and 15.9% and 8.5%, respectively, for the nebulizer ($P < 0.001$). The mean Performance Mastery Score was 84.5% for the MDI with spacer and 91.9% for the nebulizer ($P < 0.001$). Caregivers of young children with asthma demonstrate a number of errors in device use, including major ones that can potentially result in poor lung delivery, even 1 week after standardized training by an asthma educator. Mastery of the MDI with spacer delivery system appears somewhat harder than that seen with the nebulizer. These findings suggest the need for repetition of sessions reinforcing inhalation instructions at follow-up in addition to initial education of proper device use, no matter what type of delivery system is selected.

Introduction

INHALATION THERAPY has become the primary mode of treatment for most pediatric pulmonary diseases. There are a variety of delivery systems [ie, metered-dose inhalers (MDIs), dry powder inhalers (DPIs), and nebulizers], all of which share common principles of operation but have different inhalation techniques and maintenance procedures. Errors in inhalation technique can decrease intrapulmonary drug deposition, which may lead to a decrease in therapeutic response and possibly an increase in side effects.¹ We believe that the potential for decreased efficacy due to technique error probably is highest in the younger pediatric patient, where poor technique is common due to improper caregiver administration, limits in physical coordination, and other factors related to age.

There is limited information available on the outcome of instructional practices by practitioners to patients with asthma regarding proper technique in administering and maintaining the inhaler device and delivery system prescribed. The few studies that have been done have not been conducted in those younger than 6 years. They have also lacked some aspects of scientific rigor, such as independent evaluators and inter-rater reliability.^{2–4} The present study was undertaken to understand more about these actual teaching habits and their ability to result in mastery of the inhaler device selected by the physician for the younger patient with asthma.

This study examined the ability of caregivers of young children (aged 1–6 years) with asthma to correctly demonstrate how to use 1 of 2 different inhaler delivery systems (nebulizer with mask/mouthpiece, or an MDI/spacer with

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mask/mouthpiece) after being provided careful and standardized instruction on that 1 prescribed delivery system. The study took place in the “real world” setting of the clinic where the young child was first prescribed their inhaler device. The specific objective was to determine overall mastery of the child’s prescribed device by the caregiver, by measuring the total rate of caregiver error associated with use of their device. We hypothesized that regardless of standardized caregiver education, (1) error in recalling the proper use of inhaler delivery systems will occur and (2) certain devices are more difficult than others to train caregivers to use, resulting in a greater rate of error associated with their utilization.

Patients and Methods

Study design

The design was a 2-visit data collection event, targeting caregivers of young children who were being prescribed 1 of the 2 preidentified inhaler devices for the first time. The data collection took place at an already occurring clinic visit where the patient was receiving normal care. Ten outpatient allergy and asthma treatment centers were utilized from different geographical regions of the United States.

Eligibility for enrollment required the following criteria: (1) The child was between age 1 and 6 years, (2) the inhaler device prescription was one of the allowed devices, and (3) the inhaler device was new to the patient (ie, had not been previously used by the child). Institute Review Board approval was obtained from the Essex Institutional Review Board, Inc. (Lebanon, NJ).

Inhaler devices used

The treatment device was either (1) a pressurized MDI with spacer (with mouthpiece or mask) or (2) a nebulizer (with mouthpiece or mask). The inhaled medication could be either a quick-reliever medication, a controller medication, or both. To standardize the experience of the study population and keep sufficient homogeneity in the subgroups, the allowed type of nebulizer and spacer device were limited to certain brands (see Table 1).

Visit 1

Visit 1 included the following:

- Obtaining informed consent.
- Providing caregiver with a self-administered questionnaire to obtain demographics and prior personal experience with asthma and inhaler devices.

- Providing step-by-step patient inhaler device education as a part of their normal care by clinic education staff. The staff used a study-specific standardized educational checklist (see Fig. 1) appropriate to the child’s device to standardize their demonstration. The caregiver was not provided with any additional take-home materials other than the instructions that normally come with the inhaler devices.

Visit 2

Visit 2 occurred 1 week (± 1 day) after visit 1. At this second visit, the caregiver was seen by a different nurse or educator than the one who provided their training the previous week to ensure an independent assessment. During visit 2,

- The caregivers demonstrated what they recalled about how to prepare, use, and maintain/clean the device that was prescribed for their child.
- A nurse/educator observed and rated this demonstration on the standardized educational checklist that was used during their instruction at visit 1.

Standardized teaching

Only medically trained clinic staff (eg, licensed vocational nurse [LVN], registered nurse [RN], nurse practitioner [NP]) pretrained in the specific educational content, patient education methods, and study procedures were allowed to do the visit 1 caregiver teaching. The standardized educational checklist was designed for teaching correct inhaler device technique to the caregiver. The checklist for each device was developed from review of product information, the medical literature, and national asthma guidelines. The steps for proper technique were divided into 3 stages: preparation (setup), application (use or administration), and maintenance (cleaning) of the device (see Tables 2 and 3 for steps of each stage).

Inhaler device technique rating

A key part of the evaluation at visit 2 was direct observation of the caregiver’s demonstration of the correct preparation, use, and maintenance of their prescribed device. As with the trainers, raters were pretrained in the specific educational content of proper MDI inhaler with spacer and nebulizer technique given at visit 1 to the caregivers. The standardized educational checklist from visit 1 was used for this rating process (see Fig. 1). Each specific step that was expected as a part of the caregiver’s return demonstration was marked on the checklist as successfully demonstrated or incorrect. Only steps applicable to the device prescribed for the patient (ie, a spacer with mask instead of a spacer without mask) were demonstrated and evaluated.

Error rating

Before the scoring of the study data, an expert panel (2 clinicians specialized in pediatric asthma, 2 clinic nurses/educators) collaboratively designated steps on the checklist for each device as either major or minor. The definitions of a major versus a minor error were as follows:

- A major error—an error made in any step that would lead to a significant decrease in the lung delivery of the inhaled medication.

TABLE 1. INHALER DEVICES INCLUDED IN THE STUDY

<i>Inhaler device</i>	<i>Brand name</i>	<i>Description</i>
Nebulizer	Pari LC Jet	With mask
		Without mask
Spacer	Aerochamber	With mask
		Without mask
	Vortex	With mask
		Without mask
	Optichamber	With mask
		Without mask

<i>Setting up the inhaler with spacer for use (continued)</i>				
Visual	Step No.	Instructions	Taught to patient	Performed by Patient at 1 week
			Circle one	Yes (complete) Partial (correct but not complete) No (missing or incorrect) NA (not appropriate for device)
	5.	Have child: • sit up straight or stand up, near the person who will be administering the medication • relax and drop their shoulders • look straight forward, or have head back slightly	Yes No	Yes
	6.	Shake the combination of spacer and MDI well for about 5 seconds	Yes No	Partial
	7.	FOR MOUTHPIECE (NO MASK): Have child: • put the mouthpiece in their mouth • make sure it is through their teeth, tongue underneath • close their lips tightly around the mouthpiece	Yes No	Yes
	8.	IF USING A MASK: • Hold the MDI and spacer combination in one hand and place the mask of the spacer-MDI over the nose and mouth • Make sure mask fits snugly • Place the other free hand behind the head of the child, applying gentle pressure forward to ensure the mask stays snugly on the face	Yes No	NA

FIG. 1. Sample section of standardized educational checklist. MDI, metered-dose inhaler.

- A minor error—any other error made that was not determined to be major.

Tables 2 and 3 identify the steps, which, if not correctly performed, would result in either major or minor errors.

Data analysis

Inter-rater agreement. To assess the reliability and precision of the rating process, we assessed the percentage of inter-rater agreement on the designation of error scores. Four of 10 study sites were asked to have an additional person present to be able to simultaneously rate the caregiver return demonstration at visit 2. These 2 raters evaluated each step that had been taught during the caregiver education and how well it was performed during the return demonstration. The percent agreement between the errors reported in the paired ratings for each step was assessed with Kappa statistics.⁵ Inter-rater agreement results were used to establish the extent of consensus on the occurrence of errors observed by the study personnel at each site.

Device error rate. The major, minor, and total error rates for each device were calculated by dividing the number of errors (major, minor, or total) by the total possible errors (major, minor, or total) for that device. The error rate also is specifically reported for preparation, application, and maintenance steps. Differences in rates between devices were tested using Pearson chi-square tests.

Individual Performance Mastery Score. A Performance Mastery Score was calculated for each individual. It was defined as the proportion of major steps correctly performed out of all major steps possible for the given inhaler device.

Performance Mastery Score

$$= \frac{\# \text{ major steps performed correctly}}{\text{Total \# major steps for that device}} \times 100$$

The total number of major steps is dependent on the type of device prescribed (see Table 4). Performance Mastery Scores can be compared across the 2 devices, because the number of major steps correctly performed is reported as a

TABLE 2. STEPS FOR PREPARING, USING, AND MAINTAINING THE METERED-DOSE INHALER WITH SPACER

Step no.	Description of steps for MDI with spacer	Major error ^a
Steps in preparation		
1	Remove cap on inhaler or spacer	×
2	Ensure MDI canister snugly fits into the plastic canister holder	×
3	Place inhaler mouthpiece into rubber-sealed end of spacer with mouthpiece on bottom and canister on top	×
4	If using mask, ensure firmly attached to spacer/MDI	×
5	Have child sit straight or stand, relax, drop shoulders, look ahead, or head slightly back	
6	Shake MDI/spacer for ~5 s	×
7	If using mouthpiece, put in child's mouth, with teeth and lips tightly closed around it	×
8	If using mask, hold MDI/spacer in one hand—place mask over nose and mouth and ensure snug fit; place other hand behind head of child and apply gentle pressure forward to ensure mask stays snugly on face	×
9	If spacer has valve, check that it moves in/out with child's breath before activating aerosol; if not, mask not tightly sealed	
Steps in using		
10	Press down on inhaler to deliver medication into spacer—make sure spacer stays inside child's mouth	×
11	If using mask, have child breathe normally through mouth for ~10 s, using either deep, slow breaths or if not able to, normal tidal breathing	×
12	If using mask, ensure mask firmly on face during breathing; no crying	×
13	For mouthpiece, have child breathe in slowly and deeply for 3–5 s	×
14	For mouthpiece, have child hold breath for 10 s at end of inhalation	×
15	Note: Inhaling too fast may cause spacer to whistle; encourage child to breathe more slowly	
16	After dose delivered, have child resume normal breathing; wait ~10 s between additional puffs, if needed	
17	Put cap on spacer; store MDI/spacer together in clean, convenient place	
Steps in maintaining		
18	Clean spacer and MDI before first use and end of each week	×
19	When cleaning MDI, remove canister from the canister holder	
20	Each week, rinse mouthpiece and spacer in water and air dry	
21	Every 2 weeks, clean with dishwashing soap and water solution, rinse with water and air dry	

^aMajor error if step omitted or incorrectly performed.
MDI, metered-dose inhaler.

proportion of total major steps for that device. The Performance Mastery Scores were reported for each device as the percent of caregivers with scores in each quartile and as group means. The differences in mean scores by device were tested using a *t*-test for samples with unequal variance.

Additional analysis. Additional exploratory analyses using parametric and nonparametric statistics were performed to identify factors related to success in using the inhaler device on the return visit. These factors included caregiver demographic characteristics, including previous caregiver experience with asthma. Analyses were conducted using SPSS.⁶

Results

Population characteristics

A total of 287 caregivers were approached to be part of the study. Of these caregivers, 39 declined participation and 78 were screened for participation but were found to be ineligible.

A total of 170 caregivers completed visit 1 and 158 of these completed visit 2, making an overall completion rate of 92.9%. Data from 4 caregivers were incomplete and, therefore, omitted, resulting in 154 caregivers with sufficient data for analysis.

The demographic information for the participants by treatment group is presented in Table 5. Many more children

overall were prescribed the MDI with spacer than the nebulizer (110 versus 44). A greater number of older children received treatment with an MDI device (mean age, 4.1 years), whereas a greater number of younger children received a nebulizer (mean age, 2.9 years). The average age of caregivers was ~33 years for each group; all caregivers were a parent of the child. Most caregivers were women and married, with an average level of education for each group of caregivers being ~14 years. In general, other than the age of the child, the 2 groups of caregivers had similar demographics.

Inter-rater agreement

The 4 sites selected to participate in the inter-rater process provided paired ratings of each step for 45 patients (nebulizer *n* = 8, MDI *n* = 37). The level of agreement among raters was high: The Kappa statistic for both the nebulizer group and the MDI group was 0.64 (*P* < 0.001).

Error rates in device use

The error rates observed for each device are shown in Table 6. The total error rate for the MDI with spacer (24.8%) was significantly higher than that seen with the nebulizer (15.9%) (*P* < 0.001). The major error rate for the MDI with spacer (15.6%) was also significantly higher than that of the nebulizer (8.5%) (*P* < 0.001).

TABLE 3. STEPS FOR PREPARING, USING, AND MAINTAINING THE NEBULIZER

Step no.	Description of steps for nebulizer	Major error ^a
Steps in preparation		
1	Place compressor near power source and make sure clean	×
2	Connect tubing to compressor	×
3	Open nebulizer bowl and add medication	×
4	Cover and close medication cup by inserting into nebulizer bowl	×
5	Connect tubing to nebulizer base	×
6	If using mask, firmly attach mask to tubing	
Steps in using		
7	Keep child in relaxed sitting position; occupy them	
8	Hold nebulizer upright and turn on compressor	×
9	If using mouthpiece, put in child's mouth, with teeth and lips closed tightly around it	×
10	If using mask, ensure it fits tightly	
11	Have child take slow, deep inhalations of mist through mouth with occasional short rests (~every 30 s)	
12	For younger child, allow normal tidal volume breathing	
13	Occasionally tap sides of nebulizer bowl	
14	Continue nebulization until sputtering; shake cup and inhale mist until sputters again	×
15	Note: Some liquid will remain in the medication cup; nebulization takes 5–15 min	
Steps in maintaining		
16	After every use, disassemble nebulizer, wash all parts in liquid dish soap and water, and rinse with plain water	×
17	Shake off excess water; air-dry parts, or reassemble nebulizer, and turn on the compressor to dry quickly	
18	Every other use, soak all parts (except mask and tubing) for 1 h in 1:3 parts distilled white vinegar: hot water; rinse and dry	
19	Replace air filter every 3–6 months	

^aMajor error if step omitted or incorrectly performed.

The major error rate for each device by the stage of use (preparation, application, and maintenance) is shown in Table 7. In preparation of the device, the nebulizer had a lower rate of errors than the MDI with spacer (2.3% versus 11.4%; $P < 0.001$). In application of the device, the nebulizer had a similar rate of errors as the MDI with spacer (22.2% versus 20.6%; $P < 0.743$). In maintenance of the device, the nebulizer had a lower but not statistically significant difference in rate of errors compared with the MDI with spacer (11.4% versus 23.6%; $P < 0.09$).

Performance Mastery Scores of study sample

The mean [standard deviation (SD)] Performance Mastery Score for caregivers using the nebulizer was greater than that of caregivers using the MDI with spacer [91.9 (SD 11.3) versus 84.5 (SD 15.5); $P < 0.001$]. The percentages of caregivers within each level of Performance Mastery Score are shown in Fig. 2. As seen, the nebulizer group had more caregivers with higher scores than the MDI/spacer group.

Factors related to device success

There were no significant correlations between the Performance Mastery Score and any of the measured demographic characteristics, including previous caregiver experience with asthma.

Discussion

The present study assessed the ability of trained caregivers to correctly administer inhaled therapy to children younger than 7 years of age with asthma to expand the existing body of literature that focuses on errors made using MDIs, DPIs, and spacers in adult patients with asthma.^{3,4,7,8} It mainly focused on the caregiver of the child, in particular, their ability to retain and recall instructions around the proper administration of the inhaled medication and use of the prescribed delivery device.

A major finding of the study was that despite optimal training, caregivers of young children with asthma aged 6 years or younger still demonstrate a number of errors in

TABLE 4. TOTAL POSSIBLE ERRORS FOR NEBULIZER AND METERED-DOSE INHALER WITH SPACER

	Nebulizer		MDI with spacer	
	With mask (n = 42)	With mouthpiece (n = 2)	With mask (n = 63)	With mouthpiece (n = 47)
Major errors	8	9	10	9
Minor errors	10	8	8	8
Total errors	18	17	18	17

TABLE 5. DEMOGRAPHICS OF CHILDREN AND CAREGIVERS BY DEVICE

	Nebulizer (n = 44)	MDI with spacer (n = 110)
Child		
Age, mean year (SD)	2.9 (1.4)	4.1 (1.7)
Age by category, n (%)		
<1 year	1 (2.3%)	1 (0.9%)
1–4 year	35 (79.5%)	64 (58.1%)
>5 year	8 (18.1%)	45 (40.9%)
Caregiver		
Age, mean year (SD)	33.0 (7.0)	32.4 (6.4)
Gender, female, n (%)	37 (84.1%)	96 (87.3%)
Education (highest year completed), mean (SD)	15.1 (2.5)	14.2 (2.3)
Marital status, n (%)		
Married	33 (75.0%)	72 (64.9%)
Nonmarried (divorced, separated, never married)	11 (25%)	38 (28%)
Has a doctor or other health professional ever told you that you (caregiver) have asthma? Yes, n (%)	10 (22.7%)	34 (30.9%)

SD, standard deviation.

TABLE 6. ERROR RATES: NEBULIZER AND METERED-DOSE INHALER WITH SPACER

	Nebulizer			MDI with spacer		
	With mask n = 42	With mouthpiece n = 2	All nebulizers n = 44	With mask n = 63	With mouthpiece n = 47	All MDI with spacers n = 110
Major	8.3%	11.1%	8.5% ^a	16.8%	13.7%	15.6% ^a
Minor	22.1%	25.0%	22.2% ^a	40.9%	29.0%	35.8% ^a
Total	15.8%	17.6%	15.9% ^a	27.5%	20.9%	24.8% ^a

^aStatistical significance (Chi-square, $P < 0.001$) for all differences in major, minor, and total error rates between nebulizers and MDI with spacer.

device use, even 1 week after training [15.9% (nebulizer) to 24.8% (MDI with spacer)]. Errors that were considered “major” (ie, more likely to interfere with lung deposition) were less common (8.5%, nebulizer; 12.6%, MDI with spacer). This error rate was demonstrated despite standardized training conducted by skilled asthma educators, in clinics having expertise in providing care for children with asthma.

Little information is available in the literature about how well parents/caregivers are able to utilize proper technique for delivery systems with very young children, the age group studied here. One study evaluated the parents of children younger than 5 years attending a pulmonology clinic for the very first time and reported that 42% of them made at least 1 error in administration of an inhaled treatment using a spacer; however, no device training and follow-up testing of

proper technique took place, as was done in the present study.⁹ There are no published reports of the ability of children or their parent or caregiver to follow through with the proper steps for nebulization therapy. This study is the first to undertake this type of observation. The findings presented here suggest the need for not just initial education of proper device use but also re-education, with repetition of sessions reinforcing inhalation instructions at follow-up visits.

This study provided an opportunity to compare the ability of caregivers to correctly use a nebulizer versus an MDI with spacer for delivery of their child’s asthma medication after proper instructions. The number of caregivers in the MDI with the spacer group was considerably larger than that of the nebulizer group, mostly due to prescribing practices. Nevertheless, a comparison could be made. The average Performance Mastery Score was significantly higher for the nebulizer group (91.9%) than the MDI with the spacer group (84.5%), suggesting it was somewhat easier to educate caregivers on proper use of the nebulizer. The total error rate also was significantly higher for the MDI with spacer than the nebulizer, suggesting the same conclusion.

Device use in this study was divided into 3 stages: preparation (setup), application (use or administration), and maintenance (cleaning). Critical errors that can occur in any of these 3 stages may significantly impact lung deposition of medication. When the types of error were examined for both devices, more errors (total and major) were made for each device in the application stage than in the other 2. In the application stage, the nebulizer had a slightly higher (but

TABLE 7. MAJOR ERROR RATES FOR EACH DEVICE BY STAGE

	Nebulizer (n = 44)	MDI with spacer (n = 110)
Preparation of device	2.3% ^a	11.4% ^a
Application of device	22.2%	20.6%
Cleaning of device	11.4%	23.6%
Major error rate (across all stages)	8.5% ^a	15.6% ^a

^aStatistical significance (Chi-square, $P < 0.001$) for differences in major error rates.

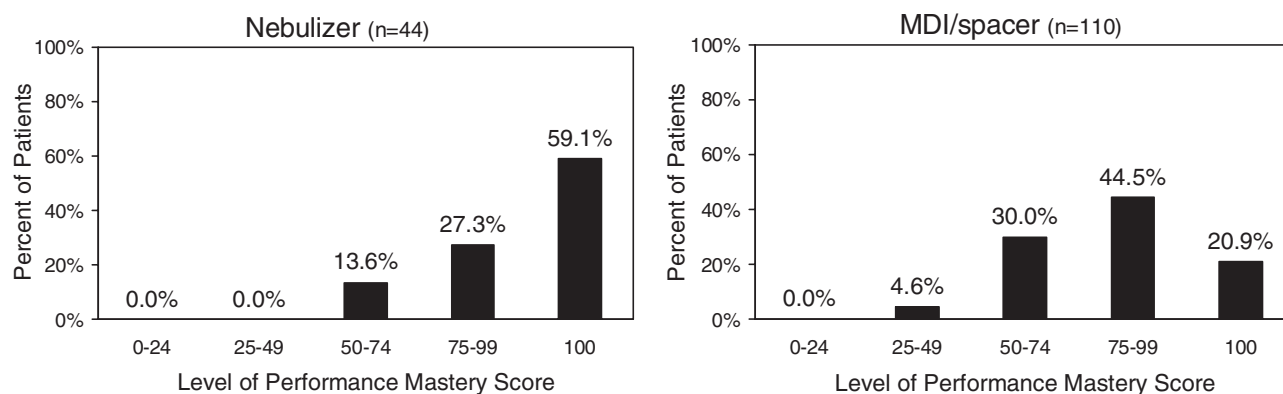


FIG. 2. Performance Mastery Scores by percentage of patients demonstrating use of nebulizer and MDI with spacer.

statistically nonsignificant) rate of major errors versus the MDI with spacer; whereas the nebulizer had a lower rate of major errors versus the MDI with spacer in the preparation and maintenance stages. When all major errors from all stages were combined, a significantly lower percentage of errors was made with the nebulizer. These results indicate that education of the proper inhaler device use is needed for all stages but should particularly focus on the specific details of the application of medication.

Comparison and preference studies looking at the ability of adults and older children to master different inhaled delivery systems for asthma (eg, MDI versus DPI) have been reported.^{4,8,10} However, none have been conducted in young children or have used a nebulizer as a comparison, as done in this study. Knowledge in this area is important, as there is a strong recent trend toward use of the MDI with spacer with or without mask for treating pre-elementary school-aged children (and even infants and toddlers) with asthma.^{11–15} In the United States, nebulization has historically been the more common way to deliver inhaled asthma medications to this age group. Regarding prescribing 1 delivery system over the other, the present study results imply that (1) the MDI with spacer delivery system may have a higher error rate in use than the nebulizer and (2) whatever delivery system is selected for the young child, errors in use of the device are likely, despite careful up-front education and personal demonstration of the device to the caregiver.

It should be noted the present study has several limitations. First, it examined error rates of 2 different delivery systems but not the impact of this error rate on actual asthma control or efficacy of therapy prescribed. That is, the clinical impact of these errors, or any differences in error rate between devices, was not assessed. Additionally, the nebulizer group was smaller than had been planned; however, the differences between groups were still found to be statistically significant. Further, there was an unavoidable difference in ages between the groups (the nebulizer group was younger than the MDI group); and it could be that the better proficiency in the nebulizer group was due to the parents of infants being more concerned than the parents of older children, so greater attention was paid to the initial training. Also, it should be noted that only 1 interactive session with the caregiver at the first visit comprised the extent of instruction in this study. The level of device mastery could have possibly been improved if the initial education had been supplemented with additional educational material (written handout or video) for the caregiver to take home to

study. Others have shown that video instructions for inhaler technique may work as well, or even better than individual one-on-one training.¹⁶ A further limitation is that an assessment of caregiver technique occurred only once, at visit 2. A longer study, with ratings performed at multiple times, to see how technique recall was maintained, would provide additional insight. Finally, the definition of a major error in device use, versus a minor one, was determined by expert consensus—it was not generated from study of clinical impact on medication efficacy.

In conclusion, errors in use of delivery devices for treating asthma in young children were demonstrated by caregivers despite standardized initial education on proper use of their child's prescribed device. Some of these errors were of the types that could likely result in poor lung delivery, thereby giving less-than-optimal clinical results. Mastery of the MDI with spacer delivery system appeared to be harder than that seen with the nebulizer. Further studies are needed to see whether these differences in error rate and device mastery lead to any differences in clinical outcomes.

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