

## Use of inhaler devices and asthma control in severe asthma patients at a referral center in the city of Salvador, Brazil\*

Manuseio de dispositivos inalatórios e controle da asma em asmáticos graves em um centro de referência em Salvador\*

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### Abstract

**Objective:** To evaluate the use of inhaler devices by patients with severe asthma treated via the *Programa para o Controle da Asma e Rinite Alérgica na Bahia* (ProAR, Bahia State Asthma and Allergic Rhinitis Control Program), recording the frequency of their errors in performing key steps and the relationship between such errors and the lack of asthma control. **Methods:** A cross-sectional study involving 467 patients enrolled in the ProAR in the city of Salvador, Brazil. The devices evaluated were metered dose inhalers (MDIs), with or without a spacer, and dry powder inhalers (DPIs; Pulvinal® or Aerolizer®). For the assessment of the inhalation technique, a checklist was used; the patients were asked to demonstrate the technique so that an interviewer could observe all of the steps performed. For the assessment of asthma control, we used the 6-item asthma control questionnaire. **Results:** Most of the patients showed appropriate inhalation techniques when using the devices. When using an MDI, few patients made mistakes in the key step of “coordinating activation and inhalation” (5.2% and 9.1% with and without the use of a spacer, respectively). During Pulvinal® use, 39% of the patients did not inhale quickly and deeply, compared with only 5.8% during Aerolizer® use. Of the patients that made use of Aerolizer® alone, 71.3% appropriately performed all of the essential steps, and their asthma was controlled. **Conclusions:** Most of the patients in this sample, all of whom had been submitted to periodic checks of their inhalation technique (as part of the program), used the devices appropriately. Proper inhalation technique is associated with asthma symptom control.

**Keywords:** Asthma; Administration, inhalation; Metered dose inhalers; Dry powdered inhalers.

### Resumo

**Objetivo:** Avaliar o manuseio dos dispositivos pelos asmáticos graves acompanhados no Programa para o Controle da Asma e Rinite Alérgica na Bahia (ProAR), registrando a frequência dos seus erros em passos essenciais e a relação desses com a falta de controle da asma. **Métodos:** Estudo de corte transversal com 467 pacientes em acompanhamento no ProAR, na cidade de Salvador (BA). Os dispositivos avaliados foram inalador dosimetrado (ID), em isolado ou com espaçador, e inalador de pó seco (IPS; Pulvinal® ou Aerolizer®). A avaliação da técnica inalatória foi realizada através de uma lista de verificação, sendo solicitado ao paciente que demonstrasse o uso para que um entrevistador observasse todos os passos realizados. Para a avaliação do controle da asma, utilizou-se o questionário de controle da asma com seis questões. **Resultados:** A maioria dos pacientes demonstrou técnicas inalatórias adequadas no uso dos dispositivos. Poucos erros foram observados na etapa essencial “coordenar disparo e inspiração” no uso de ID isolado e com espaçador (em 5,2% e em 9,1% dos pacientes, respectivamente). No uso de Pulvinal®, 39% dos pacientes não realizaram uma inspiração rápida e profunda, comparados a somente 5,8% no uso de Aerolizer®. Dos pacientes que utilizavam apenas Aerolizer®, 71,3% realizaram adequadamente todos os passos essenciais e estavam controlados. **Conclusões:** A maioria dos pacientes desta amostra, os quais eram submetidos a verificações periódicas da técnica inalatória no programa, utilizavam adequadamente os dispositivos. A técnica inalatória adequada está associada ao controle dos sintomas.

**Descritores:** Asma; Administração por inalação; Inaladores dosimetrados; Inaladores de pó seco.

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## Introduction

Asthma is a chronic inflammatory disease that is highly prevalent, affecting approximately 300 million people worldwide.<sup>(1)</sup> In Brazil, it is estimated that 11.4% of the population has asthma,<sup>(2)</sup> which is the fourth leading cause of hospitalization via the Brazilian Unified Health Care System.<sup>(3)</sup> In the city of Salvador, Brazil, the prevalence of wheezing among adolescents is reported to be 24%.<sup>(4)</sup> This disease has negative social and economic impacts, causing a reduction in quality of life, impairment of activities of daily living, and high direct and indirect costs related to emergency room visits, hospitalizations, and unscheduled outpatient visits, as well as to school and work absenteeism.<sup>(5)</sup>

The primary goal of asthma treatment is to control the symptoms and improve pulmonary function, the use of inhaled corticosteroids alone or in combination with long-acting  $\beta_2$  agonists being effective for this outcome.<sup>(2)</sup> However, achieving asthma control is not easy, and only a small subgroup of asthma patients use the medications regularly as recommended.<sup>(6)</sup>

Various factors, such as the socioeconomic aspects of the study sample, knowledge about the disease itself, poor perception of bronchial obstruction, comorbidities, adverse effects, and ability to use different inhaler devices, can influence treatment compliance and asthma symptom control. Inefficient inhaler devices and inappropriate inhalation techniques can negatively affect the pulmonary deposition of pharmacological agents (corticosteroids and  $\beta_2$  agonists) and increase the frequency of local and systemic adverse effects.<sup>(7)</sup>

The *Programa para o Controle da Asma e Rinite Alérgica na Bahia* (ProAR, Bahia State Asthma and Allergic Rhinitis Control Program) includes health care, research, and outreach. This program involves a multidisciplinary team composed of trained nurses, physicians, and pharmacists who are committed to teaching proper inhalation techniques. After its implementation, there was a 74% reduction in the number of hospital admissions for asthma in the population of Salvador between 2003 and 2006.<sup>(8)</sup>

The principal objective of the present study was to evaluate the use of inhaler devices by patients admitted to the ProAR referral outpatient clinic. We also attempted to

determine the relationship between such use and asthma control.

## Methods

This was a cross-sectional observational study conducted between August of 2008 and December of 2009. The sample consisted of 467 patients (aged 18 years or older) who had been diagnosed with severe asthma, had been under treatment by a pulmonologist at the ProAR referral outpatient clinic for more than 1 year, and had been using inhaled corticosteroids regularly for at least 3 months.

All of the asthma patients selected conformed to the ProAR schedule of nurse, physician, and pharmacist visits. During the physician visits, information on sociodemographic and clinical characteristics were collected, as were information on asthma control and regular use of inhaled medications in the last 3 months. Treatment compliance was determined indirectly by reviewing drug dispensing records and records of pharmacist visits. Subsequently, trained interviewers administered the 6-item version of the asthma control questionnaire (ACQ-6)<sup>(9)</sup> and completed a checklist for the assessment of the inhalation technique by type of device used by each patient. The ACQ-6 assesses asthma symptoms and rescue bronchodilator use in the last 7 days. This instrument was validated for use in Brazil at our facility, and, in that study, scores  $\geq 1.5$  showed the best accuracy in identifying uncontrolled asthma.<sup>(10)</sup>

The devices evaluated in the present study were divided into two groups: metered dose inhalers (MDIs), with or without a spacer, and dry powder inhalers (DPIs). For the assessment of the ability to perform the inhalation technique correctly, the patients were asked to simulate the maneuvers involved in using the inhaler device, saying out loud which step they were performing, so that all of the steps could be observed. To that end, we adopted a score based on the number of steps correctly performed, using a maneuver checklist, adapted from the one developed by Muniz et al.,<sup>(11)</sup> in accordance with clinical practice and the directions for use supplied by the manufacturer (Chart 1).

Concomitantly, we identified the “key steps” in performing the inhalation maneuvers and specifically assessed patient performance of these particular steps. The terminology

used was that suggested in the international literature,<sup>(12-16)</sup> because it indicates the steps that, when incorrectly performed by users, can significantly affect total deposition of the dose in the lungs. These steps are related to preparing the dose for total drug release and to inhaling the drug. The following were considered key steps in the present study: for the use of an MDI with or without a non-valved spacer, “coordinating activation and inhalation”; for the use of a Pulvinal® DPI, “rotating the inhaler body counter-clockwise”, “rotating the inhaler body clockwise until it clicks”, and “inhaling quickly and deeply through the mouth”; and for the use of an Aerolizer® DPI, “placing the capsule in the appropriate chamber”, “pressing the lateral buttons of the inhaler”, and “inhaling quickly and deeply”.

For the analysis of the association among the proportion of asthma patients showing appropriate inhalation techniques, correct performance of key steps, and asthma control, only the Aerolizer® DPI subgroup was considered. The Aerolizer® DPI was the device used by most of the patients in this sample and, in the study period, it was the only ProAR-dispensed device that also delivered the combination of maintenance medications (a long-acting bronchodilator and an inhaled corticosteroid). The patients who made use of more than one type of device were excluded from the analysis. The exclusion criterion related to the use of more than one inhaler device was adopted only for the analysis of the association between the proportion of patients showing an appropriate inhalation technique and asthma control, considering only the key steps. This criterion was established considering that, when using more than one inhaler device, other drugs might be added, thereby affecting asthma control.

The data were analyzed with the Statistical Package for the Social Sciences, version 17.0 (SPSS Inc., Chicago, IL, USA). We employed descriptive statistics, adopting the usual measures of central tendency and dispersion, and we calculated absolute and relative frequencies. The chi-square test was used for analyzing differences among categorical variables.

The sample size calculation was based on the following assumptions: a 5% relative margin of error; a 95% CI; a 29% frequency of patients using the devices appropriately, on the basis of data in the literature; and a power of 80%. It was thus determined that a minimum sample size of 267 patients was required.

The study was approved by the Research Ethics Committee of the Federal University of Bahia. All participating subjects gave written informed consent.

## Results

The study sample included 467 patients. Of those, 371 (79.4%) were female and 96 (20.6%) were male. The mean age was  $50.5 \pm 13.7$  years. The proportion of patients who had had  $\leq 9$  years of schooling was 52.2%, 64.5% had an income lower than two times the national minimum wage, and 57.0% were employed.

We found that 446 patients (95.5%) used an Aerolizer® DPI, 142 (30.4%) used an MDI with a spacer, 69 (14.8%) used a Pulvinal® DPI, and 38 (8.1%) used an MDI without a spacer. The study participants used between one and three types of inhaler devices (median, 1).

Patient performance of the inhalation technique is described in Table 1. The patients with severe asthma were found to perform well when using an MDI with a spacer, an Aerolizer® DPI, an MDI without a spacer, and a Pulvinal® DPI, “good performance” being observed in

**Chart 1** - Classification of the inhalation technique performance criteria adopted for the analysis, by the type of device used.

Device	Classification of the performance criteria		
	Unsatisfactory	Fair	Good
MDI (with or without a spacer)	up to 3 correct steps (up to 34% of steps correct)	from 4 to 6 correct steps (from 35% to 66% of steps correct)	7 or more correct steps of 9 (more than 75% of steps correct)
Pulvinal® DPI	up to 3 correct steps (up to 34% of steps correct)	from 4 to 6 correct steps (from 35% to 66% of steps correct)	7 or more correct steps of 9 (more than 75% of steps correct)
Aerolizer® DPI	up to 4 correct steps (up to 34% of steps correct)	from 5 to 8 correct steps (from 35% to 66% of steps correct)	9 or more correct steps of 12 (more than 75% of steps correct)

MDI: metered dose inhaler; and DPI: dry powder inhaler.

75.3%, 73.5%, 55.3%, and 52.5%, respectively (Table 1).

We found that, when using an MDI without a spacer, a large number of patients made mistakes in the steps of “keeping the mouthpiece at a correct distance from the lips”, “exhaling fully before using the device”, and “performing an inspiratory pause” (84.2%, 55.2%, and 34.2%, respectively), whereas, when using an MDI with a spacer, many made mistakes in the steps of “exhaling fully before using the device”, “shaking the inhaler”, and “performing an inspiratory pause” (50.0%, 24.6%, and 24.6%, respectively). Few patients made mistakes in the key step of “coordinating activation and inhalation” when using an MDI either with or without a spacer (5.2% and 9.1%, respectively; Table 2).

We observed that, when using a Pulvinal® DPI, a large number of patients made mistakes in the steps of “leveling the powder in the chamber”, “exhaling fully before using the device”, and “inhaling quickly and deeply” (91.5%, 59.3%, and 39.0%, respectively). The last step was classified as a key step. When using an Aerolizer® DPI, many patients made mistakes in the steps of “exhaling fully before placing the mouthpiece in the mouth”, “checking to see if there is powder left in the capsule”, and “repeating the maneuver if there is powder left in the capsule” (54.7%, 55.3%, and 52.0%, respectively). It should be noted that, during Aerolizer® use, few patients (5.8%) made mistakes in the key step of “inhaling quickly and deeply” (Table 2).

Of the patients who made use of an Aerolizer® DPI alone, 202 (88.2%) performed all of the key steps correctly. Among those 202, the most common characteristics were as follows: being female (78.2%); being 45 years of age or older (58.4%); having had ≤ 9 years of schooling (50.5%); having experienced asthma symptoms for ≥ 10 years (91.6%); and having used the

medications regularly in the last 3 months (78.7%). These results are shown in Table 3. In this subgroup of asthma patients, we observed that 144 (71.3%) had controlled asthma and 58 (28.7%) had uncontrolled asthma, as determined by the ACQ-6 scores. This difference was found to be significant ( $p = 0.04$ ), revealing an association between proper use of the Aerolizer® DPI and asthma control (Table 4).

## Discussion

In the present study, we evaluated the inhaler maneuvers performed by patients with severe asthma enrolled in an asthma control program. In general, the patients performed well when using MDIs and DPIs, suggesting that they had learned how to use them. This learning might be related to the high rate of treatment compliance (> 80%), which has been reported in another study involving ProAR patients.<sup>(15)</sup>

The various steps involved in using the devices were evaluated in accordance with the techniques recommended by the manufacturer and with clinical practice, considering the total number of steps performed correctly. Some steps are considered essential for the proper use of the different devices and were reviewed by various authors.<sup>(12-14,17,18)</sup> In the present study, we used some of the criteria established by those authors for use of MDIs and DPIs. We found that only a small number of patients made mistakes in the step of “coordinating activation and inhalation” when using an MDI, with or without a spacer. This step is recognized as the one that is most difficult to understand and is most often performed incorrectly by patients.<sup>(11-15,19)</sup> Our results, which differ from those reported in the literature in that the number of mistakes in this step was low, might be related to the fact that the patients were treated at a referral center for asthma and that they periodically received

**Table 1** - Distribution of the 467 severe asthma patients by classification of the inhalation technique according to type of device.<sup>a</sup>

Classification	Type of device			
	MDI with a spacer (n = 142)	Aerolizer® DPI (n = 446)	MDI without a spacer (n = 38)	Pulvinal® DPI (n = 59)
Good	75.3	73.5	55.3	52.5
Fair	21.9	25.6	44.7	42.4
Unsatisfactory	2.8	0.9	0	5.1
Total	100.0	100.0	100.0	100.0

DPI: dry powder inhaler; and MDI: metered dose inhaler. <sup>a</sup>Results expressed as %.

**Table 2** – Proportion of severe asthma patients who performed inhalation maneuvers improperly.<sup>a</sup>

Step	Type of device			
	Aerolizer® DPI	Pulvinal® DPI	MDI with spacer	MDI with no spacer
	(n = 446)	(n = 59)	(n = 38)	(n = 142)
Removing the cap from the inhaler	0.0	1.7	0.0	2.1
Shaking the inhaler	*	*	23.7	24.6
Holding the inhaler upright	5.1	4.3	0.0	3.5
Opening the capsule chamber	0.9	*	*	*
Placing the capsule in the appropriate chamber <sup>b</sup>	0.7	*	*	*
Closing the capsule chamber	1.8	*	*	*
Pressing the lateral buttons of the inhaler <sup>b</sup>	5.1	*	*	*
Leveling the powder in the chamber	*	91.5	*	*
Rotating the inhaler body counter-clockwise <sup>b</sup>	*	6.8	*	*
Rotating the inhaler body clockwise until it clicks <sup>b</sup>	*	15.2	*	*
Attaching the spacer	*	*	*	7.7
Exhaling fully before inhaling the medication	54.7	59.3	55.2	50.0
Correctly placing the inhaler between the lips	5.8	13.5	*	24.6
Keeping the mouthpiece at a correct distance from the lips	*	*	84.2	*
Inhaling quickly and deeply <sup>b</sup>	5.8	39.0	*	*
Performing an inspiratory pause	43.2	39.0	34.2	24.6
Coordinating activation and inhalation <sup>b</sup>	*	*	5.2	9.1
Exhaling normally	43.3	25.5	10.5	22.5
Checking to see if there is powder left in the capsule	55.4	*	*	*
Repeating the maneuver if there is powder left in the capsule	52.0	*	*	*
Repeating the procedure with the second capsule	4.0	*	*	*
Repeating the procedure if requested by the physician	*	*	10.5	14.7

DPI: dry powder inhaler; and MDI: metered dose inhaler. <sup>a</sup>Results expressed as %. <sup>b</sup>Key steps for the correct use of the devices. \*Not applicable to the device.

instructions and refresher training on the inhalation technique from nurses, physicians, and pharmacists during follow-up visits. Daily educational activities in the waiting room also represent a contributing factor. These activities are performed by the nursing team while the patients are waiting to be seen. The nurses demonstrate how to use the devices, and the asthma patients actively participate in the process, explaining their difficulties, preferences, and acceptance.

In the present study, the patients selected were asked to simulate the maneuvers involved in using the device. The number of high-performing patients might have been overestimated because the observations were based on simulated steps of use of each inhaler, with patients being explicitly told that they would be under direct observation.

When an MDI is used without a spacer, the difficulty clearly lies in the step of “keeping the mouthpiece at a correct distance from the lips”.

With the use of a spacer, there is no need to perform this step, and this ensures unidirectional flow, reduced loss of medication, and more efficient deposition of the drug in the lower airways.<sup>(20)</sup> The use of the spacer is encouraged by the professionals working in the program, and spacers are made available in the follow-up visits. However, 8.1% of the patients in the present sample did not use a spacer.

The new MDIs contain non-ozone-depleting propellants, such as hydrofluoroalkane. The use of this propellant results in an aerosol of particles that are much smaller than those produced by the old inhalers. This fact might explain the new directions for use, which no longer state that the lips should not touch the device. However, a spacer can still be needed, especially when high doses of corticosteroids are used.<sup>(21)</sup> In the present study, it is of note that the inhalers dispensed via the program do not contain such propellants.

**Table 3** – Sociodemographic and clinical characteristics of the 229 severe asthma patients who made use of an Aerolizer® dry powder inhaler.

Characteristic	Made mistakes in at least one key step					
	Yes		No		Total	
	(n = 27; 11.8%)		(n = 202; 88.2%)		(n = 229, 100.0%)	
	n	%	n	%	n	%
Gender						
Female	22	81.5	158	78.2	180	78.6
Male	5	18.5	44	21.8	49	21.4
Age bracket						
< 45 years	9	33.3	84	41.6	93	40.6
≥ 45 years	18	66.7	118	58.4	136	59.4
Level of education						
Illiterate	5	18.5	21	10.4	26	11.3
≤ 9 years of schooling	17	63.0	102	50.5	119	52.0
High school	5	18.5	73	36.1	78	34.1
College	0	0.0	6	3.0	6	2.6
Symptom duration in years						
< 10 years	1	3.7	17	8.4	18	7.9
≥ 10 years	26	96.3	185	91.6	211	92.1
Regular use of the drug in the last 3 months						
Yes	19	70.4	159	78.7	178	77.7
No	8	29.6	43	21.3	51	22.3

We observed that, when using a Pulvinal® DPI, a considerable proportion of the patients did not inhale quickly and deeply, which is a crucial step for drug release, although they showed a good inhalation technique and had no difficulty in preparing the dose. The instruction to inhale quickly and deeply is given by the multidisciplinary team, and its importance is emphasized to all who use DPIs. Our study confirms previous observations that many patients use DPIs incorrectly, not inhaling quickly and deeply being a common error.<sup>(22)</sup>

Most patients in the present study used an Aerolizer® DPI, which is considered easier to use than is an MDI, because it does not require synchronization between activation and inhalation.<sup>(18,22,23)</sup> However, we observed that many patients made mistakes in the steps of

“checking to see if there is powder left in the capsule” and “repeating the maneuver if there is powder left”. This might be a reflection of the lack of patient knowledge of this step or of the lack of importance given to this step by patients. One of the advantages of this type of inhaler is the possibility of checking to see if there is powder left in the capsule and repeating the procedure, thereby ensuring that all of the prescribed dose is inhaled.<sup>(12,17,22,23)</sup> These steps facilitate understanding of the workings of the device, thereby allowing a patient to perform the technique with greater confidence.

Of the patients who made use of an Aerolizer® DPI alone, only a small proportion (11.8%) made mistakes in key steps, results that are similar to those reported in other studies.<sup>(12-14,17,18)</sup> It has been demonstrated that,

**Table 4** – Relationship between asthma control, as assessed by the 6-item asthma control questionnaire, and proper use of an Aerolizer® dry powder inhaler.

Asthma control	Made mistakes in at least one key step				p
	No		Yes		
	(n = 202; 88.2%)		(n = 27; 11.8%)		
	n	%	n	%	
Controlled asthma	144	71.3	14	51.9	0.04
Uncontrolled asthma	58	28.7	13	48.1	
Total	202	100.0	27	100.0	



in comparison with patients who have mild asthma, those with severe asthma are more often compliant with treatment, as well as having greater knowledge regarding the disease and the use of medications.<sup>(24)</sup>

In the subgroup of those who made use of an Aerolizer® DPI alone and performed all of the key steps correctly, the proportion of patients with controlled asthma was found to be higher, demonstrating that proper use of the devices is one of the predictors of asthma symptom control. Similar results have been reported in various studies,<sup>(12,13,22)</sup> underscoring the association between proper inhalation technique and asthma control.

Correct performance of the key steps involved in using the devices was one of the factors affecting asthma symptom control. These steps are related to placing the capsule in the correct position, piercing it for the subsequent drug release, and inhaling quickly and deeply. Inhaling quickly and deeply is crucial for fully delivering the drug to the lung, and, in the present study, this key step was the one with the highest proportion of errors. This might have contributed to the lack of asthma control among those who did not take a quick and deep inhalation correctly, which corroborates the findings of another group of authors,<sup>(18)</sup> who reported that slow inhalation is one of the reasons for partial distribution of the drug in the lung. There were no significant differences regarding clinical or sociodemographic characteristics between the subgroups of patients who made use of an Aerolizer® DPI alone. However, we observed that the patients with severe asthma who made mistakes in key steps had a lower level of education and were over 45 years of age. Similar results were reported in another study, in which the error rate in using DPIs was found to be higher among patients who were older and had a low level of education.<sup>(17)</sup>

Treatment compliance was determined indirectly by reviewing drug dispensing records and records of pharmacist visits. We observed that drug dispensing was less regular and pharmacist visit attendance was lower among the patients who made mistakes in the key steps. It is possible that the asthma patients who regularly attended their scheduled visits to receive their medications underwent refresher training on the inhalation technique and were

corrected in this aspect more often. However, it is necessary to consider that family members are allowed to attend pharmacist visits, even in the absence of the patient.

Uncontrolled asthma can lead to death.<sup>(2)</sup> The inhalation technique is one of the factors affecting asthma control and should be evaluated by a multidisciplinary team. Other factors, such as comorbidities, treatment compliance, and environmental exposure, should also be investigated at each visit, because they are associated with a lack of symptom control.<sup>(25)</sup>

The present study has some limitations related to the assessment of the inhalation technique, because the patients simulated the use of the inhaler but did not actually use it; some patients made use of more than one type of device, which requires different maneuvers and might confuse the patient. The method of indirect assessment of treatment compliance, by reviewing drug dispensing records and records of pharmacist visits, is also a limitation of this study, because our analysis involved only the internal records of the pharmacy department and the drug requisition, evaluation, and authorization forms, as well as the receipts of drug dispensing with the signature of the patient or authorized representative at each dispensing visit. In addition, the varying length of enrollment in the program should be considered a limitation, because patients who had been in the program longer might have more often received instructions and participated in educational activities related to the inhalation technique.

In conclusion, ProAR patients who attend the program regularly and participate in instruction sessions on inhalation techniques, instructions that are reinforced with periodic checks by the nurses, physicians, and pharmacists, showed appropriate inhalation techniques when using an MDI with or without a spacer, as well as when using a DPI, although a subgroup of patients made mistakes in the steps that are considered essential. This identification facilitates the implementation of a tailored educational intervention, which should be developed in modules within the education programs. On the basis of our findings, we recommend that the MDI technique be systematically and regularly reviewed by the health care team and that, whenever possible, the use of a spacer be

encouraged because it makes it easier to use an MDI. Proper inhalation technique is important for symptom control, being influential in this outcome.

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