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Letter

Misuse of medical devices: a persistent problem in self-management of asthma and allergic disease

Anaphylaxis is a concerning disorder because of its life-threatening potential and increasing incidence. It is well established that intramuscular epinephrine is a life-saving therapy in anaphylaxis; however, patients frequently do not understand how to self-administer the medication. The problem of incorrect epinephrine autoinjector use is documented in the literature with rates of correct use as low as 22%.^{1,2} This misuse has been documented in cases of fatal anaphylaxis.³ Furthermore, health care professionals also lack knowledge of correct autoinjector technique.¹ Lack of certainty about device administration is a major barrier to medication use.⁴

Asthma is likewise a critically important disease. Inhalational devices are first-line therapy in asthma but are frequently misused. Up to 92% of asthmatic patients incorrectly use inhalers.⁵ Problems are not limited to one type of device. Rather, various device types are misused.⁶ Even among medical personnel, rates of correct use are suboptimal.⁷ This misuse translates into reduced clinical efficacy of therapy.⁸ Furthermore, improving technique improves clinical outcomes.⁹

This study sought to identify factors associated with incorrect use of metered-dose inhalers (MDIs) and epinephrine autoinjectors. Another objective was to determine whether the rates of correct use have improved since earlier reports. Patients (and parents of minor children) previously prescribed autoinjectable epinephrine (EpiPen or EpiPen Jr) or MDIs and spacers (various product brands) were enrolled from multiple clinic sites of an academic allergy/immunology practice. Participants demonstrated how they used the device and were evaluated compared with established standards. For epinephrine the manufacturer's instructions for use were the standard, and for MDIs a previously published standard was adapted (eTable 1).⁷ Performance of each step was scored as correct: yes or no. The χ^2 and Fisher exact tests were used to evaluate data.

A total of 102 patients using epinephrine and 44 patients using MDIs with spacers were enrolled from adult and pediatric clinics. The most common reason for epinephrine prescription was receipt of allergen immunotherapy. Other indications included food allergy, venom allergy, and anaphylaxis due to another cause. All patients with MDIs and spacers had asthma. Most patients in both groups were female. A total of 11% of patients reported previous epinephrine autoinjector use, and 80% in the MDI and spacer group reported having used their MDI with a spacer. Other patient characteristics are summarized in eTable 2.

A total of 16% of patients used the epinephrine autoinjector properly. Of the remaining 84%, 56% missed 3 or more steps (eFig 1A).

The most common error was not holding the unit in place for at least 10 seconds after triggering. A total of 76% of erroneous users made this mistake (eFig 1B). Other common errors included failure to place the needle end of the device on the thigh and failure to depress the device forcefully enough to activate the injection. The least common error was failing to remove the cap before attempting to use the injector.

A total of 7% of MDI users demonstrated perfect technique. Of the remaining 93%, 63% missed 3 or more steps (eFig 1C). The most commonly missed step was exhaling to functional residual capacity or residual volume before actuating the canister. A total of 66% of imperfect users failed to perform this step (eFig 1D). Other common errors were not realizing that a horn-type sound from the spacer indicated the inhalation was performed imperfectly and not shaking the inhaler before administering the second medication puff. The least common error was failure to insert the spacer mouthpiece between the lips.

Men more often demonstrated correct use of the epinephrine autoinjector ($P = .001$, Fig 1). In addition, younger patients and those with prior medical education, including nursing school, medical school, or emergency medical technician training, were more likely to use it perfectly ($P = .05$ and $P = .03$, respectively; Fig 1). White race was also associated with correct use ($P = .05$, Fig 1). Of epinephrine users, 42% were prescribed the device less than 1 year before enrollment. Of this group, 10% demonstrated perfect use. A total of 34% of participants received the autoinjector 1 to 5 years earlier (5% perfect use) and 24% more than 5 years earlier (1% perfect use); however, the difference in perfect users among the 3 time-based groups did not reach statistical significance ($P = .12$).

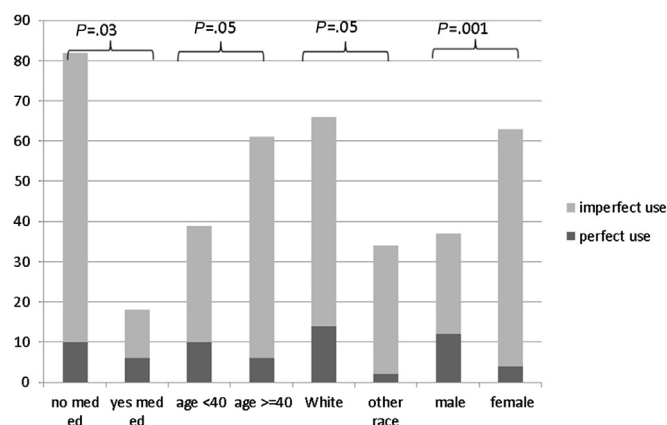


Figure 1. Differences in rates of perfect vs imperfect use based on previous medical education or training, age, race, and sex.

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Participants' ability to demonstrate correct use did not correlate with clinic site, educational level, living with a family member with the same device, or prior use of the device.

Among MDI and spacer users, 39% received the prescription less than 1 year before study participation. None of the factors examined correlated to correct device use.

We found that the problem of misuse of both epinephrine autoinjectors and MDIs and spacers persists. Despite the redesign of the device to promote ease of use, most patients continued to make at least one mistake with the autoinjector. Furthermore, most patients made multiple mistakes and would not have benefitted from self-administration of the potentially life-saving treatment if the need arose. Likewise, incorrect use of MDIs and spacers was common. Typically, multiple steps were performed improperly, consistent with previous reports. Fortunately, most participants were able to complete more than half of the steps properly, and the common errors demonstrated by MDI users would typically result in diminished drug delivery rather than no delivery at all.

Previous reports indicate that medical personnel are as likely as patients to misuse epinephrine autoinjectors. However, this study found that prior medical education correlated with perfect use of the device. Prior studies indicate that patients under the care of allergists/immunologists were more likely to use the device correctly.^{1,2} Because all participants in the current study were recruited from an allergy/immunology practice, this was not a variable, but overall rate of correct use of both devices was low despite allergist/immunologist care. This study supported previous findings that younger patients tended to demonstrate correct autoinjector use more often.

A limitation of this study is the small number of patients in the MDI and spacer group. This limitation affected the ability to identify significant correlations between patient characteristics and incorrect device use. It is clear, however, that there is room for improvement in ensuring that patients are able to correctly self-administer medications. Repeated verbal instruction and, perhaps even more effective, repeated visual education, including demonstration using trainer devices, are highly recommended. Novel methods of providing this repetitive training for patients are needed.

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Supplementary Data

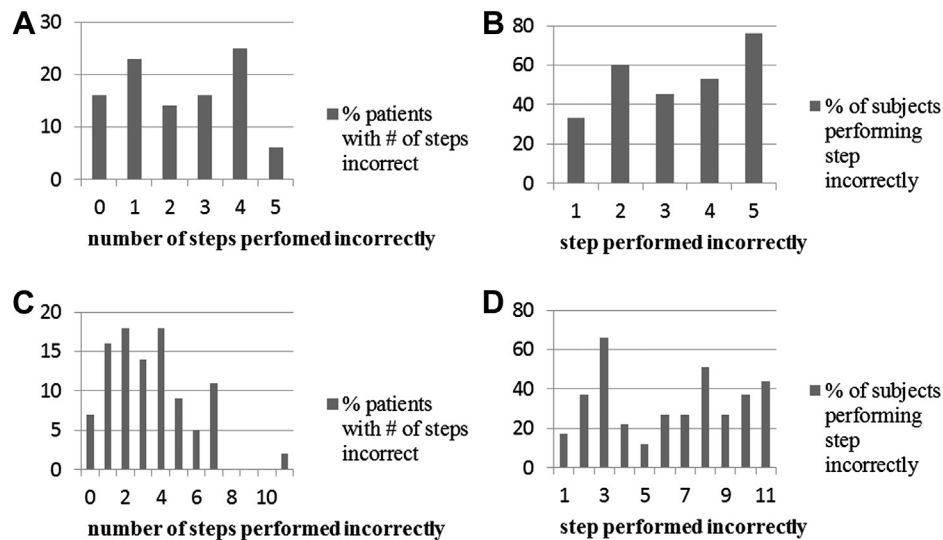
Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.anai.2014.10.016>.

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References

- [1] Sicherer SH, Foreman JA, Noone SA. Use assessment of self-administered epinephrine among food-allergic children and pediatricians. *Pediatrics*. 2000; 105:359–363.
- [2] Arkwright PD, Farragher AJ. Factors determining the ability of parents to effectively administer intramuscular adrenaline to food allergic children. *Pediatr Allergy Immunol*. 2006;17:227–229.
- [3] Pumphrey R. An epidemiological approach to reducing the risk of fatal anaphylaxis. In: Castells M, ed. *Anaphylaxis and Hypersensitivity Reactions*. New York, NY: Springer-Verlag New York LLC; 2011:13–31.
- [4] Gallagher M, Worth A, Cunningham-Burley S, Sheikh A. Epinephrine auto-injector use in adolescents at risk of anaphylaxis: a qualitative study in Scotland, UK. *Clin Exp Allergy*. 2011;41:869–877.
- [5] Sleath B, Ayala GX, Gillette C, et al. Provider demonstration and assessment of child device technique during pediatric asthma visits. *Pediatrics*. 2011;127: 642–648.
- [6] Rootmensen GN, van Keimpema AR, Jansen HM, de Haan RJ. Predictors of incorrect inhalation technique in patients with asthma or COPD: a study using a validated videotaped scoring method. *J Aerosol Med Pulm Drug Deliv*. 2010;23:323–328.
- [7] Hanania N, Wittman R, Kester S, Chapman K. Medical personnel's knowledge of and ability to use inhaling devices. *Chest*. 1994;105:111–116.
- [8] Giraud V, Roche N. Misuse of corticosteroid metered dose inhaler is associated with decreased asthma stability. *Eur Respir J*. 2002;19:246–251.
- [9] Lindgren S, Bake B, Larssen S. Clinical consequences of inadequate inhalation technique in asthma. *Eur J Respir Dis*. 1987;70:93–98.



eFigure 1. Errors in technique demonstration. (A) Number of steps performed incorrectly by patients with epinephrine autoinjector. (B) Frequency with which each step was performed incorrectly (epinephrine autoinjector). (C) Number of steps performed incorrectly by patients with a metered-dose inhaler (MDI). (D) Frequency with which each step was performed incorrectly (MDI).

eTable 1

Device technique standards

Technique for use of EpiPen

1. Remove safety cap
2. Hold device in palm
3. Using a swinging motion, place the orange tip on the outer thigh
4. Push in hard until the trainer function is heard
5. Hold in place for 10 seconds

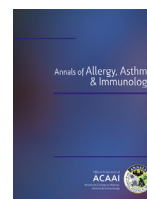
*Note: manufacturer's instructions were used as the standard though there is some evidence that EpiPen devices inject entire dose in less than 10 seconds.

Technique for use of metered-dose inhaler (MDI) with spacer

1. Remove caps from MDI and spacer and connect
2. Hold MDI and spacer together and shake
3. Exhale to functional residual capacity or residual volume
4. Tilt head back or keep level
5. Insert mouthpiece between lips
6. Actuate canister once
7. Inhale slowly and deeply
8. Should hear a hissing sound and not a whistle
9. Hold breath 5–10 seconds (may repeat steps 7–9)
10. Wait 30–60 seconds
11. Shake again before a second actuation

eTable 2
Characteristics of study population

Characteristic	Total No. (%) of patients	All steps correct, No. (%)		P value
		Yes	No	
Epinephrine autoinjector group				
Sex				.001
Male	38 (37)	12 (12)	26 (25)	
Female	64 (63)	4 (4)	60 (59)	
Race				.05
White	67 (66)	14 (14)	53 (52)	
Other	35 (34)	2 (2)	33 (32)	
Age, y				.05
<40	40 (39)	10 (10)	30 (29)	
≥40	62 (61)	6 (6)	56 (55)	
Household family member with same device	14 (14)	0	14 (14)	.12
Prescribed <5 years ago	77 (76)	15 (15)	62 (61)	.11
Has used device	11 (11)	2 (2)	9 (9)	.69
<4-Year college education	47 (47)	5 (5)	42 (42)	.27
Medical education	18 (18)	6 (6)	12 (12)	.03
MDI and Spacer Group				
Sex				>.99
Male	14 (32)	1 (2)	13 (30)	
Female	30 (68)	2 (4)	28 (64)	
Race				>.99
White	26 (59)	2 (4)	28 (64)	
Other	18 (41)	1 (2)	17 (39)	
Age, y				.54
<40	16 (36)	2 (4)	14 (32)	
≥40	28 (64)	1 (2)	28 (61)	
Household family member with same device	14 (32)	0	14 (32)	.54
Prescribed <5 years ago	17 (39)	1 (2)	16 (36)	>.99
Has used device	35 (80)	3 (7)	32 (73)	>.99
<4-Year college education	20 (45)	1 (2)	19 (43)	>.99
Medical education	11 (25)	1 (2)	10 (23)	>.99



Correspondence

Health care professionals' understanding of the use of a metered-dose inhaler



We read with interest the letter by Bonds et al¹ on the misuse of inhalational devices for asthma and anaphylaxis among patients in Texas. From an asthma standpoint, the problems with the use of a pressurized metered-dose inhaler (pMDI) include inability to coordinate inhalation with actuation, inadequate breath hold, fast inspiratory flow rate, hand strength, and ideomotor dyspraxia. Although swapping inhalers or the use of a spacer can help, proper education of patients is needed to improve technique. Studies have found a lack of knowledge of correct MDI use among health care professionals (HCPs),^{2–4} which compounds the problem. We undertook a survey of pMDI technique among HCPs.

An aerosol inhalation monitor (Vitalograph AIM; Vitalograph, Buckinghamshire, United Kingdom) provides clear feedback on 3 crucial steps needed for correct pMDI use: slow inhalation flow (<50 L/min), synchronization between inhaler actuation and inhalation, and a 10-second breath-hold pause after inhalation. A green light indicates the individual has performed a particular step properly. Correct technique is crucial for optimum delivery of medications to the airways.

This survey was conducted in a large district general hospital with approximately 1,200 beds that provides specialist services for asthma. Sixty HCPs undertook this survey, which was approved by the local hospital board committee. The survey included 18 pharmacists, 23 physicians of whom 7 were respiratory specialists, and 16 allied HCPs. The allied HCPs included ward nurses, respiratory specialist nurses, health care support workers, respiratory physiologists, and a medical student. The occupations of 3 participants were not documented.

Eleven (18.3%) of the 60 individuals achieved full scores on the initial attempt. Of the remainder, 45 (91.8%) of 49 failed on synchronization technique (similar to the findings of Bonds et al), objectively due to an excessively fast flow rate. Most participants who failed to achieve full scores were provided with a combination of written information and personalized verbal feedback. A total of 32 (65.3%) of the 49 who did not

achieve full scores on the initial attempt were reassessed. After this focused education, 15 (46.9%) of 32 were able to use the pMDI properly.

It may be challenging to improve patients' technique without similar focus to improve understanding among HCPs involved with their care. Optimal lung deposition would translate to improved control of symptoms, lesser medication use, and reduced hospital emergency visits.

Despite the development of multiple new inhaler devices, there have been no sustained improvements in patients' ability to use their inhalers correctly.⁵ Although the mantra is "training and more training," one has to accept the reality that the trainers might need education to ensure their patients are trained appropriately. The small number of participants limits this survey's effect, but, despite this shortcoming, it provides an insight into HCP knowledge on the use of pMDIs. We therefore advocate that "training the trainers" is as critical as choosing an inhaler device and educating the patients when it comes to optimal asthma management.

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References

- [1] Bonds RS, Asawa A, Ghazi AI. Misuse of medical devices: a persistent problem in self-management of asthma and allergic disease. *Ann Allergy Asthma Immunol.* 2015;114:74–76.e2.
- [2] Interiano B, Guntupalli KK. Metered-dose inhalers: do health care providers know what to teach? *Arch Intern Med.* 1993;153:81–85.
- [3] Jones JS, Holstege CP, Riekse R, White L, Bergquist T. Metered-dose inhalers: do emergency health care providers know what to teach? *Ann Emerg Med.* 1995;26:308–311.
- [4] Kesten S, Zive K, Chapman KR. Pharmacist knowledge and ability to use inhaled medication delivery systems. *Chest.* 1993;104:1737–1742.
- [5] Crompton GK, Barnes PJ, Broeders M, et al. The need to improve inhalation technique in Europe: a report from the Aerosol Drug Management Improvement Team. *Respir Med.* 2006;100:1479–1494.

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