

Shigeaki Nonoyama, MD
Isabella Quinti, MD, PhD
John M. Routes, MD
Mimi L. K. Tang, MD, PhD
Klaus Warnatz, MD

Division of Immunology, Boston Children's Hospital, Boston, Mass.

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Corresponding author: Francisco A. Bonilla, MD, PhD, Division of Immunology, Boston Children's Hospital, 300 Longwood Ave, Boston, MA 02115. E-mail: Francisco.Bonilla@childrens.harvard.edu.

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Updated epinephrine autoinjector labeling



To the Editor:

I read with interest the clinical communications article by Brown et al,¹ reporting a total of 21 cases of leg lacerations after EpiPen autoinjector use in children.

I would like to report an additional case that occurred in our clinic when EpiPen Jr was administered to a petite 8-year-old boy weighing 20.6 kg for a systemic allergic reaction to an oral food challenge. Before administration, one nurse straddled his arms as he was reclining in the examination couch, and another held his legs down while injecting the medication into the bare skin of his anterolateral thigh. Despite that, the child jerked his legs violently, resulting in a 4-cm-long laceration and a bent, uncovered needle

(approximately 75° angle). Bacitracin ointment, Steri strips, and Tegaderm were applied to the wound. Fortunately, a repeat dose of epinephrine was not required. A follow-up phone call revealed normal healing of the wound, but the mother reported experiencing nightmares about being unable to administer the medicine effectively, and expressed concern about the functionality of the device.

Unfortunate occurrences such as these are traumatizing and disquieting for individuals at risk for anaphylaxis. With timely autoinjectable epinephrine being the medication of choice to treat severe allergic reactions,^{2,3} it is understandable why the possibility of inadequate or ineffective dosing is anxiety provoking. Fortunately, we were able to share the precautions suggested by Brown et al,^{1,4} and use the illustrations to provide education regarding child restraint options that could be used during administration of the device. The family was assured that we would report the event to the Food and Drug Administration (FDA), and was also encouraged to file a report.

The authors are to be commended for bringing these unintended consequences of use of a life-saving device to everyone's attention, and for their untiring advocacy efforts. We just learned that the FDA, alerted in part by these publications, has promptly and appropriately responded to this public health concern by updating the labeling of the epinephrine autoinjectors to include a recommendation for caregivers to hold the child's leg during administration. In addition, as advocated by the authors, the updated patient instructions for EpiPen now instruct the user to hold the device in place for just 3 seconds. This is a decrease from the previous hold time of 10 seconds and should help minimize laceration injuries. Similar scrutiny should be given to the optimal holding time for other currently available epinephrine autoinjector devices, including the generic versions, to minimize the chance of these injuries. The Auvi-Q device (currently recalled off the market) has a needle that self-retracts in less than 2 seconds,⁴ though the patient instructions for the Auvi-Q device state a hold time of 5 seconds in the interest of ensuring a good administration technique.

The links to the updated information are as follows:

EpiPen: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019430s061lbl.pdf

Adrenaclick: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020800s034lbl.pdf

Auvi-Q: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/201739s004lbl.pdf

While allergists need to provide education regarding the proper technique and restraint maneuvers at each office visit,⁵ we must continue to advocate for improvement in autoinjector design (ie, self-retracting and less pliant needles, more obvious needle end) and instructions (shorter hold time). In other words, we must urge the manufacturers to distinguish between user error and use error, and avoid relying more on training rather than effective design to ensure safe performance.⁶

Another call for action is the public health issue of escalating costs of the epinephrine autoinjectors that present an economic burden to many families.⁷ In March, the American Academy of Pediatrics made "reducing the cost of epinephrine autoinjectors one of their top 10 resolutions" at the Annual Leadership

Forum (<http://www.aappublications.org/news/2016/04/27/FoodAllergy042716>). Allergists must join hands to champion for these issues on behalf of our patients and families.

Chitra Dinakar, MD

Division of Allergy, Asthma, and Immunology, Children's Mercy Hospital, Kansas City, Mo.

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Corresponding author: Chitra Dinakar, MD, Division of Allergy, Asthma, and Immunology, Children's Mercy Hospital, 2401 Gillham Road, Kansas City, MO 64108. E-mail: cdinakar@cmh.edu.

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