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INNOVATIVE MEDICINE

Best Practices

Anaphylaxis Preparedness Starts in Your Office: Insights on Caregiver Readiness and Epinephrine Device Selection

Approximately 8% of children in the United States have one or more severe food allergies, placing them at risk for anaphylaxis, a potentially life-threatening severe allergic reaction.¹ Epinephrine is the first-line treatment for anaphylaxis, and prompt administration has been shown to reduce both morbidity and hospitalizations.^{2,3} Unfortunately, when a severe allergic reaction occurs, many patients and/or caretakers are not prepared to administer their epinephrine auto-injector. Leading reasons for not administering during anaphylaxis included inability to recognize anaphylaxis symptoms, not knowing when and how to administer epinephrine, and not having epinephrine on hand.^{4,5}

However, a recent usability study revealed that the type of epinephrine auto-injector prescribed significantly impacts the likelihood of caregivers successfully administering epinephrine to their child.

Critical gaps in anaphylaxis preparedness among caregivers⁶

A usability study published in *The Journal of Allergy and Clinical Immunology: In Practice* authored by Evelyn Zhang, et al., looked at whether the type of epinephrine auto-injector prescribed would impact the likelihood of caregivers successfully administering epinephrine to their child. This study recruited 154 caregivers of children with severe food allergies and an epinephrine prescription. At the onset of the study, caregivers were asked whether they knew how to use their child's epinephrine auto-injector. Nearly all caregivers

(96%) believed they knew how to use their child's device. The caregivers were then asked to demonstrate how they would administer epinephrine with a corresponding trainer device.

Successful demonstration required caregivers complete four steps across all device types: 1. remove all safety caps before administration, 2. placed correct end on patient's body, 3. push down to administer, 4. hold device in place for the minimum appropriate time.

The results of the study showed that only 61% of caretakers were able to administer correct use of their prescribed epinephrine auto-injector. The most frequent errors were made after the epinephrine auto-injector was in place against the patient's body with 33% of caregivers removing the injector too soon and 22% not pressing down on the injector firmly enough.

The rates of correct use varied significantly, depending on which device had been prescribed. As shown in the figure below, caregivers of children with AUVI-Q[®] (epinephrine injection, USP) were two times more likely to correctly demonstrate use compared to caregivers of children with EpiPen[®] (epinephrine injection, USP), and 3.5 times more likely than caregivers of children with Adrenaclick (Table 1).

After controlling for confounding factors or variables, the strongest predictors for correct use by caretakers of their prescribed epinephrine auto-injector was having private medical insurance, owning an epinephrine auto-injector for at least 5 years, owning an AUVI-Q,

and having had education on epinephrine auto-injector use by in-person demonstrations.

Caretakers who had been taught epinephrine auto-injector administration in person by a medical provider were more likely to demonstrate correct epinephrine auto-injector use. Parents indicated that they overwhelmingly preferred in-person training compared to videos or just verbal and written instructions.

Pediatricians can address gaps with caregiver education⁶

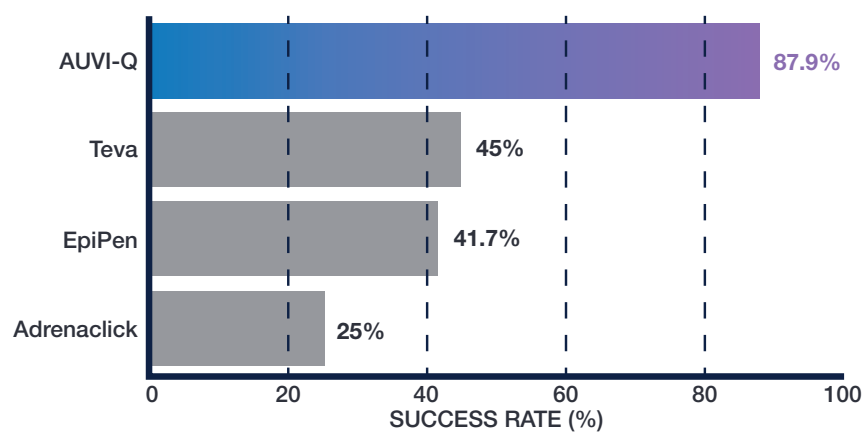
The findings from this study point out a significant gap in caregivers' self-reported knowledge of how to use their child's device compared to their ability to correctly administer epinephrine should their child experience an allergic emergency.

While pediatricians cannot influence patient insurance status or prescription history, the study did provide valuable information for pediatricians, helping them support families of children with severe food allergies.

In medicine, we often say, "Show one, do one, teach one." In this case, it means the pediatrician shows the caregiver how to use the epinephrine auto-injector training device, the caregiver does a simulated epinephrine auto-injector injection using the training device, and then the caregiver teaches another caregiver how to use the device to reinforce correct use. Furthermore, caregiver demonstration of how to use their child's epinephrine

Table 1

RATES OF CORRECT EPINEPHRINE AUTOINJECTOR DEMONSTRATIONS



device should be a routine part of patient education during every office visit as patients and caregivers often forget proper usage over time.

The study also showed that the prescribed epinephrine auto-injector device can significantly impact epinephrine auto-injector device caregiver success in epinephrine auto-injector administration. Even when controlling for sociodemographic factors and epinephrine auto-injector teaching history, owning an AUVI-Q injector was significantly associated with correct epinephrine auto-injector demonstration, suggesting the injector itself may have properties that make it easier to use.

Study limitations included that caregivers recruited were from a single healthcare system in the US; however, the participants did reflect wide racial and socioeconomic diversity, which suggests the study is generalizable to the larger US population. Additionally, training devices were used by participants and may not reflect caregiver use during an actual allergic emergency.

Dr. Wallace is a paid advisor of Kaléo.

Indication

AUVI-Q® (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens,

idiopathic and exercise-induced anaphylaxis. AUVI-Q is intended for patients with a history of anaphylactic reactions or who are at increased risk for anaphylaxis.

Important Safety Information

AUVI-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care. **In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care.** Each AUVI-Q contains a single dose of epinephrine for single-use injection. More than two sequential doses of epinephrine should only be administered under direct medical supervision. Since the doses of epinephrine delivered from AUVI-Q are fixed, consider using other forms of injectable epinephrine if doses lower than 0.1 mg are deemed necessary.

AUVI-Q should **ONLY** be injected into the anterolateral aspect of the thigh. Do not inject intravenously, or into buttock, digits, hands, or feet. Instruct caregivers to hold the leg of young children and infants firmly in place and limit movement prior to and during injection to minimize the risk of injection-related injury.

Rare cases of serious skin and soft tissue infections have been reported following epinephrine injection. Advise patients to seek medical care if they develop any

of the following symptoms at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Epinephrine should be administered with caution to patients with certain heart diseases, and in patients who are on medications that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics. Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions. Common adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

Please see the full Prescribing Information and the Patient Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

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