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Representative Amedee

Emergency Access to Epinephrine in Public Places

Bureau of Emergency Medical Services

Office of Public Health

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Introduction

House Resolution 258 of the 2018 Regular Session requests that the Louisiana Department of Health (LDH) conduct a study concerning the most cost-effective means by which to facilitate emergency access to epinephrine in public places. The resolution also asks for the appropriate dosages of epinephrine and the duration for which epinephrine auto-injectors (EAI) can be stored. The Office of Public Health issues its findings and recommendations below.

Costs Analysis of Epinephrine Auto-Injectors

Epinephrine is the first-line treatment for systemic allergic reactions to foods, insect stings or bites, medications, and other allergens. The early use of EAIs can be life-saving; however, EAIs can be expensive and worldwide availability is limited.

Decision analysis software has been used to evaluate the cost of generic EAIs versus the EpiPen using a model that tracked spending for individual subjects over 20 years, with the assumption that each subject needs two 2-packs yearly, one for home and one for school or work.¹ The cost for the EpiPen over a 20-year model duration totals \$58,667 versus \$45,588 for the generic EAI.

The model also incorporates other food allergy-related costs, such as specialist visits, grocery costs, and loss of work time for parents of food-allergic children. These costs are assumed to be the same for all subjects regardless of the type of EAI prescribed.

The price of EAIs also affects school districts and communities. The Michigan legislature mandated that all public schools stock EAIs. It estimated the cost for two EAI 2-packs, one adult and one pediatric, at \$140, while the “recently reported costs for commercial sources” was \$1200, according to the authors of the article. The annual calculated cost to Michigan public schools based on these two cost estimates ranges from \$565,460 to \$4,846,800.² In this study, few public school patients received epinephrine for anaphylaxis and the vast majority occurred in communities with rapid advanced life support response. The direct annual supply cost of the school EAI mandate was determined to be substantial. More research is needed on the complexity of drug pricing and on the optimal methods to determine individual and societal costs.

Cost-Effective Epinephrine Legislation

Thirty-four states have now passed what are called “entity laws” (*as of November 1, 2018*), legislation that permits venues to maintain an EAI, with the intention of reducing the time it takes to get lifesaving epinephrine to a person having a sudden anaphylactic reaction. The definition of entities varies from state to state, but for illustrative purposes, may include day camps, youth recreation programs, theme parks, daycare centers, restaurants, sports arenas, and college campuses.

¹ Westermann-Clark, E., Pepper, A. N., & Lockey, R. F. (2018). Economic considerations in the treatment of systemic allergic reactions. *Journal of asthma and allergy*, 11, 153–158. doi:10.2147/JAA.S159851

² Chelsea Steffens, Benjamin Clement, William Fales, Ahel El Haj Chehade, Kevin Putman & Robert Swor (2017) Evaluating the Cost and Utility of Mandating Schools to Stock Epinephrine Auto-injectors, *Prehospital Emergency Care*, 21:5, 563-566, DOI: [10.1080/10903127.2017.1308610](https://doi.org/10.1080/10903127.2017.1308610)

These laws may provide exemption from civil liability and outline specific requirements for training personnel, as well as how to obtain, maintain, store and administer the epinephrine. Multiple states have passed legislation that permits, but does not require, various public venues, referred to as entities, to stock undesignated epinephrine for use in case of an emergency. Below are some examples of existing legislation in other states:

Indiana Act 1454 (2015)

This law allows a health care provider with prescriptive authority to prescribe auto-injectable epinephrine to a business, association, or governmental entity or an entity's branch office. It sets requirements for certain individuals employed by an entity to fill, store, and administer auto-injectable epinephrine. The law also provides civil immunity for:

1. a certain entity's employees in the administration of auto-injectable epinephrine; and
2. health care providers in the prescribing of auto-injectable epinephrine and in the training of employees in the administration of auto-injectable epinephrine. The fiscal note for this Act 1454 indicated that there was no fiscal impact.

Utah SB147 (2015)

This legislation amends the Emergency Injection For Anaphylactic Reaction Act in the Utah Health Code. This bill permits certain qualified entities to obtain a prescription for a supply of EAI for use by a trained, qualified adult. It requires the qualified entity to store the supply of EAI in accordance with standards developed by the Department of Health.

Liability protection is expanded to include a medical professional prescribing a supply of EAI, a person conducting training; and a qualified entity. The bill also provides administrative rulemaking authority to the Department of Health. The fiscal note for SB147 indicated that there was no fiscal impact.

Idaho SB1322 (2016)

The purpose of this legislation is to:

1. authorize certain entities to voluntarily maintain a supply of EAI for the treatment of life-threatening allergic reactions,
2. provide requirements for training of agents of authorized entities who may administer EAI,
3. provide protection from civil liability for entities, agents and health care practitioners when administering an EAI in good faith,
4. amend the pharmacy practice act to allow authorized entities to stock epinephrine, and
5. allow pharmacists the ability to prescribe EAI in certain circumstances.

Most authorized entities would be in the private sector and participation is voluntary. The fiscal note for SB1322 indicated that there was no fiscal impact.

Epinephrine Dosage

Suggested dosing of Epinephrine for Children and Adults			
Age Group	Weight	Epinephrine injectable (1:1000 dilution); IM=(1mg/mL) Minimum dose: 0.05mL	Epinephrine auto-injector 0.15mg or 0.3 mg
1-6 mos	9-19 lbs	0.05 mL (or mg)	Off Label
7-36 mos	20-32 lbs	0.1 mL (or mg)	Off Label
37-59 mos	33-39 lbs	0.15 mL (or mg)	0.15 mg/dose
5-7 yrs	40-56 lbs	0.25 mL (or mg)	0.15 mg/dose
8-10 yrs	57-76 lbs	0.3 mL (or mg)	0.15 mg/dose or 0.3 mg/dose
11-12 yrs	77-99 lbs	0.4 mL (or mg)	0.3 mg/dose
≥13 yrs	100+ lbs	0.5 mL (or mg)	0.3 mg/dose

*Oregon Health Authority

Epinephrine Storage & Duration

According to the American Academy of Allergy, Asthma, and Immunology, epinephrine is light sensitive and should be stored in the outer case provided to protect it from light. It should be stored at 68°- 77°F; excursions permitted to 59°- 86°F. Epinephrine should not be refrigerated.

Epinephrine auto-injector are approved by the U.S. Food and Drug Administration (FDA) for a 20-month shelf life. Due to an epinephrine shortage in August 2018, the FDA extended the expiration date of the 0.3 milligram auto-injectors marketed by Mylan by four months beyond the labeled expiration date. This change beyond the approved 20-month shelf life was based on stability data provided by Mylan and reviewed by the FDA.

Recommendation

The Office of Public Health recommends having legislation that permits, but does not require, various public venues to stock undesignated epinephrine for use in case of an emergency. States such as Indiana, Utah, and Idaho have been successful in passing such legislation with no fiscal impact.

To be cost effective, the legislation will have to allow entities to voluntarily maintain a supply of epinephrine auto-injectors while granting pharmacist-prescribing authority as well as providing accessibility to entities who chose to voluntarily maintain a supply. The legislation should also provide for training requirements and protection from civil liabilities for these entities and pharmacists.

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