The Heterogeneity of Stock Epinephrine Legislation in the United States

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Anaphylaxis can occur anywhere, especially in schools, so it is unsurprising that legislation continues to develop across the United States to increase public access to epinephrine. Approximately 24% of at-school administrations of epinephrine may occur in children not known to have life-threatening allergy. This underscores the importance of having a non—student-specific stock of epinephrine auto-injectors (EAIs), commonly called stock or, less commonly, unassigned epinephrine (as opposed to epinephrine prescribed to a specific patient), available whenever students or personnel are on campus. Stock epinephrine legislation is sometimes vague and varies by state. In addition, many potential prescribers are left uncertain of how to prescribe stock epinephrine and the potential liability involved. We sought to clarify the legislation for prescribers and, in the process, have characterized the heterogeneity of stock epinephrine guidelines across the country.

REGULATORY VARIATIONS

From May to July of 2021, we reviewed U.S. legislation regarding stock epinephrine, utilizing online search engines to identify credible sources of legislation, such as .gov sites. We then analyzed the legislation, comparing and contrasting content among states. These searches and analyses revealed several regulatory variations.

The first variation is the existence of stock epinephrine legislation (Figure 1). All states except Hawaii have legislation. The second variation is whether legislation pertains to individuals and/or entities. For example, Alaska’s legislation is specific to individuals and permits individuals to obtain their own stock supply of epinephrine, as opposed to an entity obtaining the supply. The third variation is whether the legislation bifurcates entities into 2 categories: schools and other entities. Most states define schools as public K-12 schools, but some states include nonpublic K-12 schools and preschool programs. The other entities category often includes recreation camps, colleges and universities, daycare facilities, and restaurants. The fourth variation pertains to whether schools are mandated to stock epinephrine.

SCHOOLS AND OTHER ENTITIES

Forty-seven states have passed explicit legislation that either permits (35 states) or mandates (12 states) unassigned epinephrine to be stocked in schools for emergency use. mandates should be interpreted with caution because some code reads that stock epinephrine is mandated pending state funding.

Regarding other entities legislation, 29 states permit entities, such as businesses, to stock epinephrine. Minnesota and Wisconsin have legislation for entities (schools and other entities), plus their code was recently updated to allow individuals to carry and use unassigned epinephrine for emergencies: Dillon’s Law. It is important to note that local and state codes can vary. One example is New York State, where stock epinephrine is permitted in daycares; however, in New York City, it is mandated.

AUTO-INJECTORS

Another difference across legislation is the approach to medication management and administration. The quantity of EAIs recommended or required per school varies by state. Also, most states’ laws specify that unassigned epinephrine should be stocked in the form of auto-injectors, with some states prohibiting devices be used for stock if they leave a used needle exposed. Seven states do not specify auto-injector, and some explicitly permit the vial—syringe method. Although many prescribers agree that epinephrine for anaphylaxis is most safely used when administered via an auto-injector, legislation that does not specify auto-injector can create precarious situations. In at least 1 state with an unfunded mandate that does not explicitly require auto-injectors, school nurses were left stocking epinephrine vials and syringes (less expensive than EAIs) when a free EAI program was delayed. Whereas the vial and syringe method technically fulfilled the law, this method is a less safe, less efficient method in an emergency, community setting than an EAI.

TRAINING AND LIABILITY

Legislation heterogeneity is apparent in training requirements and in training curricula approval processes. For example, states vary on the frequency training is recommended (unspecified frequency vs annually vs every 2 years), the format of the training (online vs in-person), and the approving body (state vs local). In New York City, Elijah’s Law recently passed, requiring child day care facilities to establish preparedness plans for anaphylactic emergencies, and is somewhat unique by including daycare facilities in school legislation. Also of note, only some state laws, such as Ohio’s Allison Rose Act, indemnify training organizations and prescribers, in addition to the individuals administering
stock epinephrine. This act also requires school-targeted education to include input from board-certified allergists.

**DISCUSSION**

Epinephrine legislation across the United States is heterogeneous, and data are lacking on which policies are most effective at not only treating anaphylaxis but also preventing it. The question of cost arises in these discussions, especially regarding schools. Recent cost simulation analyses (in which stock epinephrine is defined as 2 EAI twin-packs) concluded that stock epinephrine is cost-effective provided stock supply cost does not exceed $338 per school annually. Currently, at least 1 program provides 2 EpiPen twin-packs at no cost to K-12 schools, and another offers schools and state-approved entities AuviQ twin-packs at $246.99 (S. Bradley, email communications, June 1, 2021 and June 9, 2021).

Of some debate is whether schools that stock epinephrine should also require students who are at risk of anaphylaxis to supply their own devices. Some data suggest it would be cost-effective not to require students supply their own devices if stock epinephrine is available at the school. We retain the position that such a decision lies with the patient, patient’s parents, and patient’s physician and should take into account, among other factors, (1) the patient’s transition journey from a pediatric care model to an adult care model (eg, learning the responsibility of self-carrying) and (2) that stock epinephrine devices are not always available, such as on school buses and field trips.

Stock epinephrine policy decisions are complex. Liability concerns, albeit understandable, are 1 of many barriers to making epinephrine accessible, thus underscoring the importance of prescriber indemnification in stock epinephrine legislation. Until more opportunities arise to teach prescribers about stock EAIs, allergists will benefit from a roadmap to guide them when schools request stock EAIs (Figure 2). Furthermore, studies are needed to evaluate which components of legislation result in best possible outcomes, and allergists should be included in these decisions.
FIGURE 2. Prescriber approach on how to write stock epinephrine prescriptions for schools. Note that some prescribers prefer to have a memorandum of understanding (MOU) in place with the school and/or school system to clarify expectations of all parties, including liability. Although not legally binding, MOUs clarify the agreement and should align with the state’s legislation regarding stock epinephrine.

REFERENCES


