The Need for Required Stock Epinephrine in All Schools: A Work Group Report of the AAAAI Adverse Reactions to Foods Committee

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ABSTRACT

Epinephrine is the first line of treatment for anaphylaxis which can occur outside a medical setting in community environments like schools. Patients with diagnosed IgE-mediated food allergy at risk of anaphylaxis are prescribed self-injectable epinephrine and given an individualized anaphylaxis action plan. As students, such patients/families provide their school with completed medication forms, a copy of their anaphylaxis plan, and additional studentspecific epinephrine. However, students approved to self-carry prescribed self-injectable epinephrine may forget to do so or have other reasons for lacking prescribed epinephrine such as familial inability to fill the prescription due to cost or other access barriers. Undiagnosed students lacking prescribed epinephrine may also experience anaphylaxis at school. The presence of non-student specific school stock epinephrine allows school nurses and other staff the ability to treat anaphylaxis on-site while awaiting emergency medical services. Notably, not all states legally mandate K-12 schools to stock epinephrine. In states with laws only voluntarily allowing schools to stock epinephrine, it provides the ability to opt-out. Herein, we present a comprehensive review of barriers to school stock epinephrine, related improvement strategies, and workgroup recommendations supporting the need for mandated stock epinephrine in all schools in every state. Proposed solutions include ensuring legal immunity from liability for prescribers; advocacy for legislation to stabilize cost of self-injectable epinephrine; educational initiatives to schools promoting merits and safety of epinephrine and related anaphylaxis training; and partnerships between patient advocacy groups, medical and nursing organizations, public health departments and other health professionals to promote laws and district policies addressing need for stock epinephrine and school nurses to train and supervise school staff.

KEY WORDS: Anaphylaxis, food allergy, stock epinephrine, self-injectable epinephrine, schools, school nurses, unlicensed assistive personnel, medication administration, anaphylaxis training, unassigned epinephrine

ABBREVIATIONS: AAP: American Academy of Pediatrics; A/I, allergy/immunology; CDC: Centers for Disease Control; EDD: epinephrine delivery device; EMS: emergency medical

services; FA: food allergy; NASN: National Association of School Nurses; RN: registered nurse; SE: stock epinephrine; SN: school nurse; UAP: unlicensed assistive personnel

INTRODUCTION

Epinephrine is deemed an essential medicine by the World Health Organization¹ and is standard first line treatment of anaphylaxis.^{2,3} Prompt anaphylaxis diagnosis with immediate treatment using epinephrine has long been associated with lower rates of mortality or near-fatality.³⁻⁵ Therefore, in both medical and community settings, direct access to epinephrine is a critical factor in preventing anaphylaxis-related fatalities as is education on anaphylaxis diagnosis and management, including proper use of epinephrine devices.

Schools or child care centers are the setting for up to 29% of reported cases of anaphylaxis in children.⁶ This report focuses on the need for mandated school stock epinephrine to facilitate prehospital anaphylaxis treatment and promote positive outcomes. In this report, the term stock epinephrine (SE) refers to unassigned non-student specific epinephrine available at school. Students with prescribed epinephrine delivery devices (EDD) may or may not be approved to self-carry this medication while at school. If allowed to self-carry, they may forget to do so or lack ability to fill an epinephrine prescription. Additionally, there is high incidence of epinephrine administration in school settings for first-time reactors with no prior diagnosis of allergy who lack prescribed epinephrine.^{6,7}

This report describes ten barriers to SE, related improvement strategies, and additional workgroup recommendations. Figure 1 is a concept map summarizing overarching themes reflected in the literature review which highlighted the need for education and advocacy to reduce barriers to SE. Improving epinephrine access is imperative to optimizing student safety. Providing legal means for some schools to opt-out of having SE, versus mandating SE in all states, may undermine student safety and risk adverse health outcomes.

BARRIERS TO SCHOOL STOCK EPINEPHRINE & RELATED IMPROVEMENT STRATEGIES

BARRIER 1: INDEMNIFICATION CONCERNS

The primary purpose of legislation allowing or mandating schools to stock epinephrine is to establish and clarify indemnification of specified school personnel who may administer EDD during suspected anaphylaxis. Indemnification is the one component common to all state statutes pertaining to SE. Prior to passage of these laws and rules, it may have been technically possible in some jurisdictions for school nurses (SNs), or other personnel, to obtain a prescription for administration of SE to students experiencing suspected anaphylaxis. However, no liability protection for school personnel, prescribing physicians, pharmacists, or their employers existed.

Nebraska was the first state establishing rules requiring SE in schools.⁸ Subsequently, states approached this issue statutorily, mostly in the early 2010s,⁹ with different categories of relevant personnel named as indemnified parties in these laws. Relevant parties included at minimum were SNs, school administrators and districts, but in some cases, amended laws included additional indemnified parties, (e.g. teachers; other school personnel), provided they completed district or state authorized anaphylaxis training.

No federal civil liability protection for Good Samaritans rendering bystander emergency first aid exists as such assistance is governed by civil liability laws that vary among states.^{10,11} This is partially because in some states, one cannot be a 'Good Samaritan' if one is performing duties of one's paid employment, which may include rendering epinephrine if training for this task is completed.

Real or perceived liability concerns can influence the school's actions or reluctance to invest in resources required for SE program implementation. Financial incentives granted to states in the 2013 School Access to Emergency Epinephrine Act, applied only to states mandating school SE and certified civil liability protection.¹² Notably, even in states mandating SE, there is variation in liability protection.¹² While most states provide liability protection to districts, boards of education, schools, employees, and prescribers, all parties should review state law verbiage and address concerns with legal counsel.¹³

IMPROVEMENT STRATEGIES FOR BARRIER 1: PROVIDE IMMUNITY FROM LIABILITY

A literature review found no details on history of amendments to bills expanding indemnified parties, nor studies on the role of indemnification in decision making of school personnel regarding SE administration. It is unclear how perceived lack of liability protection influences bystanders when deciding whether or not to render anaphylaxis first aid. Such concerns may limit access and use of community-based emergency SE as evidenced by an anaphylaxis fatality of a teen in Ireland denied epinephrine by a pharmacist.¹⁴ In states with laws allowing voluntary stocking of SE, a paucity of research investigating related issues and outcomes makes it difficult to discern if some schools elect not to have SE because of liability concerns or other reasons (e.g. perceived lack of need). Future studies are needed on the role of indemnification and knowledge thereof, in a school's decision to have SE and train personnel.

BARRIER 2: EDD COST

EDD costs increased 500% from 2007 to 2016.¹⁵ Despite the increased number of different EDDs available on the market, including generic versions, cost is still high.¹⁶ A survey of Ohio SNs found cost as the greatest barrier to SE.¹³ Of schools with SE, the majority was acquired through the manufacturer (76.2%), paid for by the school district (14.7%), donated (4.9%), and other (2.1%) or unknown (6.3%).¹³ Studies have attempted to calculate cost of SE. A study of Michigan public schools reported a wide range in results based upon low and high cost estimates for unsubsidized SE ranging from \$565,460 to \$4,846,800 per year.¹⁷ This study did not include training and staffing costs given significant variability among school size and number of staff needing training on recognition of anaphylaxis signs and symptoms and its treatment.¹⁷ Costs associated with staff time and materials for preparation and training should be considered. Such costs will vary depending on the number of staff trained and cost of training materials. See resource table E1 in the online journal repository for website links to EDD options.

IMPROVEMENT STRATEGIES FOR BARRIER 2: PROMOTE BETTER EDD COST STRUCTURE

Strategies to reduce EDD costs to schools must be multifaceted to address this complex issue in various ways. A fundamental targeted approach must be to improve EDD cost structure and outof-pocket expenses to patients, families and schools. Allergy/immunology (A/I) professionals can increase awareness and utilization of programs providing free or low-cost EDDs, such as Viatris/Mylan's EpiPen4Schools program, while advocating for similar programs from additional pharmaceutical companies.¹⁸ State provision of targeted funding to school districts aimed at off-setting cost of SE may also mitigate financial barriers. In 2013, the School Access to Emergency Epinephrine Act encouraged states to have SE, and states developing implementation plans were given preference for federal grants.¹⁹ Additional public and private sector strategies are needed to combat barriers related to high EDD cost.

BARRIER 3: EDD ACCESS OBSTACLES

Difficulties with EDD access contribute to having insufficient prescribed EDDs in schools. National EDD shortages were recognized in May 2018, but manufacturers still experience sporadic shortages.²⁰ The requirement for students to bring prescribed EDDs to school also leads to gaps in care. Students may not provide prescribed EDDs to schools due to a variety of factors including EDD cost and lack of healthcare access.²¹⁻²³ Some students may have undiagnosed food allergies (FA) and thus were never prescribed EDDs. Approximately 15 to 31% of students needing EDD for anaphylaxis did not have an allergic history and would have been untreated without SE.^{6,7,24-26} Age appropriate students allowed to self-carry prescribed EDD may forget to consistently do so.²⁷ While every state legally allows students to self-carry EDD,²⁸ related ambiguous school policy, lack of policy, or inconsistent adherence to existing policy may prevent self-carrying of prescribed EDD by students approved to do so from their allergist, parents/caregivers, and SN.^{29,30} State regulations or district policy may also not allow SE be taken off school property for field trips or after school activities.²⁹

IMPROVEMENT STRATEGIES FOR BARRIER 3: INCREASING EDD ACCESS AT SCHOOL

Improving prescribed EDD access at school can help overcome barriers for having SE. As prevalence of anaphylaxis increases globally, EDD demand is anticipated to increase.³¹ To match higher demand, legislation should aim to increase supply and stabilize EDD prices.¹⁶ This can be done through incentives to encourage pharmaceutical companies to create more generic EDDs. Additionally, motivation for more EDD manufacturers to produce EDDs will increase competition. Legislation can also set limits on EDD price increases to improve affordability as cost is often a limiting factor.

Local level strategies to improve EDD access include increasing knowledge of physicians and nurses regarding all available EDD products and adjusting prescribing practices based on availability in pharmacies.¹⁶ Families can be referred to EDD manufacturer patient assistance programs and online medication coupon sites.³² Schools can work with available EDD school donation programs such as Viatris/Mylan's EpiPen4Schools program. During EDD shortages, it may be prudent to allow extension of expired EDDs by 4 months, which was FDA approved for certain EpiPen® lots in 2019.³³⁻³⁷

Approaches to control EDD demand may include mandating SE and prescribing fewer EDD devices to certain patients. Shaker et al. found cost effectiveness for two EDD prescriptions is low unless probability of requiring a second epinephrine dose is more than 25%.³⁸ Given current high EDD cost, as a cost-effective strategy Shaker et al. recommend limiting routine prescriptions for a second EDD only to patients with a past medical history of anaphylaxis especially in settings with limited resources.³⁸ However, EDDs are only sold as two-dose devices per pack eliminating the choice of a one-dose only prescription. Although prescribing one EDD compared to two devices is an individualized decision after discussion with the patient, universal recommendation of prescribing two EDDs may need to be revisited with more studies. Use of an ampule of epinephrine and syringe in anaphylaxis is substantially cheaper than EDDs. Unfortunately, studies show even in non-emergent situations, the time for drawing up the dose was too slow and dosing inaccuracies were a problem.³⁹

BARRIER 4: LACK OF SNs OR INADEQUATE NUMBER OF SNs

School nursing practice includes providing evidenced-based school health services, care coordination, quality improvement, leadership, and public health initiatives based on standards of practice.⁴⁰ SNs also direct, create, implement and evaluate educational training programs for non-medical school staff on health conditions and medical emergencies.^{29,41-43} For example, SNs are qualified to lead and provide training of non-medical school staff on anaphylaxis prevention, preparedness, and management.^{32,44,45} This is critical as absence of trained staff may result in unrecognized, untreated, or improperly treated anaphylaxis.⁴⁶ While SNs are vital to student health and safety, existing barriers create obstacles to achieving optimal numbers of SNs in every school.

Disparities in SN Staffing Models

Student volume per SN is often tied to school funding per student and state nurse practice acts.^{41,47} SN caseload can range from several hundred students to thousands.^{41, 48} Workload imbalances may jeopardize SN ability to optimally provide health services to students at risk of anaphylaxis and to educate staff on anaphylaxis management. This is detrimental since SN provided anaphylaxis education may increase staff confidence and minimize their anxiety while supporting a safer learning environment.⁴⁹

Disadvantages of Inadequate SN Coverage

Approximately 25% of U.S. public schools have no SNs; only 52% have a full-time SN; and approximately 32% - 35% employ part-time SNs often covering multiple school buildings.^{47,50, 51} Such disparities can lead to inadequate SN coverage to direct, create, implement and evaluate school anaphylaxis programming thereby compromising safety of students at risk of anaphylaxis. Insufficient SN coverage also results in:

- Increased use of nonmedical staff to administer SE in districts with high building to SN ratios.⁵²
- Negatively influencing effectiveness of implementing undesignated school SE programming.⁵¹
- Exacerbating the current lack of school SE.^{21,29}

SN Staffing Discrepancies Despite Increased Need for School Health Services

Children with chronic conditions increased 400% from 1960 to 2010 and more students have social determinants of health concerns.^{41,53-56} One of every 13 children, or 8% under 18, has food allergy.⁵⁷ The need for SN services has increased amidst SN staffing disparities.

Barriers to SN Full-Time Employment and Funding

Commonly cited reasons for not having SNs include:

- Cost and school size.⁴⁷
- Lack of funded school nursing positions. Budget constraints with subsequent elimination or reduction in SNs.^{53,56}
- State has no mandate for a SN in every school.^{53,56}

• SN role, scope of practice, and health service provision may be unseen or misperceived by budget decision makers lacking knowledge regarding health service delivery.^{47,48,58,59}

IMPROVEMENT STRATEGIES FOR BARRIER 4: INCREASE NUMBER OF SNs IN SCHOOL DISTRICTS

Increase Awareness of SN Educational Preparedness

Allergists and allergy nurses can promote clarification of SN educational preparedness, regulatory oversight, and scope of practice which may dispel misconceptions of budget decision makers thus facilitating higher employment levels. NASN recommends SNs have a nursing baccalaureate degree and RN license to meet minimum entry-level practice standards.⁶⁰ Some states require post-baccalaureate SN board certification.⁶⁰

Promote Understanding of Regulatory Oversight of SNs

SNs are required to adhere to state nurse practice acts, school nursing scope and standards of practice, and nursing ethics parameters.^{41,61-64} SNs must follow state education statutes and regulations; public health and school codes; and related laws.^{41,47} School board policies also influence school health services and SN practice.⁴¹

Clarify SN Role to Dispel Employer Misconceptions

District budget and policy decision makers should be well-informed regarding SN scope of practice so SNs function at the highest level of their license and credentials.^{47,65} Examples of FA related SN services include:

- Providing evidenced-based school management of FA and anaphylaxis.
- Delivering FA and anaphylaxis health education to students/families.
- Creating individualized health care plans for those with diagnosed FA.
- Providing case management and assisting students with FA self-management.
- Administering epinephrine during anaphylaxis.
- Directing, implementing and evaluating anaphylaxis education of non-medical staff.
- Offering referrals to local allergists and/or prescribed EDD access resources as needed.
- Collecting and reporting EDD and SE administration data.^{40,41,47,48,54,62,65,66,67}

Increase Understanding Regarding Benefits of SNs in Every School

A full-time SN for every school is the best practice recommendation of the American Academy of Pediatrics (AAP).⁶⁶ Understanding benefits of SN presence may assist advocacy efforts to increase hiring of SNs. Among other benefits of on-site SN directed health services are:

- Improved student health, safety, and educational outcomes by identifying and addressing student health needs, social determinants of health, and health care provision.^{40,48,66,68,}
- Cost beneficial use of public funds.^{29,48,56,65,66,69}
- Improved student self-management of chronic health conditions resulting in decreased absenteeism.⁶⁷
- Enhanced medical management through SN communication facilitation between schools, families and clinical teams.⁵⁴
- Improved health service access for students with healthcare disparities as SN may be the only healthcare provider they regularly see.^{41,54,59,70}

Promote SN Staffing Models Based on School & Student Specific Indicators

Allergists and allergy nurses can advocate for optimal SN workload to support safer learning environments for their patients. NASN recommends determining optimal SN workload by analyzing student and school-specific indicators.⁷¹

Increase Recruitment, Retainment and Available Funding for Full-Time SNs

Allergists and allergy nurses can advocate at local and state levels for increased exploration of funding options to hire more full-time on-site SNs and to support their recruitment and retention.

BARRIER 5: DIFFICULTIES REGARDING DELEGATION OF MEDICATION ADMINISTATION TO UNLICENSED ASSISTIVE PERSONNEL

SNs direct school-based acute and chronic disease management often requiring complex medication management for students on a routine or emergency basis. Some students may have undiagnosed or untreated health conditions requiring medication administration before emergency medical services arrive.⁷² The quantity and diversity of medications administered at school has increased.^{73,74} Yet, many schools do not employ a registered nurse (RN) on-site to oversee and provide health services, including medication management.⁴⁷

Utilization of Unlicensed Assistive School Personnel

Unlicensed assistive personnel (UAP) are school staff lacking a healthcare license (e.g. health aides; office staff).⁷⁵ While optimal for a RN to administer medications in schools, UAP are often utilized to administer medications with SN oversight. The SN conducts and documents initial and ongoing medication administration training and evaluation of UAP.^{70,71,73,75,76} SN delegation of medication administration to UAP can only be done if allowable by district policy; state nurse practice acts; and state laws, standards and regulations.^{42,75} Acuity and stability of a student's health condition, task complexity, SN case load, UAP documented training and competencies, SN ability to provide UAP supervision, and student's health outcomes should be evaluated prior to such delegation.⁷⁷

Potential Limitations of School Medication Administration Laws & Regulations

Regulatory entities (e.g. state nursing board; state health and education departments) provide school health oversight.⁷⁶ However, inconsistencies occur among states regarding laws and regulations addressing delegation of health services to UAP and district policies within states may be contradictory.^{65,73,76,78} For example, in Massachusetts, UAP are only allowed to be trained to administer prescribed EDD and not over-the-counter medications such as diphenhydramine.^{79,80} Some states may only allow a SN versus UAP to administer SE to students with undiagnosed allergies experiencing anaphylaxis.⁸¹ Conflicting authority exists when state codes grant school administrators ability to assign medication administration as a task, versus a SN delegated assignment to UAP.^{76,82,83}

Increased Risk, Liability, Medication Errors & Parent Dissatisfaction with UAP Use

Medication administration by UAP can result in increased risk, liability, medication errors, and parent dissatisfaction.^{66,73,75,76,84} The Institute of Safe Medication Practices reports reliance on UAP administered medication has resulted in up to a three-fold increase in medication errors.^{72,74,76,81} Delayed anaphylaxis treatment at schools commonly occurs because staff did not follow emergency medication procedures and contacted the student's family first for direction.⁷⁶ Medication errors increase when SNs are responsible for managing UAP at multiple schools.⁷⁶

Potential for Insufficient Quantity of UAP for Medication Administration

Despite having full legal authorization, UAP may be unwilling to accept responsibility for medication administration especially if their job description does not include the task and/or they

have liability concerns.⁷⁶ Risk for medication errors increase when related policies, procedures and trained personnel are lacking which can result in poor student health outcomes.⁷² Table I summarizes potential barriers to safe medication administration in schools.

IMPROVEMENT STRATEGIES FOR BARRIER 5: PROVIDE LEGAL ABILITY FOR SNs TO DELEGATE MEDICATION ADMINISTRATION TO UAP

AAP recommends having a full-time RN in every school.⁶⁶ Having such SN coverage may decrease reliance on UAP for medication administration which may decrease risk, liability and medication errors; and promote parent satisfaction and positive student health outcomes. All states need laws and district policies allowing SNs to delegate medication administration to UAP when a SN is not available. Even with SNs on-site daily, multiple student needs or distance within a school campus setting may require UAP assistance after SN training, evaluation, and oversight.

Increase Number of UAP Trained to Administer Medications

More UAP may be willing to accept responsibility for medication administration after SN training, evaluation and supervision, if districts provide incentives such as a financial bonus, non-financial rewards, positive public recognition, and/or continuing education credit per state guidelines.

National and State Guidelines on School Medication Administration

Creation of national guidelines on school medication administration may minimize current inconsistencies between and within states regarding related laws, regulations and policies.⁷⁶ Authorship of such guidance should include SNs. A model example is SN-authored Colorado Medication Administration Guidelines in School and Childcare Settings which were subsequently adopted and published by Colorado's Department of Education.⁸⁵

American Academy of Pediatrics Recommendations

AAP recommendations to physicians for positive student health outcome promotion:

- Prescribe medications requiring administration during school hours only if necessary.
- Be knowledgeable about local SN services and medication policies.
- Clearly state specific instructions on school medication forms since administration may be delegated to UAP.
- Collaborate with school boards, districts, and departments of health and education to secure creation and funding of adequate school health services, staffing, and medication policies.

- Support state laws and regulations specifying policies for effective and safe school medication administration.
- Partner with local district's school health council and advocate for comprehensive health programs.⁶⁶

BARRIER 6: PITFALLS ASSOCIATED WITH UAP ANAPHYLAXIS TRAINING

Inadequate UAP training on anaphylaxis recognition and response, including EDD use, is a major barrier to having SE. A key to successful implementation of school SE is properly conducted UAP training on correct epinephrine administration. It is critical to provide accurate anaphylaxis education including training on proper EDD use, intramuscular epinephrine's safety profile, low incidence of severe side effects, and also instill confidence in the learner's ability to enact related skills when necessary.⁸⁶

When training UAP on correct epinephrine administration, clarifying key tasks is important. These tasks include proper identification of anaphylaxis signs and symptoms and need for epinephrine; correct EDD injection technique; and next-steps after EDD administration.^{42,45,87, 88} Factors to consider regarding comprehensive anaphylaxis training include quality and delivery of training content and assessment of learner's skills post-training.

Quality and Delivery of Training Content

Amongst states permitting or mandating SE, variability exists regarding anaphylaxis training requirements. Some states defer to school districts for how to conduct training, whereas other states clearly define training requirements in legislation.¹¹⁵ Even with detailed training requirements, content may not be developed with board-certified allergists or other allergy professionals (e.g. nurses) as authors or peer-reviewers. Thus, non-evidenced-based protocols may potentially be enacted. Heterogeneity also exists regarding who may train UAP.^{90,107,115} Many states permit SNs to train UAP on SE use but many schools lack SNs. In schools with SNs, some may be overextended with responsibilities which impede ability to have adequate time to provide UAP anaphylaxis education.

Assessment of Learner's Preparedness

Anaphylaxis preparedness can be assessed through post-education evaluation and should consider anaphylaxis and EDD knowledge, skills regarding EDD use, and confidence in recognizing and responding to anaphylaxis.⁸⁶ Knowledge can be assessed through post-learning quizzes⁸⁶ or virtual seminars where learners discuss scenarios in which students experience anaphylaxis and learners determine next steps.⁸⁹ Skills can be assessed through in-person or virtual workshops whereby learners demonstrate proper EDD use and can ask questions. Doing so may increase learners' self-efficacy with such skills which may be assessed through questionnaires and focus groups.

Anaphylaxis emergency response follow-up may include SN led post-anaphylaxis debriefing with UAP.^{42,87} Such debriefing can benefit learners and anaphylaxis program creators to support educational improvements based on real-life experiences. Applicable findings from debriefing can also be incorporated into the school's medical emergency response plan. During debriefing, emergency response is reviewed including, but not limited to, the following:

- Promptness of anaphylaxis recognition and response time.
- Use of proper epinephrine administration technique.
- Confidence level of responders, especially those who completed anaphylaxis training.
- Steps to optimize response.
- Identification of any policy or protocol gaps with discussion of questions, concerns and needed changes.⁴⁰

IMPROVEMENT STRATEGIES FOR BARRIER 6: EXPAND AVAILABILITY OF EVIDENCED-BASED UAP ANAPHYLAXIS TRAINING

SNs Can Train UAP on Anaphylaxis and EDDs

Many states authorize SNs to educate UAP on anaphylaxis recognition and response. State legislation may include required anaphylaxis training content and necessary trainer qualifications. For example, Table II lists New York's required training content. A state, school district, or other state authorized entity may also have approved anaphylaxis education programs SNs use for UAP training. Schools should be aware of their states' guidelines and be in compliance.

Many organizations (e.g. NASN) offer SNs anaphylaxis UAP training materials for free or a small fee. State SN organizations may have peer-reviewed evidenced-based anaphylaxis training toolkits including related state-specific laws, health codes, regulations, policies, forms, prescriber information and state approved resources. NASN's anaphylaxis toolkit is readily applicable to their recommendation that SNs provide tiered levels of UAP anaphylaxis education which may involve varying timeframes needed for training completion.^{45,88} For example, tier one involves all school staff receiving fundamental anaphylaxis education (e.g. anaphylaxis symptom recognition; need for SE to be stored securely in unlocked and easily accessible locations).⁹⁰ Advanced tiered anaphylaxis education requires more time and targets UAP having frequent contact with students with diagnosed FA and prescribed EDD.^{45,88,90} Training time constraints determined by administrators may impede a SN's ability to provide comprehensive UAP anaphylaxis education.⁴²

In schools without SNs, administrators may seek alternative resources for staff education. Schools must review state guidelines and legislation regarding SE obtainment and staff anaphylaxis training requirements. Local and state health departments, state SN consultants, hospital or university RNs, and local allergists and allergy RNs, may assist in providing evidence-based training. Local licensed prescribers providing SE prescriptions may also offer training resource recommendations.

Key Content to Include in UAP Anaphylaxis Education

In states where SE is legally permitted but not required, there may be less awareness that schools legally can, and should, possess SE. Whether a school has SNs or not, staff should have training on recognition and response to medical emergencies. Table E1 in the online journal repository lists anaphylaxis training program examples. Such programs help SNs, administrators, and prescribers empower learners to recognize and respond to anaphylaxis and be confident in EDD use. Since there are multiple EDD devices available, it is imperative that manufacturers provide device trainers to schools for utilization by school nurses in staff training. Every school should have a medical emergency response plan including a medical emergency response team (MERT). This team of designated responders may respond to medical emergencies, administer available emergency medications or devices as needed, and care for ill or injured individuals until a SN and/or EMS arrives.⁴² School MERT members may be SN selected, trained and

supervised with delegated responsibilities allowable by and in accordance with state law, nurse practice acts and district policies.

BARRIER 7: PRESCRIBER RELATED CHALLENGES

School SE may be cost effective and a beneficial alternative when prescribed EDD is unavailable at school.¹⁶ Nevertheless, SE use is a relatively new concept with frequent logistical barriers to its availability. For example, in 2015, Texas legislature requested school districts adopt policy making SE available for emergency use, effective August 1, 2018.⁸² However, to secure SE, schools need a licensed prescriber to provide a prescription.⁴² Nationwide implementation barriers include finding a willing physician to prescribe SE.¹³ Rules for SE licensed prescribers vary by state.⁹² Unless legally indemnified, prescriber concerns for liability can be a barrier.

IMPROVEMENT STRATEGIES FOR BARRIER 7: EXPAND NUMBER OF SE PRESCRIBERS

Individual physicians usually prescribe EDDs for specific students. It may be helpful for school SE to be prescribed by local physicians such as A/I specialists, school physician consultants, or local health department physicians.⁴² Prescriber options may also include a district's chief medical officer, or senior most medical official in the county or state.⁹² The prescribing physician should consider reviewing the school SE policy. Regarding legal aspects, these physicians will not know which students use their community-prescribed SE and should be ensured immunity from any resulting liability per state law. The aim is to expand efforts to increase the number of physicians willing to prescribe SE. For example, state legislation could require the State Department of Health designate a default prescribing physician if no licensed prescriber is found. To assist licensed prescribers, an American College of Allergy, Asthma and Immunology toolkit offers a template SE prescription form, state law listing, and resources.^{42,93} More awareness and access to such resources may allow prescribers to be more effective in prescribing SE.

BARRIER 8: OBSTACLES ASSOCIATED WITH SCHOOL ADMINISTRATORS & SCHOOL BOARDS

Currently, the majority of states do not have a mandate for school SE.^{12,92,94} However, in states where SE is legally allowed on a voluntary basis, not all districts exercise this option.²¹ A 2019

Ohio SN survey reported 42.6% of responding schools did not have SE.¹³ In schools with no SE programs, 50% of SNs reported that school administrators chose not to participate.¹³ Despite legislative authority, SE policy adoption can be hindered without support from school districts, boards, and administrators.¹¹⁵

Opposition to SE

Historically, not all school leadership entities have supported SE policies and programs. Early SE support came from entities such as food allergy patient advocacy organizations, CDC, NASN, and National School Boards Association.⁹⁵⁻⁹⁸ However, opposition was mounted by the American Association of School Administrators⁹⁹ and some state teacher associations.¹⁰⁰

Bureaucratic Hindrances

Complacency and perceived optionality exist regarding SE programs and policies. Although the strong connection between student health and academic achievement is well documented, some school administrators and boards are concerned about diversion of time and resources from learning.¹⁰¹ While A/I clinical teams and other healthcare professionals may advocate for comprehensive school anaphylaxis management programs, collaborators must understand the structure of public educational governance, school operational practices, and be aware that schools may have multiple student health issues to address and other unfunded legal mandates to uphold. This legal and structural hierarchy must be considered to effect change on a state, district, and local school level. Figure 2 depicts a simplified public education governance structure. Each level may require multiple reviews before policy decisions are adopted which lengthens the decision-making process.

Gaps in Understanding Implications of Lack of School SE

School districts, boards, and administrators may not understand implications of SE inaction, yet are involved in decision-making regarding school health services¹⁰² and accountable for school activities and outcomes.¹⁰³ SNs have a critical role in influencing best practices. However, misperceptions regarding their role, scope of practice, and expertise may influence school boards and administrators to economize by not employing RNs or hindering their practice through autocratic leadership.¹⁰³ SNs must adhere to state nurse practice acts and educational statutes

while navigating administrator management styles and authority.^{102,104} In schools without SNs, resistance by administrators due to training time, resources, and lack of understanding and commitment to best practices may be exacerbated.

Rural and Low Income Schools Disproportionately Lack SE

Schools and districts with fewer students diagnosed with FA and prescribed EDD may perceive SE as a lower priority. Disparities in school anaphylaxis policy, including SE availability, disproportionately affect poor, rural, and minority children.¹⁰⁵ Frequency of FA diagnosis in children from household incomes less than \$25,000 annually has occurred half as often as children from homes with annual income of \$50,000-\$99,000.⁵⁷ Thus likelihood of undiagnosed FA anaphylaxis may be greater in schools with these demographics. Texas schools with higher socioeconomic status had 6 times the number of EDDs, stock or prescribed, compared to schools with lower socioeconomic status.^{23,105} Research demonstrates lack of SE and anaphylaxis training occurs more frequently in rural and low-income schools.¹⁰⁵

IMPROVEMENT STRATEGIES FOR BARRIER 8: ADVOCACY & EDUCATION TO ADMINISTRATORS & SCHOOL BOARDS

Promote Advocacy and Education to Schools on SE Merits

National and state medical and nursing organizations and local healthcare professionals can provide advocacy and education at any level of the public educational governance structure regarding need for SE. Organizational position statements and resolutions can lend strong credibility and support to such efforts. A/I clinical team members could partner with schools on mutually beneficial goals for establishing SE programs particularly in states lacking legally mandated SE.^{21,101} Becoming well-versed in state laws and guidelines and building synergistic relationships with school administration is critical as they are key in defining daily school operations and program implementation.¹⁰⁴ Figure 3 reflects a high functioning collaboration between SNs and administrators. Collaborators can reinforce that SE programs complement versus compete with schools' existing priorities. However, they must plan for contingencies, align with stakeholder allies, and understand avenues previously explored.¹⁰¹ Optimally, administrators, boards and SNs collaboratively develop and approve comprehensive anaphylaxis management school policy.^{42,49} Table III lists NASN recommended policy components.^{42,106}

Support SNs

Data suggests SNs administer the majority of EDD doses in school anaphylactic emergencies and higher rates of SE exist in schools with full-time SNs.^{29,81,107} Schools and school nursing do not exist in isolation but rather reflect communities they serve.¹⁰¹ High performance school nursing and health of the school community is relevant and interfaces with A/I practices, clinical teams, and their patients' optimal health and safety goals.

BARRIER 9: CHALLENGES ASSOCIATED WITH HEALTHCARE PROVIDERS

Student-specific anaphylaxis action plans and medication forms are typically required by schools at the beginning of the academic year with updates as needed. Unfortunately, studies indicate not all students diagnosed at risk of anaphylaxis have an emergency plan at school.^{7,108} This may be due to the healthcare provider not providing an emergency plan, the family not giving the plan to the school, or possibly these forms were not provided due to lack of follow up, lack of a diagnosis, and/or healthcare access disparity. These same factors exacerbate the unavailability of prescribed EDD at school for the allergic individual, all of which support the need for SE. Similarly, lack of student-specific anaphylaxis action plans underscores the need for comprehensive school anaphylaxis management programming.

IMPROVEMENT STRATEGIES FOR BARRIER 9: ENSURE PRESENCE OF SE & PROVISION OF SCHOOL MEDICAL FORMS

A team approach to managing food allergies in schools is recommended by the CDC.⁹⁶ Clinician knowledge regarding evidenced-based anaphylaxis treatment is necessary when educating patients, families, and schools. Physicians should provide education and collaborate with other clinical team members to ensure families and schools have accurate, evidence-based recommendations to keep children safe at school. The healthcare provider should ensure a current student-specific anaphylaxis action plan is completed and school medication forms are given to patients/families annually.¹⁰⁹ Clinician willingness to complete these school forms in a timely manner is critical for student safety. Active involvement of physicians and other clinical team members with schools can include advocacy and education on the importance of having SE for individuals lacking prescribed EDD and those undiagnosed who may experience their first anaphylaxis episode at school. Clinical team members can partner with schools to ensure presence of an accurate and complete generic anaphylaxis action plan to be implemented with SE use. The NASN offers a sample generic protocol for treating anaphylaxis in K-12 students.¹¹⁰ Table E1 in the online journal repository provides website links to the NASN's sample protocol and individualized anaphylaxis action plan templates.

BARRIER 10: FAMILY OR STUDENT DIFFICULTIES

A recent meta-analysis found lack of EDD availability was the most likely pitfall in EDD administration for anaphylaxis, and EDD access barriers included provider and patient issues.¹¹¹ Once FA is diagnosed, familial or student factors such as health disparities^{22,23} and cost obstacles ^{112,113} can be associated with poor availability of prescribed EDDs in schools. Individual patient or family specific barriers include inadequate communication with the school regarding the student's treatment plan, lack of providing an anaphylaxis action plan, inconsistent follow up with the student's health care provider, and healthcare access barriers. These factors may be inherently tied to health literacy which is intimately affected by health care disparities.

IMPROVEMENT STRATEGIES FOR BARRIER 10: ADDRESS HEALTHCARE DISPARITIES & PROVIDE COMPREHENSIVE PATIENT EDUCATION & REFERRALS

Improvement strategies to overcome family and student factors associated with prescribed EDD access barriers must include individual and societal level approaches addressing health care disparities. At clinic level, comprehensive, evidenced-based education of newly diagnosed patients and families is a key approach to assess and address familial barriers to providing prescribed EDDs for school. Open communication with the family may help providers learn about patient hesitation in providing the school with EDDs due to cost or other barriers.¹¹⁴ Overcoming factors such as poor communication with the school and attempts at mitigation of cost obstacles can begin with interventions such as efforts to obtain insurance prior authorization for EDDs if needed. This requires significant time during a provider visit and may include patient education provision from multiple interprofessional clinical team members.

For interventions to be effective, patient and familial health literacy and socio-economic background are confounders that need to be addressed concurrently.¹¹³ Such confounders may require additional referrals, education reinforcement, and other resources. The goal is ensuring patients and families clearly understand and can apply newly acquired FA and anaphylaxis patient education with school provision of prescribed EDDs. However, school SE could significantly mitigate familial and student EDD access barriers by ensuring available epinephrine regardless of cost obstacles, health literacy issues, and/or healthcare access disparities.

CONCLUSION

This workgroup report presents ten barriers to SE and proposed improvement strategies summarized in Table IV. Table V presents workgroup recommendations that A/I professionals, medical and nursing organizations, EDD manufacturers, and states can undertake to improve epinephrine access in schools and support widespread evidenced-based anaphylaxis education to school staff. Ongoing research is required to address gaps in evidence as noted in Table VI. Suggested resources to support school-based anaphylaxis management are listed in Table E1 in the online journal repository.

Mandated SE maximizes school staff ability to treat anaphylaxis on-site while awaiting EMS arrival thereby promoting positive health outcomes. In states lacking a SE mandate that instead legally permit schools on a voluntary basis to have SE means schools can opt-out. Schools legally allowed to avoid having SE thereby create health and safety inequities and risk adverse health outcomes for students and staff compared to states with mandated SE. Allergists, nurses and other A/I professionals can offer authoritative advocacy and education that promotes mandated SE in all schools.

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[Please note: serving as a manuscript reviewer does not necessarily infer that the reviewer agreed with all recommendations and conclusions in this report.]

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- Figure 1: Strengthening the safety chain to support school stock epinephrine. Used with author permission from Abigail Tarr Cooke, MSN-Ed(c), BSN, RN, RDH EDD = epinephrine delivery device

Figure 2: Public education governance structure, simplified (Carr & Modzeleski, 2014).¹⁰¹

Used with author permission.

Figure 3: High-Performance professional interaction model for building administrator and school nurse to optimize student health, well-being, safety, and achievement (Davis & Lynch, 2018).¹⁰³ Used with author permission.

TABLE I: Potential barriers to safe school medication administration.

| POTENTIAL BARRIERS TO SAFE SCHOOL MEDICATION ADMINISTRATION |
|--|
| • Inconsistent medication administration delegation laws, regulations, and policies among and within states. |
| • Inadequate quantity of registered nurses staffing and directing school health programs. |
| • Lack of trained personnel, related policies, and procedures. |

TABLE II: Required SE school training program content in New York⁹¹

The following objectives must be addressed by a school stock epinephrine training program seeking approval in New York State.

- 1. Identify common causes of allergic reactions.
- 2. Identify the signs and symptoms of a mild and severe allergic reaction (anaphylaxis).
- 3. Identify how signs and symptoms of anaphylaxis differ from other medical conditions.
- 4. Demonstrate knowing when epinephrine should be administered and when it should not be administered.
- 5. Demonstrate determining the correct dose of autoinjector, adult or pediatric, to administer.
- 6. Demonstrate the steps for administering epinephrine by an autoinjector.
- 7. Describe the methods for safely storing and handling epinephrine and appropriately disposing of the autoinjector after use.
- 8. Demonstrate the steps for providing for on-going care of the patient until Emergency Medical Services (EMS) arrives.
- 9. Demonstrate knowledge of appropriate documentation and reporting of an event in which an epinephrine auto-injector was administered.
- 10. Understand the New York state laws that allow an individual to possess and use an epinephrine autoinjector in a life-threatening situation.

Table III: NASN recommended key components of a comprehensive anaphylaxis management school policy ^{42,106}

| 1. Individuals covered, including those with first-time anaphylaxis emergencies. | | | |
|--|--|--|--|
| 2. School programs and environments covered. | | | |
| 3. Epinephrine: | | | |
| School prescription and standing order. | | | |
| • Stock locations, usually multiple – with signage. | | | |
| • Ensured secured access. | | | |
| • Stock supply: dosages; number of doses. | | | |
| Procurement: initial and periodic. | | | |
| • Disposal: after use and expiration. | | | |
| Administration and documentation. | | | |
| • Reporting. | | | |
| 4. Individuals authorized to administer. | | | |
| 5. Emergency protocol for administration. | | | |
| 6. Education, training, notification: | | | |
| • When to administer. | | | |
| • Who will be educated: every staff member needs to be trained to know signs and | | | |
| symptoms of anaphylaxis and know how to initiate the emergency protocol. | | | |
| Levels of education to be provided. | | | |
| Parent notification. | | | |
| 7. Communication plan for the district, school, parents, healthcare provider, EMS, and community (part of a school's all-hazard emergency plan). | | | |

Table IV: Summarized barriers to school stock epinephrine and potential improvement strategies.

| BARRIERS TO SCHOOL SE | IMPROVEMENT STRATEGIES |
|---|--|
| Indemnification concerns of prescribers and | • Ensure legal immunity from liability in every |
| school staff. | state. |
| EDD cost | • Utilize free or low-cost school EDD programs from EDD manufacturer and advocate for more similar programs from additional pharmaceutical companies. |
| | Advocate for targeted state funding to school districts. |
| EDD access factors | Advocate for legislation to increase EDD supply at stabilized cost. Expand EDD generic options. Increase awareness of physicians and nurses regarding all EDD options. Work to address EDD shortages. Advocate for one EDD injector pack option. |
| Lack of SNs or inadequate quantity of SNs per student and school needs. | Increase number of SNs in school districts with aim of at least one per school. Clarify accurate SN educational preparedness, |

| Absence of or inconsistent quality of comprehensive evidenced-based anaphylaxis training of school UAP. | scope of practice, and role. Promote understanding of benefits of full-time SNs in every school. Utilize SN staffing models based on individual school and student indicators. Increase recruitment, retainment, and available funding for full-time SNs. Increase awareness of available free or low- cost peer-reviewed training materials. Promote understanding of SN competency as leaders in providing comprehensive anaphylaxis management education to UAP. |
|--|---|
| Obstacles to delegating medication administration to school UAP by SNs. | Promote legal ability for SNs to delegate medication administration to school UAP. Advocate for at least one full-time SN in every school building. Ensure incentives to increase quantity of willing school UAP to be SN trained and supervised for medication administration. |
| Licensed prescriber hesitancy or absence of sufficient quantity of willing licensed prescribers for school SE. | Improve quantity of willing licensed prescribers by utilizing school or district physicians when present and/or local physicians, including those from local health departments. Advocate for state legislation as needed to require state department of health designate a default prescribing physician if no willing local physicians are available. Provide accurate information on immunity from liability per state laws and regulations. Ensure availability of toolkits containing current resources and materials to facilitate licensed prescriber ease in ordering school SE. |
| Legislative challenges | • Improve legislative support for mandated school SE in all states. |
| School administration and school board factors Healthcare provider factors | Provide advocacy and education to schools on merits of SE. Promote support of SNs. Counsel that ample time is needed for provision of effective anaphylaxis education to school personnel. Utilize collaborative team approach to school |
| | anaphylaxis management with family/student, SN, school staff, and student's clinical physicians and nurses. Provision by clinical teams of current and complete student-specific anaphylaxis action |

| | plans and school medication forms to patients/families and schools at start of academic year and as needed. Educate schools on the need for SE for students with no prior diagnosis of anaphylaxis. |
|----------------------------|---|
| Family and student factors | Provision of comprehensive culturally competent anaphylaxis education to students/families by SNs and student's clinical team of physicians and nurses. Delivery of all necessary completed medical and medication forms to schools by family/student. |

Table V: Workgroup recommendations

| ALLERGISTS, ALLERGY NURSES & OTHER HEALTHCARE PROFFESIONALS | | | | |
|---|--|--|--|--|
| • Partner with national and state medical and nursing organizations; public health departments; hospital administrators; local healthcare professionals; and patient advocacy organizations to support, educate and advocate at the local, state and national level for mandated school SE and evidenced-based anaphylaxis management programs in all K-12 schools. | | | | |
| • Educate primary care colleagues on school SE barriers and mutually collaborate and advocate on these issues together on a district, local, state and national level. | | | | |
| • Partner with medical and nursing organizations, hospital administrators, and patient advocacy organizations to provide advocacy to school boards and administrators for state mandates which include targeted funding to hire more full-time SNs with the aim of at least one SN in every school. | | | | |
| • Provide authoritative recommendations and advocacy efforts to promote laws, regulations and district policies in every state addressing need to allow SNs to train and supervise UAPs for medication administration. | | | | |
| NATIONAL & STATE MEDICAL & NURSING ORGANIZATIONS | | | | |
| Pass resolutions and/or position statements supporting a legal mandate for SE in every K-12 school in all states. Provide advocacy to school boards and school administrators for state mandates which include targeted funding to hire more full-time SNs with the aim of one SN in every school. Provide authoritative recommendations and advocacy efforts promoting laws, regulations and district policies in every state addressing need to allow SNs to train and supervise UAPs for medication administration. Advocate for amendments of current state legislation to address requirements for sustainable school-based anaphylaxis management programs, training content standards, and required trainer qualifications. | | | | |
| EPINEPHRINE DELIVERY DEVICE MANUFACTURERS | | | | |
| Offer consumers a packaged one-dose single EDD as an option versus only dual-dose packs. Provide schools with discounted pricing for EDDs. | | | | |
| STATES | | | | |
| • All states should have legislation mandating SE in all K-12 schools that also includes a Good Samaritan clause for indemnification. | | | | |

- Craft, pass, and/or amend state SE legislation to include sustainable targeted funding for districts to hire more SNs and to cover their additional time and workload related to school anaphylaxis management programming.
- Require standardized reporting of SE and EDD administration and related factors from all schools by using NASN's Report Form for Epinephrine Administration with subsequent data collected by the state with researcher accessibility.
- Develop comprehensive state-wide data reporting, collection and analysis of factors related to school anaphylaxis management, health outcomes, and use of EDD and SE.

Table VI: Future research recommendations

| _ | |
|---|---|
| | FUTURE RESEARCH RECOMMENDATIONS |
| • | Study collected data regarding school anaphylaxis management and epinephrine administration between states with SE mandates versus states that voluntarily allow SE. |
| • | Compare student health outcomes from anaphylaxis between schools in states with mandated SE versus those in states that legally allow SE on a voluntary basis. |
| • | Explore school reporting and state data collection of school EDD and SE administration and whether this data is publicly available. |
| • | Investigate implementation of standardized school reporting of EDD and SE administration and related factors through use of NASN's Report Form for Epinephrine Administration with subsequent data collected by state. |
| • | Study the role of indemnification in school decision-making regarding SE and provision of SN-led anaphylaxis management staff training. |
| • | Study evaluation data on effectiveness and health outcomes associated with elements of school- based anaphylaxis management training. |
| • | Ongoing investigation of school SE benefits related to reduction in healthcare disparities, cost to families, other social determinants of health issues, and environmental impact, while increasing ability to treat unanticipated anaphylaxis in students with no known history of allergy and those lacking prescribed EDDs. |

TABLE FOR JOURNAL ONLINE REPOSITORY

 Table E1: Selected resources

| RESOURCE | WEBSITE |
|--|---|
| Anaphylaxis Emergency Action Plans | |
| American Academy of Allergy, Asthma & Immunology | https://www.aaaai.org/aaaai/media/mediali brary/pdf%20documents/libraries/anaphyla xis-emergency-action-plan.pdf |
| American Academy of Pediatrics | https://downloads.aap.org/HC/AAP_Allerg y_and_Anaphylaxis_Emergency_Plan.pdf |
| Food Allergy Research & Education | https://www.foodallergy.org/living-food- allergies/food-allergy-essentials/food- allergy-anaphylaxis-emergency-care-plan |
| National Association of School Nurses: Sample Protocol for Treatment of Symptoms of Anaphylaxis | https://higherlogicdownload.s3.amazonaws .com/NASN/3870c72d-fff9-4ed7-833f- 215de278d256/UploadedImages/PDFs/Get %20Trained/GetTrained_Epi_Protocol_20 15.pdf |
| Anaphylaxis School-Based Education Programs | |
| Allergy Home | https://www.allergyhome.org/schools |
| American Red Cross | https://rdcrss.org/3pSHUnd |
| Code Ana | https://codeana.org |
| Food Allergy Research & Education | https://www.foodallergy.org/our- initiatives/education-programs- training/fare-training/keeping-students- safe-and-included |
| National Association of School Nurses Anaphylaxis Toolkit | https://www.nasn.org/nasn- resources/practice-topics/allergies- anaphylaxis |
| Safe Schools | https://www.safeschools.com |
| State School Nurse Organizations & State Departments of Education | State of Colorado example: https://www.cde.state.co.us/healthandwelln ess/snh_healthissues |
| Epinephrine Delivery Devices | |
| Auvi-Q® | https://www.auvi-q.com |
| Adrenaclick | https://www.adrenaclick.com/ |
| Adrenaclick Generic: Impax Epinephrine Injection, USP | https://epinephrineautoinject.com/ |
| EpiPen® & Generic: Epinephrine Injection, USP | https://www.epipen.com |
| Symjepi | https://www.symjepi.com |
| Teva Generic Epinephrine Injection, USP | https://www.tevaepinephrine.com |
| State Laws on School Epinephrine | |
| American College of Allergy, Asthma & Immunology | https://college.acaai.org/sites/default/files/ ACAAI_EpinephrineToolkit-2015.pdf |
| Food Allergy Research & Education | https://www.foodallergy.org/our- initiatives/advocacy/food-allergy- issues/school-access-epinephrine |

[Please note: this resource list is not exhaustive and is intended for informational purposes only. The authors do not necessarily endorse any resource or product listed.]



The Public Education Gevernance Structure, Simplified 🤝



"Note: Each state's governments structure is unique: lines of authority among policymature very.

