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Epinephrine Administration Recommendations

2013

Authorizing legislation: Engrossed Senate Bill 5104 (http://apps.leg.wa.gov/billinfo/summary.aspx?bill=5104&year=2013)

Student Support
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Executive Summary

About one out of every 13 children has a food allergy according to the American Academy of Allergy, Asthma and Immunology.

Of that group, more than one in three (about 27,000 children in Washington state) has a history of severe reactions to allergies. The reaction, known as anaphylaxis, can also be caused by insect stings or allergies to other drugs. And it can occur anywhere: at home, on a school trip, on the playground, in the classroom.

Because anaphylaxis can be fatal, a quick response is essential. The most efficient way for that to happen is through the use of epinephrine (also known as adrenaline). The epinephrine is injected into the patient using an "epinephrine autoinjector."

The safety of all our public schools students is of utmost importance. Our state Legislature, recognizing this, passed a law in 2013 that allows school districts to have standing orders and a prescription, written by a licensed health-care provider, for the emergency use of epinephrine.

The law also requires that the Office of Superintendent of Public Instruction recommend whether non-nursing staff should be trained to administer autoinjectors if a nurse is not available.

In short: State Superintendent Randy Dorn believes schools ***should*** designate other trained school employees to administer epinephrine autoinjectors to students demonstrating anaphylaxis symptoms when a school nurse is not available.

Superintendent Dorn recognizes the complexity of his opinion. An allergic reaction can happen anytime, anyplace: a playground, a school bus, a field trip. To safely and effectively implement this law, all of those possibilities need to be addressed. Policies and procedures must be developed – and costs identified – that answer the following questions:

- Which staff, and how many staff, are to be designated?
- How and when will routine and ongoing staff training occur?
- How will the autoinjectors be obtained, stored, managed, used and disposed of?
- What are the ratios for the number of epinephrine autoinjectors per group of students?
- What are the total costs, and, if implemented, how will it be funded?

Introduction

The 2013 Legislature passed Engrossed Senate Bill 5104, which allows school districts to maintain standing orders and a prescription, written by a licensed health-care provider, for the administration of epinephrine.

This new authority allows for a supply of epinephrine autoinjectors for emergency use, by a nurse, in the event of a student presenting with an anaphylactic reaction, who already has a prescription on file or who is undiagnosed. The effect of the new law is to allow schools to keep a supply of epinephrine autoinjectors on hand for undiagnosed students (which could be administered only by a school nurse).

Currently, a school nurse or a designated trained school personnel can administer epinephrine autoinjectors *for a student with a prescription on file*. The new law expands a school's ability to help save the life of an *undiagnosed* student with an anaphylactic reaction.

Definition of Anaphylaxis and Autoinjectors

Anaphylaxis – a life-threatening allergic reaction that may involve systems of the entire body – creates a medical emergency that requires immediate medical treatment and follow-up care by a licensed health-care provider. Death can occur if the immediate recognition of the symptoms, as well as the response to the symptoms, is delayed.

Administration of epinephrine, also known as adrenaline, is the treatment of choice for acute anaphylaxis. Epinephrine works by relaxing airway muscles and tightening blood vessels to maintain blood pressure. Sometimes a second dose is required even before an individual is transported to a medical facility for further emergency care.

In a life-threatening situation there are no absolute contraindications to the use of epinephrine. An "absolute contraindication" means a reason for not using a particular medical intervention because it poses a grave risk to the individual being treated.

During anaphylaxis, temporary assistance is possible through the use of an epinephrine autoinjector, a spring-loaded syringe used to deliver a single measured dose of the drug. Trade names for epinephrine autoinjectors include EpiPen, Twinject, Adrenaclick, Anapen, Jext, Allerject, and Auvi-Q. Epinephrine autoinjectors are most frequently used for the treatment of acute allergic reactions to avoid or treat the onset of anaphylactic shock.

Incidence of Anaphylaxis

Data on the incidence and prevalence of anaphylaxis is sparse, imprecise and contradictory, related to both the diagnosis and severity. A multinational study noted an increasing incidence of allergies and anaphylaxis, as well as epinephrine prescription rates.

Many studies continue to note the need to improve training and education in order to prevent deaths because many fatalities are due to a lack of prompt administration of epinephrine.

> "(I)t is noteworthy that in 28 percent of cases (deaths caused by anaphylaxis), death results from cerebral anoxia following collapse within a few hours to three days and not treated by adrenaline in a timely fashion**.** This underlines how much information and training is necessary for emergency staff, health professionals and the general public with regard to first-line treatment of anaphylaxis**."**
>
> *Allergy* ***http://onlinelibrary.wiley.com/doi/10.1111/j.1398-9995.2005.00785.x/full***

Washington State Department of Health (DOH) data for death rates among children from birth to 18 from 1999–2012 indicate one known death: a nine-year-old Caucasian boy from Spokane who died in 2001 and whose underlying cause of death was anaphylactic shock due to adverse food reaction**.** The boy had a known food allergy to peanuts; according to current policies, he would be required to have a **health plan in place.**

Potential benefits

Epinephrine autoinjectors – when properly sourced, stored, and administered – can provide a life-saving intervention until Emergency Medical Services arrive.

The new law also provides general awareness among school staff of the potential for students to have anaphylactic reaction at school or during school-sponsored activities.

Potential challenges

Improper administration

National data sources reveal deaths occur due to a hesitation to administer epinephrine in a timely manner, or because of ineffective administration of the medication**.** This hesitation may be, in part, due to misunderstanding of symptoms or seriousness and lack of sufficient education and training**.** Medscape studies noted that even among Emergency Medical Technicians (EMT), medication was not delivered correctly, and more than half of the fatalities occurred away from home. These sources raise a concern about the ability of staff who have limited medical training to correctly identify and react appropriately to anaphylaxis.

Epinephrine side effects

If the medication is delivered in an acute anaphylaxis episode there are no contraindications (no instances when it should not be given in an emergency). However, caution is noted for individuals who have certain heart conditions. Heart arrhythmias, including fatal ventricular arrhythmias have been reported. Individuals with certain medical conditions who take medications for allergies, depression, hypertension and diabetes may also be at greater risk for adverse reactions. There is little data available about the risks in treating undiagnosed children with a history of heart or mental health disease.

The cost of epinephrine autoinjectors

Epinephrine autoinjectors vary in price between $110 to $140 for one autoinjector, and $220 to $300 for a twin pack. The expiration rate on autoinjectors is approximately 12 to 18 months.

Discount and free autoinjector programs

Bioridge Pharma offers the EpiPen4Schools program created to allow qualified schools, based on Bioridge's criteria, to obtain EpiPen autoinjectors at no cost. Each qualified school can receive up to four free EpiPen or EpiPen Jr. autoinjectors in the form of two EpiPen 2-Pak® cartons, two EpiPen Jr. 2-Pak® cartons, or one 2-Pak of each kind. Each EpiPen 2-Pak contains two single autoinjectors, instructions for use and a training device with no drug product or needle, to help those who administer the autoinjector with becoming familiar with the administration technique.

In addition to the EpiPen4Schools program, Mylan Specialty offers a discount program through which schools can purchase, upon qualification, EpiPen 2-Pak cartons (0.3 mg) and EpiPen Jr. 2-Pak cartons (0.15 mg) at a discounted price of $112.10 each. A school/school district will only receive EpiPen autoinjectors in accordance with all applicable laws. The school/school district must submit a valid prescription for EpiPen autoinjector(s) in order to qualify for this program. Mylan Specialty reserves the right to modify or discontinue the EpiPen4Schools program and school discount programs at any time and without prior notice.

Storage of autoinjectors

The medication must be stored in a proper environment at 77 degrees Farenheit. The medication is specifically not to be stored in areas of extreme cold, heat, or light (and therefore should not be refrigerated or stored in a car glove box). This poses difficulties storing the medication at school for an extended period over weekends, breaks, or summers when schools traditionally are not heated or cooled.

ESB 5104, Section 2 (3)(c), states that epinephrine autoinjectors may be used on school property, including the school building, playground, and school bus, as well as during field trips or sanctioned excursions away from school property. If a district provides for every potential risk, epinephrine would be required in all locations. In that event, if the district contracts for its transportation services, the contract may need to be revised if the current contract prohibits bus drivers from administering the autoinjectors.

Number of autoinjectors

A question that emerged in public testimony at the OSPI forums was, "What is the correct number of devices per number of students or per school?" To answer the question, OSPI contacted both the National Conference of State Legislatures and the Education Commission of the States. Neither organization has determined a baseline device-to-student ratio in schools.

Besides not having a standard baseline, determining the proper ratio is complicated by other factors, including dosage variations by student weight and where the device or devices will be stored. Schools will most likely need several devices to accommodate those factors.

Standing Orders and Protocols

Standing orders are directions from a licensed health-care provider about how to administer prescriptions that are not tied to a particular person but would be available to a general population; in this case, students. Standing orders exist rarely in medical practice, and there is a lack of precedence in a non-medical setting such as a school. Therefore, we cannot be sure that doctors will be willing to write standing orders for epinephrine autoinjectors in schools.

There is currently no written guidance for unlicensed staff to carry out and follow standing orders. Therefore, each school district would have the responsibility of finding a health-care provider to prescribe and write the standing orders and protocols for unlicensed staff to administer the epinephrine as well as determining the number of autoinjectors required for each building. In addition, it is uncertain whether a non-licensed staff person can legally interpret a standing order from a licensed health-care provider with regard to administering the medication.

Overall costs of the new law

The new law, ESB 5104, is permissive, not compulsory. OSPI does not know how many districts will participate. Any estimate of costs is further complicated by the following scenarios, each of which must be factored:

- The ratios for the number of epinephrine autoinjectors per group of students;
- Which staff, and how many staff, are to be designated;
- How and when routine and ongoing staff training will occur; and
- How the autoinjectors will be obtained, stored, managed, used and disposed of.

For these reasons, OSPI is not able to provide an overall cost estimate at this time.

Recommendations from the public

OSPI held two public forums during the summer and fall of 2013. Below are recommendations for successful implementation of the new law made by the public at the forums.

1. Request official guidance from the Washington State Nursing Commission, the Washington State Medical Association and the Washington State Pharmacy Commission regarding standing orders in the school setting for registered nurses and unlicensed staff.

2. Require annual training and practice drills for school personnel on the administration of epinephrine. School staff would be required to have a minimum of First Aid and CPR training and perhaps an additional certification in medication administration to meet the minimal student safety requirements. School districts will expect guidance from OSPI on a training program or minimum requirements.

3. Clarify policy to determine who is able to provide training to unlicensed staff in the administration of epinephrine to undiagnosed students.

4. Identify community trainers capable of providing training to unlicensed staff on the emergency administration of epinephrine to undiagnosed students.

5. Clarify the expectation to provide for all students in any possible scenario at school, on a school bus, on field trips, before or after school or school related activity.

6. Create a category of school first responders with specific training criteria (CPR, First Aid and possibly Certified Medical Assistant and Medication Administration Certification). The first responders could be hired to work in school districts as health-room assistants in lieu of para-educators or secretaries. A licensed health-care provider would be responsible to train and delegate the care to the first responders. School districts would be financially responsible for the hiring and employment. These employees would be on campus and it would be up to each district to determine if this would extend to transportation and before and after school activities.

7. Hire athletic trainers who are health-care professionals and who work in collaboration with physicians. This would certainly offer another avenue to provide for students during sporting events. They are not school district employees and would require a contractual agreement.

8. Provide financial support to school districts to hire a full time school nurse for every school. This would eliminate the need to designate unlicensed staff to administer epinephrine on school campus. Washington has a very low number of school nurses who serve a large caseload of students in comparison to other states and ranks at 43rd, at more than 1:2000 as calculated by the National Association of School Nurses in 2011.

9. Collect additional data, including the incidence of use with specific information such as the known allergen, who administered the epinephrine, how quickly medics responded and the outcome for the student.

Recommendations from OSPI and next steps

Student safety is paramount to the Legislature, OSPI, and the state's 295 school districts. ESB 5104 was clearly written to provide for increased student safety.

OSPI has concluded that schools *should* designate other trained school employees to administer epinephrine autoinjectors to undiagnosed students demonstrating the symptoms of anaphylaxis when a school nurse is not in the vicinity.

But the law must be implemented safely. For that to happen, OSPI would require additional guidance from the Legislature. If the Legislature adopts policy that directs and funds implementation, the following steps would be necessary:

- **Guidelines and policies.** The complexity and variety of issues demand additional clarification for districts. OSPI would develop guidelines and recommended policies and or procedures for safe implementation of the law.

- **Standing orders.** OSPI Health Services would need to seek clarification from the Nursing Care Quality Assurance Commission and the Pharmacy Commission regarding standing orders in the school setting for registered nurses and unlicensed staff. We also would explore adopting "standing orders" language from the state of Illinois.

- **Storage.** OSPI would need to share with schools a list of storage-related materials, such as wall-holders for epinephrine autoinjectors, fanny packs for bus drivers, etc.

  OSPI Facilities office would need to inform schools of specific heating and maintenance protocols to ensure that the storage of the devices meet the temperature and light exposure requirements of the new law.

- **School buses.** OSPI Pupil Transportation would need to advise district transportation staff on the proper storage protocols for these medical devices in both the transportation facility or school and the school bus, including protocols about driver behavior related to storage, transportation, control, use, and disposal.

  OSPI Pupil Transportation, in conjunction with regional transportation coordinators, would explore the language of school district and subcontractor employment contracts, to assure that drivers are allowed to carry out the goals of the law. Special attention should be paid to right-of-refusal language and identification of additional staff who can be available to carry out the law if a particular driver refuses the responsibility, before May 2014, to meet the spring hiring deadlines.

  OSPI Pupil Transportation would work with the Washington State Patrol to insure the inspection requirements for school transportation vehicles accommodate the presence of epinephrine autoinjectors.

  OSPI Fiscal Office would work with risk managers to assure that the indemnification under the law is sufficient to reduce school district liability. Special attention shall be given to the

National Association of State Boards of Education Anaphylaxis & Epinephrine Policy Discussion Guide.

- **Numbers of devices.** Because no national standards exist, each school district would have to determine the number of autoinjectors required for the buildings in that district.

- **Cost assumptions.** OSPI does not have a current cost estimate from school districts (the new law is permissive, so any estimate is indeterminate) on the comprehensive costs of the bill. A number of scenarios will need to be factored, such as:
  - Which staff, and how many staff, are to be designated;
  - How and when routine and ongoing staff training will occur;
  - How the autoinjectors will be obtained, stored, managed, used and disposed of; and
  - What are the ratios for the number of epinephrine autoinjectors per group of students.

- **Delegation vs. designation.** OSPI Health Services has consulted with the OSPI Special Assistant for Legal Affairs, who has sought clarification from the Office of Attorney General to clarify the language in the bill regarding "designated trained school personnel" and whether this puts the nurse in the position to be delegating the administration of epinephrine to both students with known diagnosed anaphylaxis and students with unknown anaphylaxis.

- **Routine and ongoing school staff training.** OSPI Health Services would recommend school staff anaphylaxis and epinephrine training after reviewing school staff training requirements noted in OSPI Guidelines for Care of Students with Anaphylaxis (2009) and compare with current national first aid trainings and recommendations from Food Allergy Research and Education and the American Academy of Allergy Asthma and Immunology.

The above recommendations are designed to inform and speed safe implementation of the OSPI recommended policy. If the Legislature implements the recommendations, OSPI would prepare protocols and policies.

Appendix A

Several current statutes address the treatment and use of epinephrine in schools:

Current Anaphylaxis Statutes

Children with life-threatening conditions (RCW 28A.210.320)

Requires students to have an Emergency Care Plan, medication treatment orders, medication and training in place before the students first day of attendance.

Students with asthma (RCW 28A.210.370)

Requires a uniform policy for all school districts providing the in-service training for school staff on symptoms, treatment and monitoring of students. This law also provides that students may self-administer and self-carry medications for asthma and anaphylaxis and an entitlement to have back up medication, provided by the guardian.

Anaphylaxis (RCW 28A.210.380)

Guidelines were developed for schools to prevent anaphylaxis and deal with medical emergencies resulting from it. The policy guidelines were developed with input from pediatricians, school nurses, and other health-care providers, parents of children with life-threatening allergies, school administrators, teachers, and food service directors. These include strategies such as staff training, care and communication plans, and avoidance strategies.

Epinephrine Autoinjectors in schools (ESB 5104, 2013)

School districts and nonpublic schools are allowed to maintain a supply of epinephrine autoinjectors at schools. Licensed health professionals with prescription authority may prescribe epinephrine autoinjectors in the name of the school district or school that can be maintained for use at the school.

Epinephrine prescriptions must have a standing order for the administration of school-supplied, undesignated epinephrine autoinjectors for potentially life-threatening allergic reactions. Epinephrine autoinjectors may be donated to schools, but must be accompanied by a prescription. If a student does have a prescription for epinephrine, the school nurse or designated trained school personnel may administer an epinephrine autoinjector maintained by the school to respond to an anaphylactic reaction under a standing protocol.

Epinephrine autoinjectors may be used on school property, including the school bus, and during sanctioned trips away from school property. The school nurse or designated trained school personnel may carry epinephrine autoinjectors on these trips. If a student is harmed due to the administration of epinephrine: licensed health professionals and pharmacists may not be liable for the injury unless they issued the prescription with a conscious disregard for safety; and school employees, schools, school districts, the governing board, and the chief administrator are not liable

if the school employee administering the epinephrine did so in substantial compliance with a prescription and policies of the district.

School employees, except licensed nurses, who do not agree in writing to using epinephrine autoinjectors as part of their job description, may file with the school district a written letter of refusal to use epinephrine autoinjectors. This letter may not serve as grounds for actions negatively affecting the employee's contract status. The Office of Superintendent of Public Instruction must make a recommendation to the Legislature by December 1, 2013, regarding whether to designate other trained school employees to administer epinephrine autoinjectors to students without prescriptions when a school nurse is not in the vicinity.

Appendix B

Data from Other States

The National Conference of State Legislators Legisbrief on food allergies in schools in October 2011, noted seven states—California, Florida, Kansas, Missouri, Utah, Illinois and Georgia—authorized schools to maintain a general supply of epinephrine to use in an emergency involving a student not known to have allergies. These states also grant immunity to school districts, schools and school officials as long as there is no negligence.

During 2012–2013 legislative sessions, at least 15 additional states have enacted legislation that permits school personnel, often subject to training requirements or a standing order from a prescriber to the school, to administer epinephrine to students without a prescription if there is a good-faith belief that a student is experiencing an anaphylactic reaction. States enacting such legislation in 2012–2013 include Arizona, Arkansas, Arizona, Kentucky, Louisiana, Minnesota, Montana, Nevada, Oklahoma, Oregon, South Carolina, Tennessee, Vermont, Virginia, Washington and West Virginia.

Notable items from the National Conference of State Legislators Legisbrief on food allergies in October 2011:

- Most state legislatures have enacted some type of law related to anaphylactic reactions in children.
- Forty-seven states (including Washington) and the District of Columbia allow students to carry and self-administer their own prescribed epinephrine.
- All 50 states allow trained school nurses to administer epinephrine.
- Fifteen states (including Washington) authorize teachers, principals, or other trained school personnel delegated by a school nurse to administer epinephrine. It is unclear if that authority extends to all districts that contract certain services, such as bus drivers.
- Six states grant wide discretion to trained school personnel to administer epinephrine to any student that the school nurse or trained employee believes is having a life-threatening anaphylactic reaction.
- Seven states (including Washington) authorize schools to maintain a general supply of epinephrine, to use in an emergency involving a student unknown to have food allergies. These states also grant immunity to school districts, schools and school officials as long as there is no negligence.
- Almost all states also provide immunity from lawsuits for police officers, fire fighters, schools, school districts and employees.

Some state legislatures have addressed treatment for anaphylactic reactions in before-and after-school programs, day camps and summer camps as well**.** This year, Arkansas, Florida, Maine, New York and South Carolina passed legislation allowing trained camp employees to administer epinephrine. The New York law authorizes camps to purchase their own supplies of the drug.

Connecticut lawmakers passed a bill requiring trained camp employees or volunteers to supervise children with medically diagnosed allergic conditions at the request of a parent or guardian.

Since anyone observing someone suffering an anaphylactic reaction should call 9-1-1, New York, Kentucky and Washington lawmakers have passed bills requiring ambulances to carry the drug.

Connecticut and Washington now require all emergency medical technicians be trained specifically on how to respond to anaphylactic shock. Usually local officials decide the appropriate level of training and what medicines ambulances may carry, including Washington State.

We cannot necessarily compare or duplicate the practice of another state as each state has varying degrees and levels of nursing practices and medical practices by law. Additionally, some state's schools have medical directors (not a practice in Washington) or are a part of their Department of Health and have varying levels of student-to-nurse ratios.

Alaska, Arkansas, Connecticut, Illinois, Massachusetts, New Jersey, New York, North Carolina, Rhode Island, and Virginia and West Virginia allow only school nurses to administer epinephrine and have standing orders in schools, but most of these states have a higher student-to-nurse ratio and several have a nurse in every building. Incidentally, Massachusetts has one of the highest rates of prescribed epinephrine.

Alaska and Rhode Island allow nurses to train unlicensed staff to administer epinephrine only to students with a specific diagnosis and order to provide this care (similar to Washington). Connecticut has specific language in the statute preventing delegation of this task to unlicensed personnel.

Other states allow unlicensed staff to administer epinephrine with additional training and certification standards which vary widely.

References

Nursing Laws

RCW 18.79 Nursing Care; this law describes nursing practice including the administration of medications, treatments and other care provided for compensation.

RCW 18.79. 260 Registered nurse — Activities allowed — Delegation of tasks

(3) A registered nurse may delegate tasks of nursing care to other individuals where the registered nurse determines that it is in the best interest of the patient.

(a) The delegating nurse shall:

(i) Determine the competency of the individual to perform the tasks;

(ii) Evaluate the appropriateness of the delegation;

(iii) Supervise the actions of the person performing the delegated task; and

(iv) Delegate only those tasks that are within the registered nurse's scope

RCW28A.210.260-270 Public and private schools — Administration of medication — Conditions; Allows nurses to delegate, with training and supervision, the administration of oral medication, topical medication, eye drops, or ear drops to any student by unlicensed school staff under specific conditions. RCW 18.79.240 (1)(b) allows for the administration of injectable medication in the case of an emergency. The nurse may not delegate nursing judgment and each nurse must use the decision tree to determine if a particular task is within the nursing scope of practice.

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