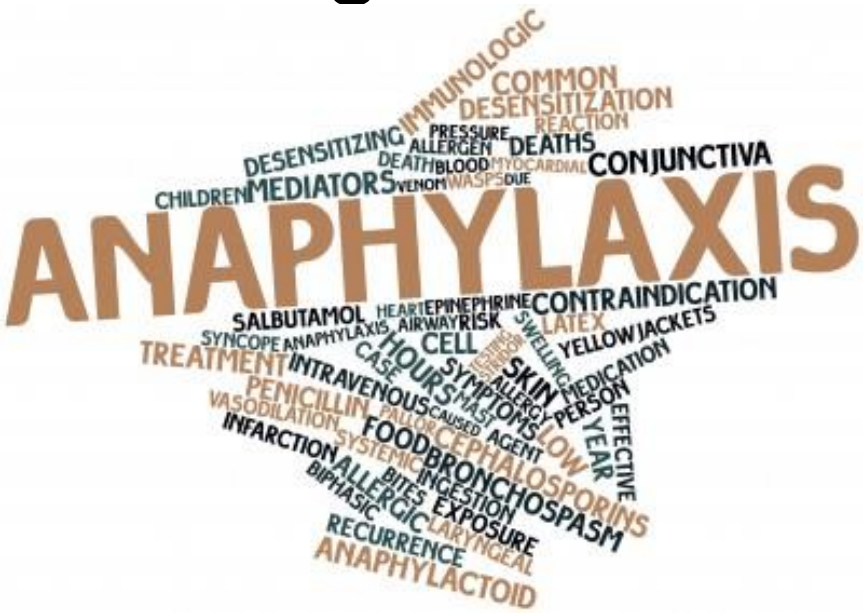
Where are we now? Epinephrine and Outdoor Programming 2014

Frances Turner Mock, Esq.
frances@francesmock.com
919-382-9090

Dr. Seth Hawkins, MD
hawk@aya.yale.edu
828-368-6221

Introduction & Disclaimer

- The topic and the issue
- A risk management approach to understanding the issue



What are you doing?

What we will cover:

- Anaphylaxis diagnosis (“new” standard)
- Treatment options
- Potential reasons for different incidence
- Current trends in US law
- Legal issues
- Practical advice and resources

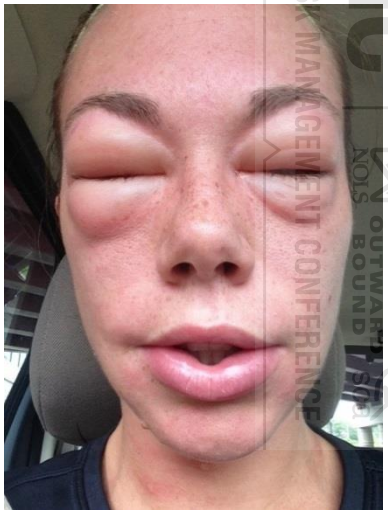
Statistics: Food Allergies

- Per the Food Allergy Research and Education
  - 15 million Americans have food allergies
  - Affects 1 in 13 children (under 18 years old)
  - Teenagers and young adults with food allergies are at the highest risk of fatal food-induced anaphylaxis.
- Per the CDC
  - food allergies have increased 50% between 1997 and 2011, and currently affect 4-6% of children

Statistics: Animal Allergies

- >50 fatal sting reactions annually in USA
  - ½ had no history of previous sting reaction
  - Hymenoptera (bees, wasps, fire ants) are most lethal animals to humans
- 3% of insect stings result in systemic allergic reaction
- Insect sting anaphylaxis rate 0.3-3% of population

The “new” diagnosis



Anaphylaxis

Anaphylaxis Definitions

1. Acute onset of an illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (generalized hives, pruritus or flushing, swollen lips-tongue-uvula)

AND AT LEAST ONE OF THE FOLLOWING

a. Respiratory compromise (dyspnea, wheeze-bronchospasm, stridor, hypoxemia)

b. Reduced Blood Pressure (BP) or associated symptoms of end-organ dysfunction (hypotonia or collapse, syncope, incontinence)

2. Two or more of the following that occur rapidly after exposure *to a likely allergen for that patient* (minutes to several hours):

a. Involvement of the skin-mucosal tissue (generalized hives, itch-flush, swollen lips-tongue-uvula)

b. Respiratory compromise (dyspnea, wheeze-bronchospasm, stridor, reduced PEF, hypoxemia)

c. Reduced BP or associated symptoms (hypotonia or collapse, syncope, incontinence)

d. Persistent gastrointestinal symptoms (crampy abdominal pain, vomiting)

3. Reduced BP after exposure to *known allergen for that patient* (minutes to several hours):

a. Infants and children: low systolic BP (age specific) or greater than 30% decrease in systolic BP*

b. Adults: systolic BP of less than 90 mm Hg or greater than 30% decrease from that person's baseline

*Low systolic blood pressure for children is defined as less than 70 mm Hg from 1 month to 1 year, less than (70 mm Hg [2 age]) from 1 to 10 years, and less than 90 mm Hg from 11 to 17 years.

3 Different Paths to Anaphylaxis Diagnosis After Exposure

- Hypotension (low blood pressure)
- Respiratory compromise
  - Wheezing or stridor
- Two or more organ system involvement
  - Rash/itching
  - Mouth or facial swelling
  - Abdominal cramping/vomiting

CDC Guidelines for Managing Food Allergies in Schools

Epinephrine should be administered “at the first signs of an allergic reaction, especially if the child’s breathing changes.”

This early administration “may result in administering epinephrine [when] the allergic reaction does not progress to life-threatening anaphylaxis. However…[t]he risk of death from untreated anaphylaxis outweighs the risk of adverse side effects from using epinephrine in these cases.”

Treatment options

- Syringe vs. auto-injectors
- Issues with administration

Rates of incidence

What's going on?

What some programs are doing

- Wilderness medicine training program
  - Teaches students how to diagnose and treat anaphylaxis
- Medical advisor:
  - Advises on proper protocols for dispensing meds
  - Writes prescription
  - Advises staff in the field during incident
- Pharmacy—fills script
- Organization—put script in first aid kit, has policy for use
- Instructor—diagnoses condition and administers drug
- Participant—informed through organization's literature? Gives consent?

Different Approaches

- Approach depends on:
  - program activities/environments
    - Front country vs. backcountry
  - Level of staff training
  - History of incidents at org
  - Laws where you operate
  - Philosophical view

What's wrong with this picture?

Historically, the law (in most states)

- For Doctors
  - Can't prescribe to an organization
  - Can't prescribe for an individual she has not seen
- For Pharmacies
  - Can't dispense a script to organization
- For Instructors
  - Can't practice medicine
  - Can't carry or administer prescription drugs
- For Organizations
  - Can't have a policy requiring staff to violate the law

New federal law

- School Access to Emergency Epinephrine Law
  - Became effective Nov. 2013
  - Rewards states for **requiring** schools to train staff to administer epi and have epi available for use
- Did it work?

State laws

- According to FARE, all the other states (except two) have laws allowing teachers to be trained and allowing schools to have epi available (legislation is pending in 4 states)
- Mostly applicable to schools.
- Check FARE website for a map and listing of each state's law.
  - http://www.foodallergy.org/advocacy/epinephrine/map

Other state laws

- Some have limited definition (camps, i.e. New York; higher ed in New Jersey)
- Some have a broader application--if have responsibility for others (i.e. Utah 26-41-101 et. seq., California, Arkansas, Florida, Maryland,)
- Some allow any lay person to be trained to administer epi
  - Alaska (AS 17.22.010)
  - North Carolina (10A NCAC 13P .0509)
  - North Dakota (23-01-05.2)

Alaska's model statute (AS.17.22.010)

- Covers:
  - Auto injectors and ampules
  - Can use for anaphylaxis or severe asthma
  - Allows for getting a rx and purchasing epi
  - Outlines what training is required
  - Includes immunity from liability

Current state of the law

- Doctor's ability to prescribe
- Pharmacies ability to fill a script to an organization or individual who is not the end user

Is this practicing medicine?

- Considered first aid by:
  - American Red Cross (offers class)
  - American Medical Association
  - Amer Acad of Allergy Asthma and Immunology
  - American Academy of Pediatrics (implied)
  - Wilderness Medical Society
    - Scope of practice, WMS panel recs
  - CDC advocates use by lay people
- Some states explicitly say not practicing med or that it is first aid

The Good News

- Doctors have lower threshold for defining anaphylaxis
- CDC recommends giving at first sign of reaction
- Generally regarded as basic first aid
- Most states (44/50) have laws that allow (or require) staff at school to be trained
- More states are allowing others to be trained
- Epi-Pens are becoming more mainstream—advertising on national TV

The Bad News

- Likely is still illegal for many to administer it.
- Most states don't cover our industry.
- NY and Missouri explicitly prohibit it unless it is expressly authorized.
- Some states even prohibit EMTs from using auto-injectors.
- Real disconnect in the law. Thus,
- **You must know the law in the states where you operate.**

Potential legal issues

- Can be negligence per se
  - If you violate a law intended to protect one from harm that happened
- Insurance may have exclusion for illegal acts
- Affects medical advisor, pharmacy, organization, and staff
- May be implications on professional licenses

Giorgi v. City of Sacramento
Sacramento Co. Superior Court
2104-00162222, filed 4/18/14

- 13 year old died at camp after ingesting Rice Krispies made with peanut butter
- Only prior evidence of allergy was mild reaction at age 3
- Father, a physician, administered 2 doses of child's own epi
- Camp had epi in locked cabinet, could not find key. Father broke cabinet and administered third dose but it was delayed.

Allegations:

- Camp had been told about peanut allergy.
- Failed to identify food with nuts when knew had allergy.
- Was foreseeable that might have anaphylaxis and need for emergency medication.
- Negligent for failing to have epinephrine readily available.

NOW WHAT?

OPTIONS AND ACTIONS

You must know the law in the states where you operate.

Then, consider your options.

Carry where legally authorized only

- Complete research in every state where operate
- Complete staff training, if necessary, and obtain certification or other evidence of authorization
- Varying policies within org?
  - Geographically
  - Confusing for staff
- Adjust policy/inform staff
- Inform participants of risks/remote operations and/or have bring own?
  - Policy if does not bring own?
  - Logistically feasible?

Have students bring own supply

- Is this a requirement?
- What to do if student does not or chooses not to bring?
- Mandate type, dosage, etc.?
- What is policy for administering to others?
- Disclosure to clients?

Have medications available/teach administration of meds regardless of law

- Be certified in state when possible
- Understand penalties and defenses
- Inform staff
- Inform participants/get consent?
- Inform wilderness medicine trainers and students
- Confer with consulting physicians
- Contact dr. before administering?
- Limit to non-urban settings?

Change the law

- Position statements from medical entities
- Include wilderness organizations
- State vs. federal law
- State law vs. agency regulations
- Work with land managers (NPS, Forest Service, etc.)?

What to do in any event

- Learn the law in the state where you offer programs
  - Confer with a knowledgeable attorney
- Confer with your medical advisor
- Confer with your Board
- Decide what your policy will be
- Advise staff of your policies and the implications
- Include in curricula for wilderness medicine courses
- Provide notice to participants about your policies and consider getting consent for treatment in writing in advance
- Try to have a doctor available for field staff to consult before administering or as soon as possible after the administration (if you decide to carry)
- Advocate with state agencies, state legislature, and/or Congress for changes in the law, if needed

Resources

- Article by Rufus Brown, Maine attorney, on legal issues related to epi. Lists what states are doing and relevant statutes. www.brownburkelaw.com/articles-epinephrine.html
- FARE list of state laws re schools http://www.foodallergy.org/advocacy/epinephrine/map
- CDC Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs http://www.foodallergy.org/cdc
- Wilderness Medical Society guidelines http://www.wemjournal.org/article/S1080-6032(10)00202-4/fulltext
- Auto-injector additional epinephrine retrieval www.wemjournal.org/article/S1080-6032(13)00094-X/fulltext