Overview

In 2015, Allergy & Asthma Network hosted three USAnaphylaxis Summits across the United States due to the generous support by Mylan Specialty L.P and Sanofi US. The summits were held in September 18 in San Ramon, CA; October 2 in Dallas, TX; and October 16 in Boston, MA. Participants were invited to attend based on their experience, commitment and passion for increasing anaphylaxis awareness. Of the 180 participants, 17 were Anaphylaxis Community Expert (ACE) volunteers. They came from 22 states and included board-certified allergists and pediatricians; allergy-related patient advocate organizations; school nurses; food allergy bloggers; support group leaders; parents of food-allergic children; psychologists and social workers; asthma educators; nurse practitioners; school teachers; and Mylan Specialty L.P. and Sanofi US sales and advocacy staff.

After each speaker presentation, participants at each table discussed scenarios related to the topic. The discussion’s purpose was twofold:

- Develop anaphylaxis awareness best practices to share with everyone after the conference;
- Help participants build stronger connections within their state or region.

The following is a summary of the presentations and collective discussion feedback.
Erika Gonzalez-Reyes, MD
Board-Certified Allergist and Chief of Allergy/Immunology at Baylor College of Medicine Children’s Hospital of San Antonio
Dr. Gonzalez-Reyes, an Anaphylaxis Community Expert (ACE) volunteer, presented in Irving, TX.

John Lee, MD
Clinical Director, Food Allergy Program and Co-Director, Eosinophilic Gastrointestinal Disease (EGID) Program at Boston Children’s Hospital and Instructor in Pediatrics at Harvard Medical School
Dr. Lee, an ACE volunteer, presented in Boston, MA.

Travis Miller, MD
Medical Director, The Allergy Station @ SacENT in Sacramento, CA.
Dr. Miller, an ACE volunteer, presented in San Ramon, CA.

Drs. Gonzalez-Reyes, Lee and Miller provided the first presentation at each summit, titled “Oral Immunotherapy Treatment & Epinephrine Auto-Injector Trends.” They provided context for what anaphylaxis is as well as its symptoms and where it is likely to occur. They also addressed risk factors for fatal anaphylaxis that include:

- Failure to treat with epinephrine
- Delayed treatment with epinephrine
- Improper administration of epinephrine
- Rapid progression of symptoms

The speakers noted that the top three locations for where anaphylaxis most often occurred were in the home (51%), hospital/clinic (14%), and family/friend’s home (7.3%).

Epinephrine Auto-Injectors (EAIs)
Presenters reviewed the four commercially available epinephrine auto-injectors (EAIs): Adrenaclick, Auvi-Q, EpiPen, and Epinephrine Injection, USP auto-injector, AG Adrenaclick. In addition, they shared that a fifth EAI, with the potential approval of an AB-rated generic for EpiPen, is expected to be launched in early 2016 by Teva Pharmaceuticals.

The speakers reviewed that all of the commercially available EAIs come in two doses—0.3mg and 0.15mg—and are recommended to be administered intra-muscular versus subcutaneous. The standard age limits for the epinephrine dosage:

- 0.3mg dose (.3mL 1:1000) is for patients who weigh more than 66 pounds (30kg)
- 0.15mg dose (.3mL 1:2000) is for patients who weigh between 33 and 66 pounds (15-30kg)
• When in doubt:
  o Too little epinephrine is better than NO epinephrine
  o Too much epinephrine is better than NO epinephrine
  o Expired epinephrine is better than NO epinephrine
  o In an emergency situation...give what you have

Epinephrine Pre-filled Syringe
Adamis Pharmaceuticals filed a new drug application with the FDA in May 2014 for their epinephrine pre-filled syringe, which—if approved—will compete as a low-cost epinephrine therapeutic alternative.

Anaphylaxis Conclusions
• Increasing incidence
• Increasing causes
• Increasing number of prescriptions for EAls
• Increased preparedness
• Increased use of anaphylaxis action plans
• Increased awareness

Resources
Epinephrine Auto-Injectors Comparison Chart
Epinephrine Auto-Injectors

Oral Immunotherapy (OIT)
The speakers noted that the goal of OIT is to alter the patient’s allergic response to food allergen in either or both of the following ways:
• Desensitized: Protective effect depends on daily uninterrupted ingestion of food allergen; protective effect may be lost if dose is interrupted.
• Tolerant: Permanent tolerance allows food to be ingested without allergy symptoms despite periods of abstinence.

OIT is still considered experimental and will not be applied in clinical practice until it has been carefully evaluated for side effects. Patients start on a very small daily dose of allergen and gradually move to a maintenance dose. Currently OIT is being conducted with milk, egg, and peanut allergies.
• Milk: When compared to children on a milk elimination diet, children were 10-fold more likely to develop full tolerance and 5-fold more likely to develop partial tolerance. Risk of adverse reaction was 34-fold higher; approximately 10% needed epinephrine.
• Egg: Appears to be effective in desensitizing most patients, although permanent tolerance is induced less frequently. Protocols were done using egg-white powder. Mild allergic symptoms were common, particularly in the first 10 months of dosing.
• Peanut: This allergy is rarely outgrown. Peanut OIT has more significant improvement in quality of life scores but also has higher rates of side effects, when compared to milk and egg OIT.

Considerations that were cited included:
• Allergic reactions during home dosing is common.
• Patients required treatment, including epinephrine, during home dosing phase.
• At least one case of life-threatening anaphylaxis during the escalation phase was reported.
• 10-20% of patients undergoing OIT have reported EGID or eosinophilic esophagitis.

In addition, the presenters briefly summarized cutting-edge peanut allergy research called Learning Early About Peanut (LEAP) Allergy and the Viaskin Peanut Allergy patch.

The LEAP Study included 640 high-risk United Kingdom infants aged 4-11 months old. The results showed an 80% relative risk reduction in high-risk infants if peanut was introduced between 4 and 11 months of age. The physicians agreed that more extensive guidelines and changes in recommendations are forthcoming. The American Academy of Pediatrics (AAP) endorsed the guidance of early peanut introduction in June 2015.

**Viaskin Peanut Allergy Patch**

This patch administers allergens through the skin in order to improve the patient’s tolerance of peanuts. The next phase in the clinical trial is a study to determine safety and effectiveness.

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**Interactive interdisciplinary group discussion related to “Oral Immunotherapy Treatment & Epinephrine Auto-Injector Trends”**

• Coordination of care (co-morbidities)
• Bias of beliefs/downplaying
• Cultural beliefs
• Language barriers
• Lack of understanding
• Denial
• Insurance coverage
• Lack of responsibility
• Use it as a talking point to educate patients about epinephrine
• Advocate for patient choice with their epinephrine auto-injectors
• Addressing media sound bites
• Dispense As Written (DAW)
• Education—social, clinical, advocacy (in office setting)
EAI Minimum Standards

- Syringe—too intimidating
- Has to be method of knowing medication is delivered
- Increased comfort level for administration
- Trainer...not necessarily talking
- Consistency across all sources

Concerns

- Exposed needle and lack of retractability (also, disposable danger)
- Putting together syringe and medication may be intimidating, frightening for children and non-medical adults
- Not being able to see through if epinephrine (liquid) has indeed been properly injected. Perhaps make device with see-through window
- Epinephrine injectors all need “click” to make sure we know medication has been given.
- Increase advocacy for patient choice as to their epinephrine auto-injector/delivery system and insurance coverage
- Increase advocacy for patients to be allowed to fill prescription for more than one set of auto-injectors per month/quarter, etc., by insurance company

Generic Epinephrine Auto-Injector Concerns

- Problematic ease of use/safety (needle guard)
  - Safety regulations and guidelines needed
  - Training
- Can schools use the stock epinephrine?
- Change laws: Device must have cover
- Economic disadvantage
- Is the new generic going to be the same quality?
- Stock epinephrine issues—parents still need to provide
- No substitutions
- Make sure that you get what is prescribed
- Obtain two auto-injectors
- Educate those around you
- Use epinephrine first
- Offer a trainer with every prescription
- No exposed needle
- Training for all injectors 2x a year with signs and symptoms
- Focus on now
- Generic isn’t always lower price
- Look for when it expires before you get it from pharmacy
- Need versus want
- Training
- Various options:
  - Demos readily on hand at pharmacy and in doctor’s office
Public Service Announcements regarding demo use and encouraging patients to practice regularly

**Education Considerations**

- Let patient know when to call 911
- Let patient know why they need two auto-injectors together and where to store them
- FAQ document to go home
- Signs and symptoms—knowing when to use epinephrine
- Medic alert bracelet
- List of resources
- Action plan, including other disease states, given
- Device training before they leave the office
- Picture references
- Local support group lists
- Need to establish standards—first responders
- Standard/Universal Anaphylaxis Plan
- Community/healthcare education
- FAQs for new therapies
- Reading/book list
  - How to read a label
  - Info on national organizations
  - Medical alert bracelet
  - Multilingual
  - Biphasic reactions (up to 25 hours later)
  - Carry two auto-injectors
  - No harm in using epinephrine—reinforce that message

**Need to Overcome**

- Lack of understanding; ask questions, play an active role
- Find support and connection
- Awareness—simplify steps and guidelines
- Epi Everywhere! Every Day! Right Away!
- Prescription assistance
- List of reliable sources/organizations
- Payer advocacy/policy advocacy
- Educate!

**Barriers**

- Time
- Payers-Insurance coverage
- $/Lack of referral
- Wait time
- Communication among team
- Shared data action plan and test results
- Silo system
• Mutual respect
• Transportation
• Policy
• Reliable information
• Cultural/language/socioeconomic
• Health literacy
• Lack of education in epinephrine for schools
• Understanding when to give and liability fear
• Huge communication gap!
• Unintentional exposure to allergens (students or CC)
• Having access to epinephrine at all times
• Safety
• Isolation
• Parental overzealousness
• Emotional health
• Reinforce known diagnosis
• Need to carry at all times
• Lack of legislation that addresses prevention and preparedness
• Lack of understanding
  o Schools
  o Doctors
  o Families
  o Self

OIT
• Limited availability for trials—zero co-morbid condition
• Cutting edge for treatment
• Increased awareness
• Not everyone has the same treatment
• Not FDA approved
• OIT Recommendation
  o Increase the amount of education surrounding the fact that OIT is still experimental due to increased news coverage
  o Include a third party (such as a mental health provider) to monitor the study participants’ well being throughout the study to ensure that participating in the study remains in the participant’s best interest.

Important Messages
• Be sure when leaving the pharmacy
  o Do you have the prescribed auto-injector?
  o Do you know how to use it?
Kimberly Turner, JD, MS  
*General Counsel and Director of Government Affairs, Allergy & Asthma Network*

Ms. Turner presented “The Evolution of Anaphylaxis Public Policy in the U.S.” at each of the three summits. She informed the audience as to the magnitude of the problem of anaphylaxis in the United States. Ms. Turner chronicled emerging anaphylaxis public policy developments in the states from getting 48 states to pass a form of stock epinephrine law, to 17 states passing entity laws, to the federal Airline Access to Emergency Epinephrine Act currently being considered in Congress. In addition, she illustrated lessons learned from these efforts.

Ms. Turner explained how to successfully influence public policy at the state and federal levels. She also informed the audience on the five keys for a successful public policy movement.

### Federal Legislation Tactics (2015-2016)

- **S. 1972**
  - Airline stock is logical next step
  - Coordinate effort in 50 states, perhaps via ACE rep for advocating this legislation
  - Consistent policy is most important
  - Review current laws that create barriers for stocking of epinephrine by airlines
  - Participant recommendations for airline stocking bill
    - Include protocol with signs and symptoms
    - Consistent national policy
    - Require that people do not shell nuts on board
    - Pre-board to clean
    - Post allergy policy on airline website
- **Truth in labeling**
  - Blanket statements such as ‘may contain’
  - Include other allergens such as sesame, spices
- **Epinephrine access in all public places**
  - Air, sea, land (mall, theme parks)

### State Legislation Tactics (2015-2016)

- **Entity legislation**
  - Schools have constant caregivers whereas entities have transient caregivers
Need to learn from schools. Entities are unique.
More education for school nurses on evidence-based studies of delayed administration of epinephrine
Need entity laws that do not conflict with the state’s nurse practice act
Shared data between entities and schools
Epinephrine auto-injectors should be with AEDs in public places (ex: Disney parks and cruise ships)
Establish consistent standards of care.
- Restaurant employee education about food allergies
  Work with state to formalize and advance safeguards

Policy Changes
  - List the actual “tree nuts”
    - What are they?
    - Put them on the label/menu
    - No more “may contain”
  - Basic EMS does not stock epinephrine auto-injectors, but advanced life support EMS does
  - More proactive FDA regarding labels
  - State legislative changes to protect school nurses
  - Need public access (AED model)
  - Need Good Samaritan laws
  - In school, EAls need to be available during after-school periods and school bus drivers need to be trained
  - Need full-time nurses
    - Medicaid/ACA predictable funding stream

Key Barriers and Concerns Regarding Stocking Epinephrine in Schools
  - Resistance to participate
  - Parents may not send epinephrine with their children who have a diagnosed life-threatening allergy
  - Cost, Access—Location of stored stock epinephrine
  - Educating clinicians about resource availability
  - Liability of nurses/district
  - Training non-medical staff
  - Nurse availability—shares schools, playground duty, etc.
  - Parent does not communicate
    - “He knows not to eat it”
    - No primary care provider, No EAI or prescription for it
Heidi Hannaman  
*Legislative Aide for California State Senator Minority Leader Bob Huff, Sacramento, CA*

Ms. Hannaman presented “Effective State-Level Advocacy: Learning from SB 1266” during the San Ramon Summit. By the conclusion of her presentation, attendees understood the lessons learned from the state’s stock epinephrine in schools bill, including successful strategies such as:

- Obtaining support from
  - Local and national food allergy organizations who sent email blasts/communications to CA residents
  - [American College of Allergy, Asthma & Immunology](https://www.acaai.org), [California Society of Allergy, Asthma & Immunology](https://www.csai.org), and [California School Nurses Organization](https://www.casn.org)
  - Board-certified allergists including Drs. Travis Miller and Kari Nadaeu
  - [California Advocates for Food Allergies](https://www.califfoodallergy.org), who continuously provided updates to constituents
- Using social media, specifically #epipenbill
- Timing—This was a three-year process
- Identifying a dedicated group of parents who want to help

Ms. Hannaman also shared strategies for educating yourself and your elected officials.

**Educating Yourself**

- How a bill becomes a law
  - There can be lots of variations
  - The process is long and sometimes makes no sense
  - Some decisions are made for political reasons that have nothing to do with the righteousness of the issue
- The players
  - Who is in leadership roles
  - What is important to them—read their bios and find out what committees they are on
  - Learn how they got elected and who supports them
  - When is their term over and what is their next move?

**Educating Your Elected Officials**

- Your opinions are valuable, so share your story with them
- Identify a member to introduce food allergy awareness week proclamation
• Invite the local ACE volunteers to participate in your food allergy awareness events; ACE volunteers provide free anaphylaxis education workshops to the community
  o Currently, there are 29 ACE volunteer teams in California
• Form a capital lobby day or hold a rally during Food Allergy Awareness Week
• Invite decision makers to your local walks and give them a role

Take Action!
• Utilize local and national food allergy awareness organizations to spread the word on legislation important to the cause
• Consider forming legislative subcommittees out of local support groups to monitor state and federal measures and educate the community as well as the elected officials
• Utilize an organization like CAFA to be a statewide clearinghouse
• Identify a strategy for what the state’s priorities are—not every food allergy bill is in the best interest of the community as a whole
• Communicate with national and local food allergy awareness organizations
Eleanor Garrow-Holding  
President and CEO, Food Allergy & Anaphylaxis Connection Team, West Chester, OH

Ms. Garrow-Holding presented “Food and Latex Allergy Policies in Restaurants” at all three USAnaphylaxis Summits. By the conclusion of this presentation, participants had learned strategies that food allergic individuals and restaurant employees can use to either eat safely or serve safe food at restaurants.

Ms. Garrow-Holding began by exploring the reason that fatalities occur in the restaurant setting. She offered the following thoughts:

- Customer error
  - Not identifying themselves as having a food allergy
  - Taking a risk by eating a food (social aspect)
- Restaurant staff error
  - Not understanding the severity of food allergy
  - Lack of or no allergen awareness training
  - Not communicating accurately with kitchen staff
  - Cross-contact during food preparation
  - Secret ingredients

Since 130 million people will be food service patrons every day in the U.S., improved communication and food allergy education is critical to ensure the safety of the growing numbers of allergic patrons. Food service personnel should understand food allergies and other dietary restrictions as well as their roles and responsibilities regarding food allergies. The keys to awareness begin at the top management levels at restaurants and include:

- **Attitude:** Allergen guests are not an inconvenience
- **Commitment:** Embrace this opportunity all of the time
- **Knowledge:** Is power; understand an allergic patron’s fear, and know what an allergen is and what it takes to serve food to an allergic patron
- **Trust:** Build trust through actions

Employees in the restaurant setting are encouraged to:

- Be proactive, not reactive.
- Take the lead in their profession.
- Partner with their food allergic patrons.
- Communicate with patrons about high-risk menu choices:
Fried foods are a high-risk choice because cooking oil often is used for many foods. Unless there is a designated fryer, steer guests with food allergies away from fried foods.

Desserts are another food to avoid because they may incorporate allergy-causing ingredients in unexpected ways. People with food allergies generally are safest avoiding desserts and selecting fresh fruit instead.

Skip the sauces—they are often used in entrées or desserts, and unless you are absolutely sure what the ingredients are, recommend that guests with food allergies skip the sauce.

Avoid pastry-covered dishes, as they prevent guests from making a visual inspection of the food he or she is about to eat.

Avoid combination foods such as stews or pot pies, as they contain many ingredients, some of which are hard to see.

Encourage simply prepared dishes.

• Say “I don’t know” if you are not 100 percent sure about the ingredients in a menu item.
• Understand that points of service such as buffets and deli and grill stations in cafeteria-style food service operations are high-risk because of the possibility of cross contact.

Note: Serving utensils may be used for several dishes, or small bits of food from one dish may fall into another dish.

Ms. Garrow-Holding shared strategies for avoiding cross contact when preparing and serving meals.

• Review food handling processes.
• If using shared equipment, utensils, pots, pans, grills, fryers, cooking areas, counters and serving containers, be sure to properly clean work area and utensils per protocols.
  o All should be cleaned with hot, soapy water or other appropriate cleaning compounds and then sanitized before being used to prepare a dish for a guest with a food allergy.
• Consider having dedicated areas and/or utensils.
• Cross contact also comes from:
  o Unclean hands or gloves
  o Garnishes
  o Splatter or steam from cooking foods
  o Deep fryers
  o Trays
  o Refilled serving containers

She described the following thoughts for employees at the ‘Front of the House’:

• When a guest makes you aware of a food allergy, be understanding, listen carefully and answer questions accurately.
• Guests depend on front of the house staff to be knowledgeable and notify other key members such as the manager and chef.
• If a mistake occurs, the only acceptable way to correct the special order is to discard the incorrect order and remake it.

Latex-allergic patrons were encouraged to ask the following questions of restaurant staff:

• Are natural rubber latex gloves used
  o Anywhere in the restaurant?
  o In serving?
  o In cleanup?
• Are balloons ever in restaurant?
• Do menu items include: banana, avocado, kiwi, chestnut?
• How is it best to communicate if someone has an allergy?
• How do you handle latex-allergy special requests?
• Does restaurant staff know the signs and symptoms of an allergic reaction?
• Does the restaurant stock epinephrine?
• Has the staff been trained to administer epinephrine?

Ms. Garrow-Holding provided the following case reviews to emphasize the need for “front of the house” employee education and cross-contact avoidance.

• **Case 1:** A guest ordered egg rolls in a Chinese restaurant, after asking if they contained peanuts. When the waitress confirmed that they did not contain peanuts, the man ordered them. He took a few bites and had an allergic reaction. Ninety minutes later, he died from anaphylaxis.
  o *How did this happen?* The waitress did not ask the manager or chef about the ingredients and didn’t know that the restaurant changed its egg roll recipe to enhance the taste by adding peanut butter.
  o *How could this have been prevented?* Be sure to direct food and latex allergy questions to only one or two designated staff members. The designated staff members should verify all ingredients of a meal with the chef so that they can accurately answer their guest’s questions.

• **Case 2:** A man with a known shrimp allergy ordered chicken scampi and his wife ordered shrimp scampi. Soon after he took his first bite, he complained that his chest was tight and he was having difficulty breathing. He died a few hours later from an allergic reaction to shrimp.
  o *How did this happen?* The kitchen staff prepared two orders of shrimp scampi and then simply removed the shrimp from one of the plates and replaced it with chicken. Enough shrimp protein was left on the man’s plate to cause a fatal reaction.
  o *How could this have been prevented?* Restaurant staff needs to understand that trace amounts of an allergen may cause a life-threatening reaction for some individuals. When ANY mistake is made on an order for a guest with food allergies, discard it and make it again from scratch.
For employees at “The Back of the House,” the following recommendations were made:

- Chef should review all ingredients to include hidden ingredients and ingredients that may have other names.
- Give complete and accurate information about the ingredients and methods of preparation.
- Before preparing the meal and to avoid cross contact, the Chef should wash hands, change his/her apron, put on a clean pair of gloves and ensure that clean utensils and cutting boards are available.
- If a mistake is made, discard the incorrect order and remake it.
- The special order should be delivered to the guest separate from other orders on tray.

Ms. Garrow-Holding provided the case studies listed below to emphasize the need for “back of the house” employee education and cross-contact avoidance.

- **Case 1:** A child with a sesame seed allergy had an allergic reaction after eating a grilled cheese sandwich at a restaurant.
  - How did this happen? The chef used a sesame seed bun and cut off the top and bottom to make the slices of bread for the sandwich.

- **Case 2:** A young woman with a milk allergy ordered the same food she always ordered at this restaurant. She ate the burrito and went into anaphylactic shock. She self-administered first dose of epinephrine, and the second dose malfunctioned before EMS arrived and she passed away.
  - How did this happen? The burrito came into contact with cheese.

- **Case 3:** A girl with a milk allergy ordered a hamburger without cheese at a fast food restaurant. The order came and the burger had cheese on it. The mother asked for a replacement burger. The child ate the replacement burger, showed signs of anaphylaxis and was rushed to the hospital.
  - How did this happen? Upon examination of the burger, cheese had been scraped off and patty turned over in the bun.

- **Case 4:** A woman with a peanut allergy ordered a cannoli—the menu said that the cannoli contained chopped pistachio nuts. The woman ate the cannoli, had an allergic reaction and was rushed to the emergency room.
  - How did this happen? The restaurant did not know that the bakery who supplied the cannoli to the restaurant used peanut pieces that were dyed green instead of pistachio nuts.
  - How could this have been prevented? Restaurant suppliers need to provide complete ingredient information for all foods and designated staff members who handle patrons with life-threatening allergies should read ingredient information for all foods prepared for those guests.
Conclusion

- Embrace your allergic patrons.
- Be knowledgeable of allergens, not just the top eight.
- Keep upper management involved.
- Know your allergen friendly distributors.
- Train, train, train and then train some more.
- Allergic patrons are not an inconvenience.

Resources

*Latex Allergy...Hidden Dangers...Restaurants/Grocers/Food Service*

2015 Latex Allergy Awareness Week Webinars

*Latex Allergy 101 Webinar with Dr. Kevin Kelly*

*Hidden Latex Allergy Dangers in Food Service Webinar with Dr. Michael Zacharisen*

*American Latex Allergy Association*

*Food Allergy & Anaphylaxis Connection Team*

Interactive interdisciplinary group discussion related to “Food and Latex Allergy Policies in Restaurants”

Group Comments:

- The allergic person/patron needs to take ownership
- Certification that restaurants are ‘Allergy Friendly’
  - Certification for allergy inspection from local health department
- Menu labeling (it is not standardized)
- Documentation that chef talked with the table/consumer
- Hostess sign—food allergy, pre-notification to the waitress/chef
- “I’d rather be sued than Yelped”
- Public education in labeling laws
  - Make clear when there are changes
  - Current standards for terminology
- Training for all staff; frequent quality control trainings
  - Include a training check-off list for all food workers
  - Have a documented procedure
  - Restaurant training module
  - Destroy the meal if it is wrong, don’t wipe it off
Amelia Smith Murphree, JD  
*General Counsel and Vice President of Civil Rights Advocacy*  
*Food Allergy and Anaphylaxis Connection Team*

Ms. Smith Murphree shared an overview of civil rights for students and families who bring food allergies to the school setting at all three summits. Civil rights advocacy focuses on the rights of individuals at risk for anaphylaxis, individuals with food allergies and individuals with asthma to safely and equally participate alongside their nonallergic individuals.

She addressed the individual student plans that outline the accommodations and healthcare that a student requires at school, including:

- **Individualized Healthcare Plans**  
  - A plan written by the school nurse to direct nursing care
- **Emergency Care Plans**  
  - A plan that directs an emergency response by school staff when needed
- **Individualized Education Plans**  
  - A plan that typically addresses educational accommodations based on 13 categories of disability as outlined in the Individuals with Disabilities Education Act (IDEA) of 1975
- **Section 504 Plans**  
  - Section 504 of the Rehabilitation Act of 1973 prohibits programs and activities that receive federal financial assistance, such as public schools, from discriminating against and/or excluding individuals with disabilities solely on the basis of their disability. This plan outlines the accommodations necessary for the qualified, disabled student to receive a “free and appropriate public education.”

Ms. Smith Murphree outlined accommodations that a student with a food allergy may require:

- Accommodations should be tailored to the specific needs of the student. Accommodations for one food allergic student may be more restrictive than what is needed by another food allergic student and vice versa, even if the students have the same food allergies.
- When crafting accommodations, some areas of concern to consider include: communication with the school and with other parents, the classroom, the cafeteria, celebrations, cleaning, transportation, substitute teachers, field trips, medications and emergency situations.

**Significant Unmet Civil Rights Need**

- Appropriate plans are not always in place to address student needs
Matthew Greenhawt, MD, MBA, MSc

Dr. Greenhawt, an Anaphylaxis Community Expert (ACE) volunteer, presented at all three Summits.

Dr. Greenhawt’s research interests include parental understanding of food allergy risk and shared decision-making, utilization of food-allergy-related health services, adherence to practice guidelines, optimal strategies for diagnosis and treatment of food allergic disorders, prevention of food allergy, and quality of life among families with food allergic diseases.

Dr. Greenhawt provided history on the early-feeding guidance from 2000:

• Dietary avoidance of certain antigens in pregnancy
• Selected avoidance of certain foods while breastfeeding to prevent eczema and asthma
• Use of partially hydrolyzed whey formula
• Delay solid food introduction until 6 months
• Delay introduction of high-risk allergens until age 3 years

All of these strategies were thought to reduce the risk of a child developing a food allergy, yet a rise was seen in the disease.

He reviewed the basics of the Learning Early About Peanut Allergy (LEAP) study, which looked at early versus delayed peanut introduction in infants that were identified as high-risk to develop peanut allergy. He reviewed screening and protocol used, the definition of the focus of the study, demographics and results. He offered the following constructive criticisms:

• No placebo group or low-risk group comparison
• 5mm skin test cut-off chosen—arbitrary
• No control group to test necessity of skin testing
• Single center, referral population
• Participation bias? >96% retention at 5yr
• Weak “high risk” criteria
• Dose/duration of exposure not tested
• Unknown effect of partial adherence or long-term outcomes after discontinuation

Dr. Greenhawt led a discussion on the impact of the study in the field of allergy management. He advised caution in implementing findings from one study and questioned the need for study replication and the ability to generalize the study to the United States. He discussed interim policy and highlighted the following in an interim consensus document:

• There is now strong scientific evidence supporting early introduction of peanut-containing products into the diet of high-risk infants early in life (between 4 and 11
months of age) in countries where peanut allergy is prevalent, since delaying may be associated with an increased risk of developing peanut allergy.

- Infants with early-onset atopic disease, such as severe eczema or egg allergy in the first 4-6 months of life may benefit from evaluation by an allergist or physician trained in management of allergic diseases to assist in implementing these suggestions regarding the appropriateness of early peanut introduction.
- Evaluation of such patients may consist of performing peanut skin testing and/or in-office observed peanut ingestion, as they deem appropriate after discussion with the family, especially for those with evidence of a positive peanut skin test.
- The study does not address use of alternative doses of peanut protein, minimal length of treatment necessary to induce the tolerogenic effect, or potential risks of prematurely stopping or sporadic feeding of peanut.

Dr. Greenhawt highlighted research related to foods beyond peanut and discussed the progress in established studies.

**Significant Unmet Research Need**
- Studies need to be replicated before widespread guidance is issued.
Michael Pistiner, MD, MMS
Pediatric allergist for Harvard Vanguard Medical Associates, a voluntary instructor of pediatrics for Boston Children’s Hospital. Co-founder and content creator of AllergyHome, Consultant for the Massachusetts Department of Public Health, School Health Services
Dr. Pistiner, an ACE volunteer, presented at the Irving, TX and Boston, MA summits.

Sally Schoessler, MSED, BSN, RN
Director of Education, Allergy & Asthma Network
Mrs. Schoessler presented at all three summits.

Mrs. Schoessler began with an overview of state legislation either allowing or mandating stock epinephrine in the school setting and identifying the issues involved in implementing the new laws on a national basis. Moving forward with school district needs for implementation, she outlined the need for a strong school district policy and outlined the following components needed for a comprehensive policy:

• Individuals covered, including those with first-time anaphylaxis emergencies
• Epinephrine – orders, locations at school, access, supply, procurement, disposal, administration, documentation, reporting
• Emergency protocol for administration
• School programs and environments covered
• Individuals authorized to administer
• Education, training, notification

Following a discussion on implementing new and existing polices, Mrs. Schoessler referred the topic to Dr. Pistiner who reviewed the clinical criteria for anaphylaxis and highlighted the need for a sound protocol. Dr. Pistiner reviewed a protocol that he assisted in developing with representatives from the American Academy of Pediatrics, the National Association of School Nurses and the National Association of State School Nurse Consultants. This workgroup was supported by Mylan Specialty L.P.
The protocol approaches the following topics:

**Signs and Symptoms with Exposure**
- Epinephrine administration
- Post-epinephrine and observation

**Signs and Symptoms with No Exposure**
- Epinephrine dosing
- Transport

**Resources**
- Epinephrine Policies and Protocols Workgroup
- ACE Spotlight: Many Schools Face Challenges Implementing Stock Epinephrine

**Significant Unmet Stock Epinephrine Needs**
- Two remaining states need legislation to be passed.
- School districts need to remove barriers to implementing stock epinephrine.

**Interactive interdisciplinary group discussion related to “Overcoming Stock Epinephrine Challenges”**

**Toolkit Contents**
- Action Plan
- Educational program
- Quick reference guides
- Magnet
- Script when calling 911
- Simple accommodations
- Local and national resources
- Free epinephrine education

**Other Comments**
- Teens are risk takers, don’t want to carry epinephrine auto-injector
- When you drop your kid off at school, you don’t want it to be for the last time

**Challenges/Barriers**
- Education/Awareness
- Share resources
- Changing standards of care—agreement
- Time constraints
- Communication among HCPs
- Stigma of food allergy
- Transparency/Honesty
- $$
• Information overload
• Expert consensus—Best practices
• Fear and anxiety
• Safety—make sure that students are included in planning and education
• Establish consistent standards of care among students/teachers/staff
• Safe actions—home and school
• Management tools
• Compliance—need continuing education and communication
• Outside/extracurricular—trainer, coach, talking with nurse
• “Will this be forever?”
• Changes, updating

Challenge
Training unlicensed school personnel to administer all different kinds of auto-injectors

Back to Basics Education
• Reteaching
• Spontaneous check-ins
• One form (CT) combination form for orders and emergency care plans
• Standardizing protocols
• Be sure auto-injectors come to school
• Parents don’t ask about policy...this has to change (504/IEP?)
• Food vendors/cafeteria, need increased awareness
• Evidence-based practice (school nurse)

Conclusion
The 2015 USAnaphylaxis Summits brought together 180 key community stakeholders from 22 states to learn about the latest anaphylaxis-related research, legislation and practical strategies for managing this life-threatening allergic reaction. In addition, the Summits enabled participants to network with each other and build new relationships, while sharing the unique perspectives that each stakeholder brought to the table.

Allergy & Asthma Network looks forward to the positive impact that these newly established connections will have on communities throughout the United States in 2016. Together, we will continue the mission to end needless death and suffering due to allergies and anaphylaxis.

Questions?
Email Brenda Silvia-Torma at ace@AllergyAsthmaNetwork.org.