

Best Practices in Allergy Care: Improving Safety, Quality, and Outcome in Allergy Delivery

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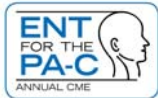
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Fourth Annual ENT for the PA-C | April 24-27, 2014 | Pittsburgh, PA

Disclosures

- This speaker has no commercial relationships to disclose.



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Learning Objectives

- Recognize how to safely provide quality allergy care.
- Describe current practice parameters on allergy immunotherapy.
- Provide a model for creating a safe allergy practice and track quality metrics.



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Relevance

- Allergy affects one-third of the US population
- 7.9 billion dollars per year spent managing allergic disease
- Allergic rhinitis and asthma are two leading causes of missed school days secondary to chronic illness
- Significant effect on quality of life
- Children with AR have cognitive dysfunction and increased fatigue
- Sleep dysfunction



Allergies are on the Rise

- National Health and Nutrition Examination Survey study 2011
 - 43.7% prevalence of atopy in the US
 - 20.2% 2–3 decades earlier

Salo PM, et al. Allergy-related outcomes in relation to serum IgE: results from the NHANES Survey 2005–2006. J Allergy Clin Immunol 2011.



Co-morbid Conditions

- Increased risk of asthma, rhinosinusitis, and chronic otitis media
- Unified airway
 - Over 80% of patients with asthma manifest rhinitis symptoms
 - Up to 40% of patients with rhinitis symptoms have asthma
- Evaluation of lower airway disease for rhinitis patients and upper airway disease in asthmatic patients



SCIT Efficacy Cochrane Review

- ↓ symptom score in 15 trials
- ↓ medication use in 13 trials
- ↑ QOL (rhinoconjunctivitis) in 5 trials
- ↓ ocular symptoms in 3 trials
- ↓ bronchial symptoms in 5 trials
- ↓ incidence of new sensitizations

Calderon MA, et al. Allergen injection immunotherapy for seasonal allergic rhinitis. Cochrane Database Syst Rev. 2007 Jan 24;(1):CD001936.



SCIT Safety

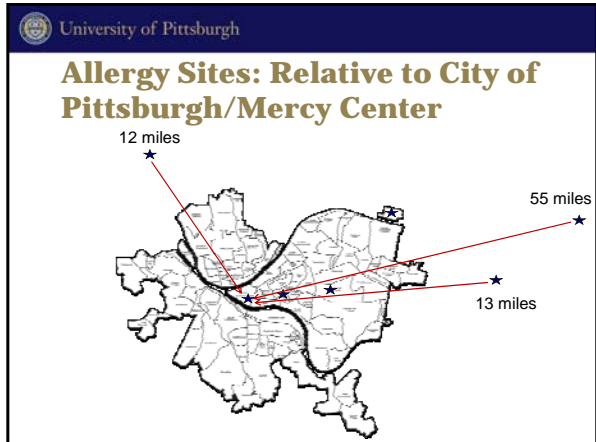
- Fatalities from immunotherapy 0.7 deaths per million injections (0.00007%)
- Dose error causes 1/3 of deaths
- Epinephrine not used in 50% of deaths
- In 2/3 of fatal cases, presence of physician was not sufficient to ensure survival

Norman PS. Safety of allergen immunotherapy. J Allergy Clin Immunol 1989.



Defining Quality Metrics

- What is a quality metric?
 - Measurement of factors associated with good patient-centered care
- Not yet defined in the delivery of allergy immunotherapy
- Need to develop appropriate metrics that assess and correlate with safety and patient outcomes
- Develop and apply quality metrics to 6 allergy practices with approximately 1500 patients
 - Anaphylaxis
 - Adherence to key safety measures via checklist
 - 5 areas of focus/intervention



- University of Pittsburgh
- ### Quality Measures
- Process (What providers do)
 - Patient outcome (What happens to patients)
 - Structure
 - Access to care
 - Patient satisfaction (What was patient's experience)
 - Efficiency (How much could be done without wasted resources)

University of Pittsburgh

Task force report

Allergen immunotherapy: A practice parameter third update

Chief Editors: Linda Cox, MD, Harold Nelson, MD, and Richard Lockey, MD
Workgroup Contributors: Christopher Calabria, MD, Thomas Chacko, MD, Ira Finegold, MD, Michael Nelson, MD, PhD, and Richard Weber, MD

- Most recommendations grade C or D
- Safety data from the otolaryngic allergy literature
- No AAOA practice guidelines yet

Cox et al. Allergen immunotherapy: a practice parameter third update. J Allergy Clin Immunol. 2011 Jan;127(1 Suppl):S1-S5.



The Affordable Care Act

- Signed into law 2010
- Prevalent theme is to improve quality care while lowering cost for all Americans
- Reimbursement algorithms will be modified by linking payment to quality outcomes
- By 2015 new provision with tie physician payment to quality of care provided



Increased Stringency of Guidelines

- Drug Quality and Security Act of November 2013 (the "Compounding Bill")
- All compounded sterile preparations must have a prescription
- Physicians and technicians need to be aware of and be compliant with **all** aspects of the USP 797 sterile compounding rules



Quality Initiative

- Allergy Quality Initiative Round Table convened with staff stakeholders including physicians, technicians, nurses, and managers
- 7 Allergy Technicians and Medical Assistants over 6 allergy sites in an academic otolaryngic allergy practice
- 46 question survey encompassing 7 key categories
- Example questions included:
 - "Do you feel your training was adequate in preparing you for allergy mixing/testing/administration?" (assessed qualitative training)
 - "Where is the emergency code cart located and what is in it?" (assessed knowledge of treating and management of anaphylaxis)

Survey Results - Training

- Mean allergy training 48 days
- Participation in biweekly allergy conference limited in 43% respondents
- Recommendations:
 - Hands-on teaching
 - Improved consistency in training
 - Increased scenario simulations
 - 1 month of training



Survey Results - Anaphylaxis

- 100% respondents noted clearly outlined and updated protocol in office
- 100% knowledge of content and location of anaphylaxis cart
- 100% regular update of emergency cart supplies
- 100% trained in BLS and/or ACLS
- 71% noted formal training in anaphylaxis management



Survey Results – Allergy Testing and Mixing

- 57% noted lack of protected time to perform allergy testing
- 67% noted distractions with 50% noting "quite frequently" or "all day"
- **Errors in mixing noted by 57% respondents and related to multi-tasking during mixing and documentation errors**





Survey Results – Allergy Care Delivery

- 100% physician availability and oversight
- 50% noted adequate mechanisms in place for reporting errors or near misses



Core Areas of Improvement

1. Need for routine and ongoing systems review with evaluation of current practice and adherence to existing practice parameters
2. Standardization of training and assessment
3. Reduction of errors in mixing, allergy administration, and documentation
4. Improved communication with data entry, access, and relevance of the electronic medical record
5. Reporting and review of errors/anaphylaxis



Methods and Interventions

1. Reviewed current practice and adherence to standards
2. Developed standardized training and assessment
3. Reduced risk of errors via audit, vial verification, vial testing
4. Improved data entry, access, and relevance
5. Implemented reporting and review of errors/anaphylaxis



1. Review of current practice and adherence to standards

- Checklist developed with key safety measures, assessment of anaphylaxis preparedness
- Audits of allergy sites performed
- Remediation performed for areas where improvement needed



Allergy Site Checklist

Equipment/Procedure	Pass	Fail	Recommendations	Technician/Manager Initials
Epi-pen adult				
Epi-pen child				
Emergency drug backdraft cart				
Oxygen tank/backup/pressure				
Injectable steroids				
Sharps pails/needle trays				
Immunization/sterile/needle trays				
Patient vital signs/monitoring				
Antigen lab tests				
Antigen expiration				
Antigen management				
Emergency plan for testing				
Emergency plan for ingestion				
Emergency plan for vaginal reactions				
MSDS/labels				
Allergy delivery protocol				
Standardize pathways protocol				
Needle stick protocol/kit				

Lee S, Stachler RJ, Ferguson BJ. Defining quality metrics and improving safety and outcome in allergy care. Int Forum Allergy Rhinol. 2014 Jan 21.



2. Allergy Training and Standardization

ALLERGIES AND IMMUNOTHERAPY

Teaching Manual

Division of Immunological Disorders and Allergy
Updated 4/15/2014

2. Allergy Training and Standardization

- Web-based training modules
 - Immunotherapy fundamentals
 - Allergy testing
 - Serum preparation
 - Immunotherapy injections
 - Anaphylaxis
- Physician oversight and sign-off on training
- Bi-weekly teleconference across satellites
- Mock anaphylaxis drills



3. Reduction of Human Error

- Centralized allergy mixing
- 2-person vial verification
- Vial testing implemented for any patient with new vial
- Protected mixing time reinforced and supported by administration



Prior to Giving Injections

- Did you have any problems after your last injection?
- Is your asthma controlled?
- Have your medications or medical history (including pregnancy) changed since your last injection?
- Did you take an antihistamine today?
- Do you have your epinephrine device with you?
- Would you please verify your name & date of birth on each vial?

4. Improvement of data entry, access, and relevance

- Central resource Sharepoint website developed
- Focus on sharing of information related to allergy testing, administration
- Modification of Epic interface
- Making “meaningful use” meaningful



5. Tracking of Errors and Anaphylaxis

- Most common types of error recorded prior to implementation of quality metrics from 2008-2012
 - Patient identification errors (n=4)
 - Vial mixing errors (n=3)
 - Dosing errors (n=2)
- 7 episodes of anaphylaxis occurred, 2 secondary to identified dosing errors
- Site visits showed 86% key safety measures followed

Anaphylaxis

- Skin (>90%): hives, swelling, itch, warmth, redness, rash
- Breathing (60%): wheezing, shortness of breath, throat tightness, cough, hoarse voice, chest pain/tightness, nasal congestion, fever-like symptoms, trouble swallowing
- Stomach (30%): nausea, pain/cramps, vomiting, diarrhea, itchy mouth/throat
- Circulation (30%): pale/blue color, poor pulse, fainting, dizzy/lightheaded, low blood pressure, shock
- Other: anxiety, feeling of “impending doom”, itchy/watery eyes, headache



What are risk factors for anaphylaxis?



Anaphylaxis Risk Factors

- Escalation phase of immunotherapy
- Seasonal exacerbation, active asthma
- Upper respiratory infection with fever
- First injection from treatment vial
- Errors
- Beta blocker treatment



AAAAI and ACAAI surveillance study of subcutaneous immunotherapy. Year 3: what practices modify the risk of systemic reactions?

Tolly G. Epstein, MD, MS^{1,2}; Gary M. Liss, MD, MS³; Karen Murphy-Berends, BS⁴; and David L. Bernstein, MD^{1,5}

¹Department of Medicine, Division of Immunology, Allergy and Rheumatology, University of Cincinnati College of Medicine, Cincinnati, Ohio; ²Cincinnati Veterans Affairs Medical Center, Cincinnati, Ohio; ³University of Texas, Austin, Texas; ⁴Cincinnati; ⁵Research Clinical Research Center 122, Cincinnati, Ohio

- Before 2002 3.4 SCIT-related deaths/year
- No fatal reactions from 2008-2011
- Systemic reaction rate 0.1% of injection visits, 83% practices
- Screening for asthma and adjustment during pollen season may be associated with decreased risk for systemic reactions



AAAAI/ACAAI Surveillance Study of Subcutaneous Immunotherapy, Years 2008-2012: An Update on Fatal and Nonfatal Systemic Allergic Reactions

Tolly G. Epstein, MD, MS^{1,2}, Gary M. Liss, MD, MS³, Karen Murphy-Berendts, BS, RRT, CCRC⁴, and David J. Bernstein, MD^{1,2} Cincinnati, OH; Indianapolis, IN; and Toronto, Ontario, Canada

- One fatality in 2009
- 43-year old man with well-controlled mild-moderate persistent asthma who had been advancing on shots
- Highly sensitive especially to weeds, reaction occurred during weed season (Oct)
- PMH: HTN, DM, obesity and started on lisinopril in previous 2 weeks
- Received 2 injections of 0.2 mL neither from a new vial
 - One vial with Bermuda and Kentucky blue grass
 - Second vial with cat, dog, and weeds

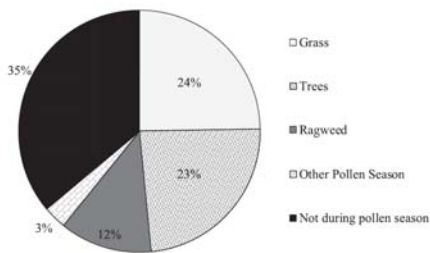


Case Report: Anaphylaxis

- Within 3-10 minutes patient experienced generalized pruritus, urticaria, angioedema, GI symptoms, upper/lower airway obstruction.
- Hypotension, LOC, shock ensued
- Epinephrine given 0.3 mg subcutaneously at onset followed by 0.3 mg IM within 1-2 minutes
- Within 5-6 minutes patient had no detectable BP and CPR initiated
- 3 additional doses of 0.3 mg of IM epi and 50 mg of diphenhydramine given
- Resuscitation not successful despite IV fluids, emergent cricothyroidotomy



Seasons for Systemic Reactions



Types of Allergens

- Perennial
 - Dust mite, Cockroach
 - Molds, Animal Danders
- Seasonal
 - Trees: Early spring
 - Grasses: Late spring/early summer
 - Weeds: Late summer/early fall



Strategies to Prevent Reactions

- Intradermal vial test
 - Dose errors
 - Initial injection from a vial
 - Treatment from wrong patient vial
 - Vials prepared by another office
- Patients with asthma must be under good medical and environmental control
- Antihistamine prior to shot
- Consider dose reduction during high pollen season

Anaphylaxis Management

- Call for help
- Follow the ABCs
- Place patient supine or in Trendelenburg position
- Give epinephrine if necessary. If patient continues to worsen – give additional dose after 5 minutes.
- Tourniquet above injection site
- Give patient H1 and H2 blockers, steroids, bronchodilators
- Transport to ER when stable, consider admission
- Debriefing session



Epinephrine: If you think of it, use it!

- Early epinephrine use for suspected anaphylaxis
- Good outcome more likely with immediate epinephrine use
- Epinephrine not used often enough to treat anaphylaxis



What is the **dose for injectable epinephrine?**



Adult Dosing of Anaphylaxis Medications

- Epinephrine 1:1000, 0.3-0.5 mL IM
- Diphenhydramine 25-50 mg IV/IM
- Ranitidine 50 mg IV/IM
- Methylprednisolone 125 mg IV/IM
- Dexamethasone 10 mg IV/IM
- Albuterol neb or MDI: Dose as for asthma

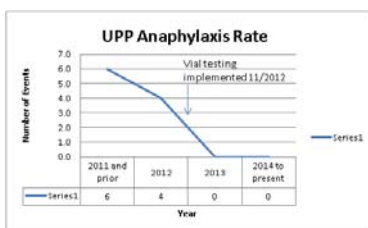
Epinephrine

- Adult 0.3-0.5 mL (1:1000) IM
- Child 0.01 mg/kg (1:1000) IM
- Autoinjector devices
- Better absorbed via IM route
- Repeat every 5 mins as needed

5. Tracking of Errors and Anaphylaxis

- National average 0.4-2.6 moderate to severe systemic reactions/10,000 injections per year.
- UPP average was high 0.4% or 4 events/10,000 injections per year prior to vial testing.
- What is vial testing?
 - 0.01 ml of allergy serum injected intradermally prior to providing full dose
 - Safety check due to potential mixing errors and lot changes
 - If reaction <13 mm give first dose
 - If >13 mm consider holding/diluting vial

Importance of Vial Testing/Verification



Outcome Measures

- Efficacy of allergy treatment on patient outcome
- Assessment of patients at initiation of immunotherapy and monthly until maintenance
- Questionnaire developed assessing the following:
 - Perceived benefit of immunotherapy
 - Experience with local reactions
 - Medication score
 - RQLQ
 - Asthma Control Questionnaire

General

1. Do you feel that allergy shots are helping to relieve your symptoms?
 Yes No Unsure

2. Are you having any of the following with allergy shots?
 Swelling at injection site Redness at injection site Rash Other: _____

Medication Usage

How many times/week did you need to use the following in the past month?

1. **Short-acting beta₂ agonists (for example: Albuterol, Risperol, Albuterol, Ventolin?)**
 Rarely/never 1-2 times/week 3-4 times/week 5 times/week

2. **Long-acting beta₂ agonists (for example: Advair, Serevent, Accolate, Foracort?)**
 Rarely/never 1-2 times/week 3-4 times/week 5 times/week

3. **Oral corticosteroids (for example: Prednisone, Methylprednisolone?)**
 Rarely/never 1-2 times/week 3-4 times/week 5 times/week

4. **Inhaled corticosteroids**
 Rarely/never 1-2 times/week 3-4 times/week 5 times/week

5. **Antihistamines or Decongestants**
 Rarely/never 1-2 times/week 3-4 times/week 5 times/week

Please complete all questions by circling the number that best describes how troubled you have been during the last week as a result of your reaction symptoms.

	Not troubled	Slightly troubled	Moderately troubled	Quite a bit troubled	Very troubled	Extremely troubled
Activities						
1. Regular activities at home and at work (your occupation or tasks that you have to do regularly around your home and/or garden)	0	1	2	3	4	5
2. Recreational activities (indoor and outdoor activities with friends and family, sports, social activities, hobbies)	0	1	2	3	4	5
3. Sleep (if you're not getting a good night's sleep and/or getting to sleep at night)	0	1	2	3	4	5
Respiratory problems						
4. Need to cut back/less	0	1	2	3	4	5
5. Need to know what happens	0	1	2	3	4	5
Other symptoms						
6. Sneezing	0	1	2	3	4	5
7. Runny nose	0	1	2	3	4	5
8. Itchy nose	0	1	2	3	4	5
Eye symptoms						
9. Itchy eyes	0	1	2	3	4	5
10. Some eyes	0	1	2	3	4	5
11. Watery eyes	0	1	2	3	4	5
Other symptoms						
12. Headaches and/or fatigue	0	1	2	3	4	5
13. Tired	0	1	2	3	4	5
14. Feeling irritable	0	1	2	3	4	5
Total						
Grand Total						



What we want to know?

- Did immunotherapy improve quality of life?
- Did patients reach their therapeutic dose without significant local or systemic reactions?
- Did patients follow-up with physicians on a regular basis?
- Did medication use decrease with immunotherapy?
- Was pharmacotherapy more effective than immunotherapy?



Nationwide Practices

- Online survey developed to collect data from academic and private allergists from both medical and otolaryngology backgrounds
- Survey questions regarding preparation of vials, management of anaphylaxis, systems review, use of quality metrics



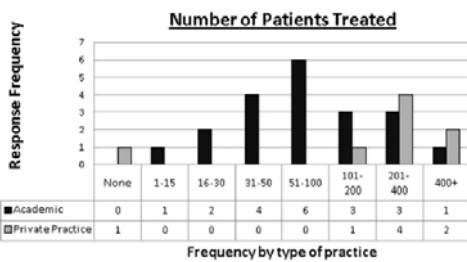
Do you perform anaphylaxis mock drills?	Yes, No
If yes, how often do you perform mock drills?	One time in 2 or 3 years, Yearly, Every 3 months, Monthly
Do you have an emergency anaphylaxis box or cart?	Yes, No, Don't know
Do you know where your emergency kit is?	Yes, No, No, but the nurse knows
How do you verify patient and vial are correct, check all applicable:	One person verification, Two person verification, Three person verification, Bar code
Does the patient have to verify their vial?	Yes, No
Do you verify the formulation of each vial with the allergy technician or nurse before/after it is mixed?	Yes, No
How long do you recommend patients wait after a shot?	No wait unless they have risk factors such as asthma, 20 minutes, 30 minutes, Longer than 30 minutes
If patients don't wait what do you do?	They sign out against medical advice, Prescription and instructions on how to use epipen, Refuse to give shot or continue immunotherapy, Nothing, It's a free country
Do you differentiate between vials which are advancing and those at maintenance and if so how?	Yes, No, by: Color caps are different for vial type, Numbers are different, Other
Do you record near misses and adverse events?	Yes (please describe), No, Sometimes
Do you perform a systems review/chart audits/site visits to assess reasons for errors or adverse reactions	Yes (please describe), No, Usually, Hardly ever
Do you have quality metrics for your allergy practice?	Yes (please specify), No, Don't know

Survey of Nationwide Practices

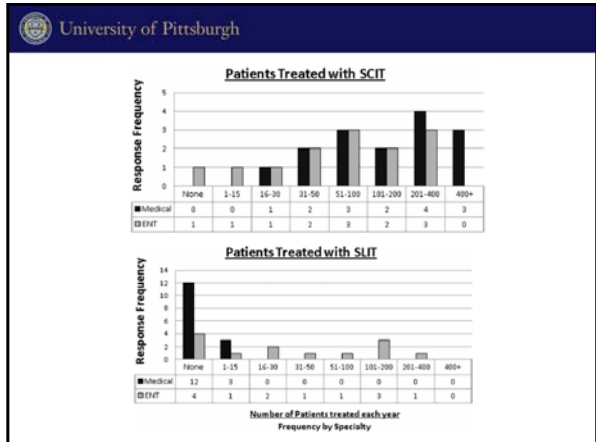
- 130 medical and otolaryngic allergists invited to participate in survey
- 33 complete responses obtained (25% response rate)
- 19 medical allergists
- 14 otolaryngic allergists
- 25 academic practices
- 8 private practices

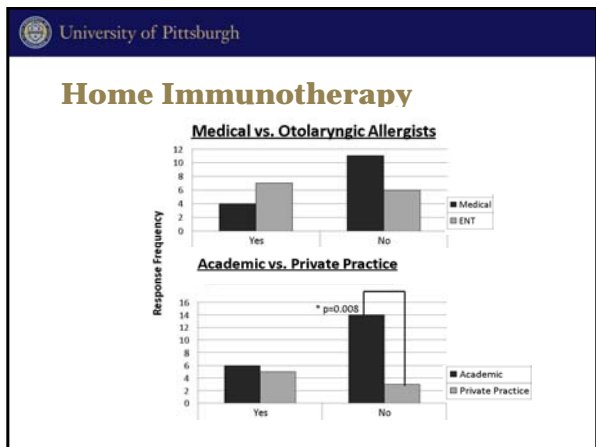
Nationwide Practices

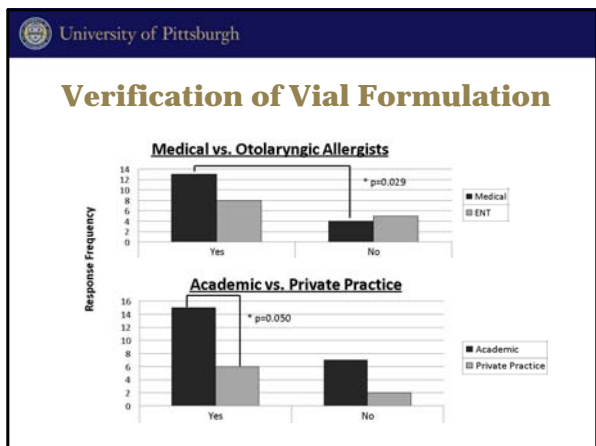
- Most allergy compounding done in one location, >90%
- 52% perform systems review/site visit/chart audits
- 27% physicians do not verify formulation of vial before/after mixed
- 87% screen for asthma prior to giving injections
- 97% require that patients wait at least 20-30 mins after shot
- 62% perform mock anaphylaxis drills
- 40% provide home immunotherapy
- 36% physicians have heard of quality metric but not sure what it means (21% answered no)

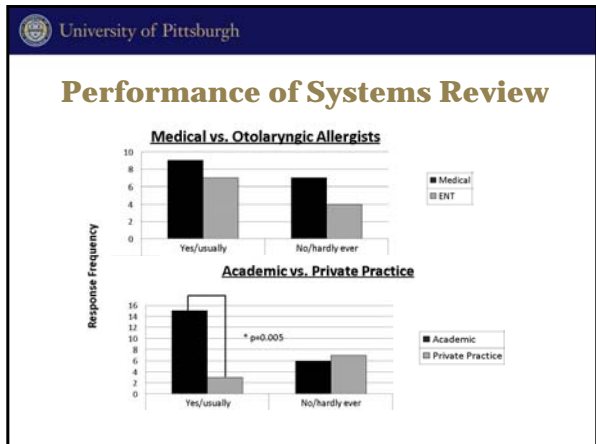


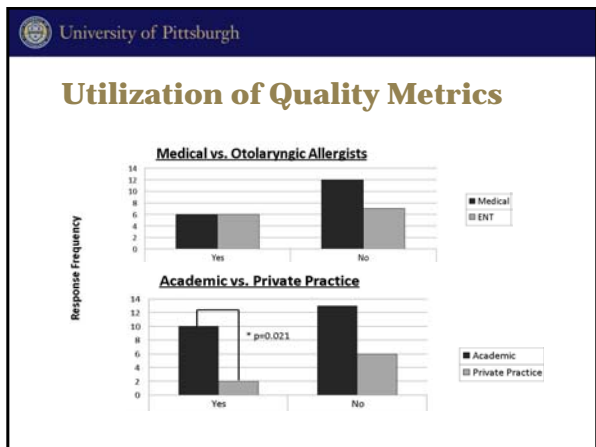
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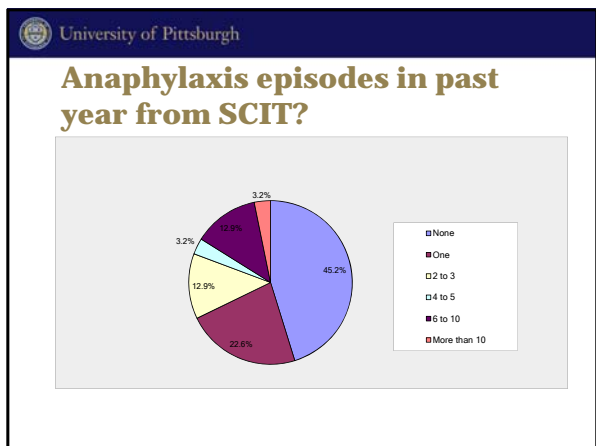




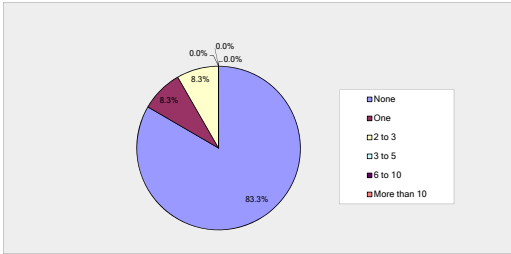








How many adverse reactions on home immunotherapy in past 5 years?



Where do we start?

- Self-Assessment/Systems Review
 - Determine strengths/weaknesses
 - Perform regular audits
 - Physician oversight of competency
- Standardize training, run mock anaphylaxis drills
- Be aware of current guidelines and utilize them!
- Decide which metrics are important to follow patients
- Become informed of new legislation and requirements

USP 797

- Simple transfer via sterile needles/syringes of commercial sterile allergen products
- Contain appropriate substances to prevent growth of microorganisms
- Thorough hand cleansing procedure with water and nail cleaner followed by washing to elbows for 30 seconds with antimicrobial soap and water
- Hair covers, facial hair covers, gowns, and face masks
- Sterile gloves compatible with sterile 70% isopropyl alcohol
- Disinfect ampule necks and vial stoppers with 70% IPA
- Label of each vial lists name, "by use date" and storage temperature range



Conclusions

- Quality metrics include process, outcome, and patient satisfaction measures
- In the current era of health reform, quality measures will become necessary
- Internal and external audits can be helpful
- Otolaryngic allergists and providers must be versed in the discussion of quality metrics



Thank you!



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