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

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Disclosures

• This speaker has no commercial relationships to disclose.

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.
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


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


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


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
Allergy Sites: Relative to City of Pittsburgh/Mercy Center

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)

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

2. Allergy Training and Standardization

   ALLERGIES AND IMMUNOTHERAPY
   Teaching Manual
   Division of Asthma and Allergy
   Updated 11/15/2015
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

- 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
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
Outcome Measures

- Consider using a validated symptom survey to follow patients
- Monitoring of asthma control
- Yearly physician follow-up
- Patient compliance, i.e., what percentage of patients have reached maintenance or completed the full course of immunotherapy?

Patient Physician Contract

- All patients required to stay 30 minutes after injection.
- Must carry epinephrine device at time of injection.
- Try to be compliant with injections.
- Follow-up with physician on a yearly basis.
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
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)
Performance of Systems Review

Utilization of Quality Metrics

Anaphylaxis episodes in past year from SCIT?
How many adverse reactions on home immunotherapy in past 5 years?

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<th>Percentage</th>
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<tr>
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<tr>
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<tr>
<td>3 to 5</td>
<td>0.0%</td>
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<tr>
<td>6 to 10</td>
<td>0.0%</td>
</tr>
<tr>
<td>More than 10</td>
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</table>

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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