A Procedural Competency Demonstration of Skin Testing and Extract Preparation

Paul J Dowling, MD
Director, Allergy/Immunology Training Program
Associate Professor, Dept. of Pediatrics
University of Missouri – Kansas City School of Medicine
Children’s Mercy Hospitals and Clinics
Disclosures

• None related to this topic
ACGME Requirements

- IV.B.1.b).(1).(b) Residents must, to the satisfaction of the program director or designated faculty member, demonstrate proficiency in performing and evaluating results for the following:
  
  (Core) IV.B.1.b).(1).(b).(i) allergen immunotherapy; (Core)
  IV.B.1.b).(1).(b).(ii) contact or delayed hypersensitivity testing; (Core)
  IV.B.1.b).(1).(b).(iii) drug hypersensitivity diagnosis and treatment; (Core)
  IV.B.1.b).(1).(b).(iv) food hypersensitivity diagnosis and treatment; (Core)
  IV.B.1.b).(1).(b).(v) immediate hypersensitivity skin testing; (Core)
  IV.B.1.b).(1).(b).(vi) immunoglobulin treatment and/or other immunomodulator therapies; and, (Core)
  IV.B.1.b).(1).(b).(vii) pulmonary function testing. (Core)
Historical Perspective: Clinical Competency Workgroup

• In 2012 the ACGME RRC for Allergy/Immunology announced they were going to be looking at Procedural Competency and wanted to set a “number”.

• Core Curriculum Education & Residency Review Committee (CCERR) of the Program Director’s Assembly wanted to decide what procedural competency should look like and developed checklists to assess competency.

• These are: knowledge based; look at performance of the test; interpretation; and the overall ability to perform the procedure competently and safely.

• Today will discuss performing skin testing and immunotherapy workshops with your own fellows.
Procedural Competency Workshop

• Offer Hands on Experience for Fellows and Nurses
• Important for fellows to know how to do be proficient not only in knowledge but skills in caring for patients
• Way of verifying these skills on an annual basis
Performing Competency Training Workshops

- Schedule during teaching conference time
- Pick relaxed quiet location
- Enlist your associate program director’s help
- **To pass they must get all the information correct / individual judgement**
- Allow 1st year fellows to do competency training while waiting to have enough experience to get signed off
Immediate Hypersensitivity Skin Testing


• Suggested Proficiency Testing and Quality assurance Technique for Skin Prick Testing

• Coefficient of variation should be less than 30%
Immediate Hypersensitivity Skin Testing
Materials Needed

- Alcohol wipes
- Scotch Tape
- Black Fine Tip Marker
- White Copy Paper
- Dermapiks (or similar skin test device)
- Skin test concentrations for histamine and saline
- Timer
- Ruler of some type
- Willing subject
Suggested Proficiency Testing and Quality Assurance Technique for Skin Prick Testing:

- Using desired skin test device, perform skin testing with positive (histamine 1-10) and negative controls (saline 1-10) in an alternate pattern on a subject's back.

- Record histamine results at 8 minutes by outlining wheals with a felt-tip pen and transferring results with transparent tape to a blank sheet of paper.

- Record saline results at 15 minutes by outlining wheal and flares with a felt-tip pen and transferring results with transparent tape to a blank sheet of paper.

- Calculate the mean diameter $X = (D + d)/2$; $D =$ largest diameter and $d =$ perpendicular diameter at midpoint of $D$.

  - **Histamine**
    - Calculate the mean and standard deviations of each mean wheal diameter.
    - Determine coefficient of variation $= \frac{\text{standard deviation}}{\text{mean}}$.
    - Quality standard should be less than 30%.

  - **Saline**
    - All negative controls should be $< 3$-mm wheals and $< 10$-mm flares.

Figure 2. Suggested proficiency testing and quality assurance technique for skin prick testing.
Alternating Skin Tests with Histamine and Saline

- Back (or forearm) is cleaned with alcohol
- Skin is marked with alternating “H’s” and “S’s” at a sufficient distance apart in 2 or 3 columns
- A total of 10 Saline prick test are placed, followed by 10 Histamine skin tests
- A timer is set for 8 minutes for measuring histamine; 15 minutes for saline
- These are followed by 4 intradermals with saline and histamine (2 each)
Taping the individual skin tests:

- After marking the outline of the wheal & flare with a fine tip black marker, apply overlapping strips of scotch tape to each wheal and flares
- Press firmly over the entire surface
- Lift the edge and remove as one piece
- Transfer to a white piece of copy paper
Measuring the Largest Diameter of the Wheal

- Calculate the mean diameter \( (X) = \frac{D + d}{2} \); \(D\) = largest diameter, \(d\) = perpendicular diameter and midpoint of \(D\)

- All negative controls should be < 3mm of wheal and <10mm of flare
Coefficient of Variation (CV)

- CV = standard deviation / mean x 100
- Should be less than 30%

How To Calculate Standard Deviation 80

By sonia

First, you need to determine the mean. The mean of a list of numbers is the sum of those numbers divided by the quantity of items in the list (read: add all the numbers up and divide by how many there are).

Then, subtract the mean from every number to get the list of deviations. Create a list of these numbers. It's OK to get negative numbers here. Next, square the resulting list of numbers (read: multiply them with themselves).

Add up all of the resulting squares to get their total sum. Divide your result by one less than the number of items in the list.

To get the standard deviation, just take the square root of the resulting number.

I know this sounds confusing, but just check out this example:

your list of numbers: 1, 3, 4, 6, 9, 19
mean: \( (1+3+4+6+9+19) / 6 = 42 / 6 = 7 \)
list of deviations: -6, -4, -3, -1, 2, 12
squares of deviations: 36, 16, 9, 1, 4, 144
sum of deviations: 36+16+9+1+4+144 = 210
divided by one less than the number of items in the list: 210 / 5 = 42
square root of this number: square root (42) = about 6.48
<table>
<thead>
<tr>
<th>Immediate Hypersensitivity Skin Test Competency Check List</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge Based</strong></td>
</tr>
<tr>
<td>A/I Fellow understands the indications for performing the test and alternatives to skin testing.</td>
</tr>
<tr>
<td>A/I Fellow understands the factors that can affect testing (age, location of placement of tests, concurrent medications).</td>
</tr>
<tr>
<td>A/I Fellow understands the need for positive and negative controls.</td>
</tr>
<tr>
<td>A/I Fellow understands when the test should be read.</td>
</tr>
<tr>
<td>A/I Fellow understands the reliability of the test depends on the skill of tester, test instrument: skin color, skin reactivity, age and potency and stability of test reagents.</td>
</tr>
<tr>
<td>A/I Fellow understands the difference between prick/puncture and intradermal testing and what allergens appropriate for each testing method.</td>
</tr>
<tr>
<td>A/I Fellow understands the risk and risk factors for systemic reactions by either prick/puncture or intradermal testing.</td>
</tr>
<tr>
<td>A/I Fellow understands the intervention needed to treat systemic reactions.</td>
</tr>
<tr>
<td>A/I Fellow adequately completes the Proficiency Testing Technique for Prick/Puncture. (Oppenheimer and Nelson, 2006)</td>
</tr>
<tr>
<td>A/I Fellow adequately completes the Proficiency Testing Technique for Intradermal tests. (Oppenheimer and Nelson, 2006)</td>
</tr>
<tr>
<td>A/I Fellow is able to differentiate significant from insignificant responses including dermatographism.</td>
</tr>
<tr>
<td>A/I Fellow understands that the preferred documentation should be measuring the wheal and flare response.</td>
</tr>
<tr>
<td>A/I Fellow adequately explains the results to the patient or patient's families.</td>
</tr>
</tbody>
</table>
Immunotherapy/Extract Mixing Workshop and Competency
Covid Protocol
Procedural Competency Workshop

- Selection of Cases covering various common scenarios
- Opportunity to do actual mixing of extracts
- Review of sterile technique
- Opportunity to do a Fill test
- Do workshop 2 times/yr.
Covid Protocol
Materials Needed

• Alcohol Pads
• Sanitizing Wipes
• Vinyl gloves
• 1 and 5 ml syringes
• 21 or 23 gauge needles
• Paper labels, labels for extract grouping, copy of skin test sheet
• 5 ml extract bottles with colored tops or tags (Green, Blue, Yellow, Red)
• Diluent or Sterile Saline
• Sharps container
• Expired extract bottles relabeled as common allergen extracts used in your clinic
Extract Mixing Case Scenario

Case 1:
A patient recently transferred into your office. He had been receiving IT for 2.5 years from an allergist in Kentucky. The family believes he is much better on shots. He has been receiving allergy shots once a month as Maintenance. The family has a copy of his prescription from his last allergist and his skin test sheet. The test are with extracts not used in your office and are reported on a scale of 1+ - 4+ with no measurements recorded. The family is requesting shots ASAP.

What do you do?
### Extract Mixing Case Materials

#### Table 1: Case Material Information

| Case No. | Description | Quantity | Date
|----------|-------------|----------|------
| Case A   | Mixing Case | 100      | 01/01/2023
| Case B   | Mixing Case | 50       | 01/02/2023
| Case C   | Mixing Case | 20       | 01/03/2023

#### Table 2: Case Material Details

| Material | Type | Source | Quantity | Date
|----------|------|--------|----------|------
| Material A | Type A | Source A | 100      | 01/01/2023
| Material B | Type B | Source B | 50       | 01/02/2023
| Material C | Type C | Source C | 20       | 01/03/2023

#### Table 3: Case Material Notes

- Note 1
- Note 2
- Note 3

#### Figure 1: Mixing Case Setup

- Diagram of case setup with materials placed accordingly.

#### Figure 2: Case Material Testing

- Results of testing materials for compatibility.

---

**Children's Mercy Kansas City**
<table>
<thead>
<tr>
<th>Knowledge Based</th>
<th>Performance of the test</th>
<th>Interpretation of the test</th>
<th>Overall Perform Competently and Safely</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/1 Fellow identifies indications for immunotherapy (IT).</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow identifies contraindications for immunotherapy</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow understands the need for positive and negative controls.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow identifies what allergens are positive on skin testing and should be included in extracts</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow differentiates which extracts can be mixed in the same vial</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow determines the optimal dose for each component in extract</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow obtains appropriate paperwork and consent prior to start IT.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow explains procedure, purpose and important information to patient and family</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow explains risks and benefits of IT.</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow identifies contraindications to receiving injection</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow receives a passing score on JCAI Immunotherapy Module</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow Demonstrates how to properly write extract prescription and order extracts. Test Patient/skin test 1 Test Patient/skin test 2</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow describes colors and demonstrates how to dilute the bottles: • 1:1000 • 1:1000 • 1:1000 • Maintenance (0)</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow Successfully performs “Fill Test” to check sterile technique</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow verbalizes potential reactions from immunotherapy</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow verbalizes treatment for reactions</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/1 Fellow verbalizes when to stop immunotherapy</td>
<td>x</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Procedural Competency Sign Off

CHECK LEARNING RESOURCES USED:
- Observation of procedure/review with faculty & staff
- Lecture(s)
- Selected readings
- Problem Based Learning / Case studies
- Web based resources

I attest that A/I fellow, ______________________ is competent in the use of immediate hypersensitivity skin testing in appropriately selected adult and pediatric patients. The fellow meets or exceeds a Level 4 Milestone for this procedure.

Date ________________ Program Director’s signature ______________________________
Chapter 797 USP Compounding Guidelines

• Beyond the scope of this talk

• USP has finalized **Chapter 797** standards for sterile compounding, including standards specifically for physician in-office compounding of allergen extracts in allergy practices. The purpose of the standards is to ensure safe treatment of an allergy clinic's patients

• Both the **AAAAI and the ACAAI** have resources on their websites outlining the new requirements

  [https://education.aaaai.org/compounding-corner](https://education.aaaai.org/compounding-corner)

• Important for your fellows and your staff to know the new requirements especially if you are doing any mixing in your clinics
Handy Hints in Preparation

• Inform fellows to avoid antihistamines for 1 week prior to Skin Testing Competency
• Check vacation schedules when planning competency testing
• Make sure the fellows have had a minimum required number of procedures under their belts prior to scheduling …i.e.. easy to do skin testing in the late Fall of year 1; Immunotherapy likely end of year 1
• Fellows may do a competency earlier for practice but will need to repeat it once they meet minimum requirements and the program director thinks they are competent.
Handy Hints in Preparation II

• Extract mixing workshop is done 2 times/year regardless of competency status for training purposes
• With new requirements important fellows and staff have training and certification in mixing in case an extract is needed immediately for training programs without a dedicated person mixing extracts on site
• I do not test for intradermals if a female fellow is pregnant, wait until after delivery
Summary

• Documenting Procedural Competencies is a required part of fellowship training

• Procedural Competency Checklists are available for all ACGME/ABAI required procedures

• Some competencies lend themselves to hands on training workshops

• With a little effort these workshops can easily be done in any program
SERENITY!
Thank You for Your Attention!

Questions ?