Allergy Extract Preparation Guidelines

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NO CONFLICTS
Allergy Extract Preparation Guidelines

• 2006 – USP proposes amendments to Chapter 797
• Allergy/ENT notified and begin discussions with USP
• USP experienced consultant retained
• New Allergy extract preparation guidelines developed
• Guidelines approved by AAAAI, ACAAI, JCAAI, AAOA
• Guidelines published in Practice Parameters and are standard of care
Why Have Vial Extract Prep Guidelines

• Specialty establishes its own standard of care
• Without specialty guidelines in this area we would be subject to USP guidelines
• Value Based purchasing of physician services coming
• Medicare database for 95010 and 95015 shows great variation in number of skin tests
  – This variation caused CMS to require us to re-establish work values for these codes
• Could be possible for other codes as well
Who May Prepare Vials

• State legislation unclear over who may prepare vials
• Has been a member issue
• Usually regulated by State Pharmacy Act
• Many states do not list physicians
• Approved by Academy and College and are in Practice Parameters
  – “appropriately trained health professionals including but not limited to, RN’s, PA’s APN’s and Physicians”
Allergy Extract Preparation Guidelines

• Extract Preparation Personnel Qualifications
  – Anyone who prepares vials must be trained – See Physician Instruction Guide – training materials online
  – Pass written quiz, every 5 years, on aseptic technique and extract preparation – quiz online www.JCAAI.org
  – Cannot fail test
  – Must pass media fill test annually – information available online
  – Failure on media fill test require re-training and re-testing

• Basic Components of training
  – Must understand aseptic hand cleaning and disinfection of mixing surfaces and anaphylaxis
  – Must be able to correctly identify, measure and mix ingredients
  – Must be an appropriately trained health professional
Allergy Extract Guidelines (cont)

• Trained physician responsible for training
• Responsible physician should review online training materials with anyone in office who prepares vials – before they take quiz
• Recommend Keep Vial Prep Binder
  – Physician Instruction Guide
  – Record of all who are trained
  – Record of all who passed quiz and media fill test
  – Completed competency assessment form for each employee
Other Acceptable Training

• On the job training from qualified co-worker
• AAAAI or ACAAI workshops and seminars
• Manuals from allergen extract manufacturers
• Journal Articles
• Online courses (in process)
  – www.instanted.com click on Project Immune Readiness: password= paper
Allergy Extract Preparation Guidelines - The rules

• Bacteriostasis: Allergy extract dilutions must be bacteriostatic:
  – Contain 0.25% phenol or, if phenol concentrate is less, contain at least 20% glycerin

• Prepare dilutions in accordance with manufacturers instructions

• Follow manufacturers expiration dates
  – Expiration date for a vial is the earliest expiration date recommended for any single extract in the mix
  – Any dilution <1:100 must have a shorter expiration than the same extract at 1:100 dilution
Extract Stability Rules – See Guidelines

• Diagnostic products
  • Percutaneous materials-one year: Intradermals – 6 month

• Immunotherapy treatment sets
  • 1:10 – 1:5000 – one year
  • 1:50,000 and weaker – 3-6 months
  • 500 AU/ml and stronger – 1 year, <500AU -3-6 months
  • 1000 BAU/ml and stronger – one year
    <1000 BAU – 3-6 months
The Rules (cont)

• Separate aqueous extracts with high proteolytic enzymes from other extracts
• Store extracts at 4°C to reduce potency loss – storage in designated refrigerator not used for food or specimens
• Do not leave vials out all day
• Label vials clearly with patient name and beyond use date
• Mixing log kept with patients name, extract used for mixing, mixing date, expiration date and lot numbers
The rules (cont)

• Aseptic Technique
  – Designate specific extract prep site which is restricted to decrease microbial contamination
  – Sanitize area with 70% isopropanol with no dyes or glycerin
  – Extract prep personnel must thoroughly wash hands to wrists with detergent or soap and potable water. May sanitize hands by treatment with alcohol containing sanitizing agents and/or 70% isopropanol
The Rules (cont)

• Aseptic Technique (cont)
  – Necks of ampoules to be opened and stoppers of vials to be needle punctured must be sanitized with isopropanol
  – Must avoid direct contamination of sterile needles, syringes and other drug administration devices
• After mixing is complete, visual inspection is performed to insure physical integrity of vial
• Single dose allergen extract shall not be stored for subsequent re-use
USP Rules for Allergy Extract Preparation

• USP Rules Enforced by The Joint Commission (TJC)
• Thorough hand cleaning including under nails with nail cleaner – followed by hand and arm wash to elbow for 30 seconds – TJC only
• Cover hair and facial hair – wear mask & gown – TJC Only
• Do antiseptic hand cleaning with IPA
• Wear powder-free sterile gloves and disinfect with 70% IPA and repeat thru session – TJC only
Allergy Immunotherapy-Physician Instruction Handbook

- Posted on line – [www.jcaai.org](http://www.jcaai.org)
- Practitioner Qualifications reviewed
- Allergen Extracts – types and sources
- Allergy Extract mixing conditions – as above
- Writing the prescription for extract
- Color coding, Labels and Expiration dates
Extract Instruction Handbook – cont

• Mixing individual patient allergy extract sets
  – How to do it in your shop
• Stinging Insect Allergen preparation
• Allergen extract stability
• Competency assessment checklist
• References
• You should instruct your staff personally
# Appendix 1: Initial and Ongoing Competency Assessment: Allergen Extract Mixing

<table>
<thead>
<tr>
<th>Name__________</th>
<th>Job Title______</th>
<th>Clinic:_______</th>
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</table>

<table>
<thead>
<tr>
<th>Allergen Extract Preparation</th>
<th>Date</th>
<th>Validated by</th>
<th>Comments or Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passed a written test on aseptic technique and extract preparation.</td>
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<tr>
<td>Passed media-fill test or equivalent verifying aseptic technique</td>
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<tr>
<td>Reviews prescription(s) for accuracy</td>
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<tr>
<td>Accurately prepares labels and shipping material (if applicable)</td>
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</table>
## Appendix 1: Initial and Ongoing Competency Assessment: Allergen Extract Mixing (cont.)

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<th>Date</th>
<th>Validated by</th>
<th>Comments or Notes</th>
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<tbody>
<tr>
<td>Checks expiration dating of antigens and diluents</td>
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<tr>
<td>Cleans mixing surface and washes hands appropriately</td>
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<tr>
<td>Uses appropriate personal protective equipment</td>
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<tr>
<td>Checks stocks &amp; mixed extracts for turbidity/particulate matter</td>
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<tbody>
<tr>
<td>Swabs vials off with antiseptic (e.g. alcohol swabs)</td>
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<tr>
<td>Draws up appropriate amounts</td>
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<tr>
<td>Disposes of syringes in an appropriate manner</td>
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<tr>
<td>Documents lot #’s and preparation details per clinic SOP</td>
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</thead>
<tbody>
<tr>
<td>Packages materials and supplies in a neat and efficient manner</td>
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</tbody>
</table>

I understand that of all the topics listed, I will be allowed to perform only those for my skill level/scope of practice and only after I have demonstrated competency.

Employee signature______________________________________________

Date__________________________
Appendix 1: Initial and Ongoing Competency Assessment: Allergen Extract Mixing (cont.)

<table>
<thead>
<tr>
<th>* Self-Assessment:</th>
<th>+Evaluation/Validation Methodologies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = Experienced</td>
<td>T = Tests</td>
</tr>
<tr>
<td>2 = Needs Practice/Assistance</td>
<td>D = Demonstration</td>
</tr>
<tr>
<td>3 = Never Done</td>
<td>V = Verbal</td>
</tr>
<tr>
<td>NA = Not Applicable</td>
<td>I = Interactive Class</td>
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</table>
RECOMMENDATIONS FOR SAFE IT

• Annual CME/CUE in safe administration of IT
• Trained Qualified Vial/Extract Preparers
• Prepare vials in quiet environment
• All vials patient specific – no off-the-board
• Standardized forms in IT parameter
• Triple identity checking
• Label vials as per Extract Preparation Guidelines

• Aaronson and Gandhi JACI 2006
RECOMMENDATIONS FOR SAFE IT (cont)

• Individual drawing up dose must be same one administering IT
• Do not draw up dose until patient in room
• Only one patient receiving IT allowed in room at time IT administered
• Advise all IT patient to wait 30 minutes after IT
• Office staff must report all incorrect injections immediately and all near misses as soon as possible
Requirements for Direct Supervision of Allergy Testing

• Medicare has rules for physician supervision of various in office procedures

• Allergy Skin testing – 2
  – Physician must be physically present in office suite and immediately available to furnish assistance
  – Physician work for Allergy skin test codes requires “test interpretation and report by physician”
Requirements for Physician Work in Vial Preparation

• Physician Determines Antigens and antigen concentration to be used
• Physician Determines Dosage Schedule
• Physician provides direct supervision for sterile preparation of vials and needed quality control of the product through testing or other means