The Changing Environment in Allergy & Immunology

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President, ABAI
Chief, Asthma, Allergy & Immunology Division, UVA Health

November 8, 2021
Changing Environment in Allergy & Immunology

The 5 W’s

- Who
- What
- When
- Where
- Why
Changing Environment in Allergy & Immunology
The 5 W’s

• Who
• What
• When
• Where
• Why

Changing Environment in Allergy & Immunology
The Who
Changing Environment in Allergy & Immunology

The Who- Precision Medicine

“One size doesn’t fit all.”

“Tailoring preventive measures and treatments to characteristics of each patient to obtain the best clinical outcomes while also enhancing the cost-effectiveness of interventions.”

Galli SJ. JACI 2016;137:1289-300

Changing Environment in Allergy & Immunology

Precision Medicine

100 yrs of AIT as a model of precision medicine

Changing Environment in Allergy & Immunology
Precision Medicine

- Future AIT precision
  - Patient selection
  - Allergens
  - Extracts
  - Adjuvants
  - Response biomarkers
  - Duration

Galli SJ. JACI 2016;137:1289-300

Changing Environment in Allergy & Immunology
The Who- AIT Disparities of Care

- At risk
  - Low income
  - Underrepresented minorities
  - Other social determinants of health

- Schedule adherence
  - Missed doses: Medicaid 32%, Medicare 24.4% (Commercial insurance16%)
  - Early discontinuation: Hispanic pts 1.5x more likely to discontinue <2yrs

- Gap reduction
  - Multi-leveled approach needed

Davis CM et al. 2021 JACI; 147:1579-93.
Changing Environment in Allergy & Immunology
The 5 W’s

- Who
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Increased allergen burden:
Higher counts
Longer seasons

Anderigg WRL et al. PNAS 2021;118 (7):e2013284118
Changing Environment in Allergy & Immunology

The What: Molecular Diagnostics

- Large arrays
- Cross-reactivity
- Components
- Prognosis
- Monitoring
- Duration

## Changing Environment in Allergy & Immunology
### The What - Manufacturing, Mixing & Standardization

<table>
<thead>
<tr>
<th>Category</th>
<th>Indications</th>
<th>Allergens</th>
<th>Extract standardization</th>
<th>Mixing &amp; mixes</th>
<th>SLIT</th>
<th>Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single ref std (FDA)</td>
<td>AR/AC, asthma, AD, venom</td>
<td>Multiple &gt;&gt;&gt; Single</td>
<td>Single ref std (FDA)</td>
<td>Manufacturer, pharmacy (NPP)</td>
<td>Tablets (liquid)</td>
<td>FDA (USP)</td>
</tr>
<tr>
<td>Multiple ref stds (manufact)</td>
<td>AR/AC +/- asthma, venom</td>
<td>Single &gt;&gt;&gt; Multiple</td>
<td>Multiple ref stds (manufact)</td>
<td>Manufacturer, pharmacy (NPP)</td>
<td>Tablets (liquid)</td>
<td>EU &amp; Member States</td>
</tr>
</tbody>
</table>

- **Indications**: AR/AC, asthma, AD, venom
- **Allergens**: Multiple >>> Single
  - Unmodified
  - Aqueous >>> Adsorbed
- **Extract standardization**: Single ref std (FDA)
- **Mixing & mixes**: Phys office > manufacturer
- **SLIT**: Tablets (liquid)
- **Regulation**: FDA (USP)

### Changing Environment in Allergy & Immunology
### The What - FDA Extract Review & Classification

- **2004**: CBER, FDA formed internal committee to review scientific and medical data and peer reviewed literature on safety and effectiveness of non-standardized allergen extract products (Category IIIA products from 1983 review)
- **2011**: Non-standardized licensed allergen extracts were classified into 5 categories. The list was presented to APAC (Allergenic Products Advisory Committee) for review.

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Mahler V et al. JACI 2019;143:813-2
1,269 Allergen Extracts Classified

<table>
<thead>
<tr>
<th>Classification</th>
<th># Extracts</th>
<th>Addressed in Literature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1</td>
<td>480</td>
<td>Diagnosis and Treatment</td>
</tr>
<tr>
<td>Table 2</td>
<td>134 (Foods)</td>
<td>Diagnosis addressed</td>
</tr>
<tr>
<td>Table 3</td>
<td>73 Non-Food</td>
<td>Diagnosis addressed</td>
</tr>
<tr>
<td>Table 4</td>
<td>565</td>
<td>Minimal to No Literature Relating to Diagnosis or Treatment</td>
</tr>
<tr>
<td>Table 5</td>
<td>17</td>
<td>Potential Safety Issues</td>
</tr>
</tbody>
</table>

13 removed by FDA for safety concerns
Ongoing voluntary manufacturer withdrawals

Changing Environment in Allergy & Immunology
The What- Standardized Extracts (U.S.)

**Standardized Pollens**
- Bermuda Grass (Cynodon dactylon)
- Kentucky (June) Bluegrass (Poa pratensis)
- Meadow Fescue Grass (Festuca elatior)
- Orchard Grass (Dactylis glomerata)
- Redtop Grass (Agrostis alba)
- Perennial Ryegrass (Lolium perenne)
- Sweet Vernal Grass (Anthoxanthum odoratum)
- Timothy Grass (Phleum pretense)
- Short Ragweed (Ambrosia artemisiifolia)

**StandardizedVenom or Venom Protein**
- Honey Bee Venom (Apis mellifera)
- Wasp Venom Protein (Polistes spp)
- Yellow Hornet Venom Protein (Dolichovespula arenaria)
- Yellow Jacket Venom Protein (Vespula spp)
- White Faced Hornet Venom Protein (Dolichovespula maculata)
- Mixed Vespid Venom Protein (mixed yellow jacket, yellow hornet, and white faced hornet)

**Standardized Epidermals**
- Cat Hair (Felis domesticus)
- Cat Pelt (Felis domesticus)

**Standardized Insects**
- Mite D.f. (Dermatophagoides farinae)
- Mite D.p. (Dermatophagoides pteronyssinus)

**Sublingual Tablets**
- Ragwitek® (Ragweed)
- Grastek® (Timothy)
- Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue)
- Odactra™ (Dust mites- Df, Dp)
Changing Environment in Allergy & Immunology
The What- Immunomodulator co-administration

- Omalizumab add on therapy
  - Grass, Birch, HDM AIT
  - 4 RCTs, 1 real-world trial
  - Decreased AEs &/or enhanced efficacy
  - No AE’s starting AIT on omalizumab
  - No AE’s withdrawing omalizumab on AIT
  - Cost limitations
  - Build-up greatest potential
  - More studies needed

- Other immunomodulators?

Pfaar et al JACI 2021;9:1791-803
Changing Environment in Allergy & Immunology

The 5 W’s

• Who
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• Why

Emerging data impacting allergen immunotherapy initiation, schedules & mixing needs?

- SLIT
  - pre/co-seasonal
  - continuous
  - sustained responsiveness

- SCIT
  - Treatment
  - Treatment & prevention
  - Prevention

Prevention of New Sensitivities in Children
Dp AIT for 3 Years


Preventive Allergy Treatment (PAT) Study

- Multi-center prospective European study
- 205 children, ages 7-15, with allergic rhinitis:
  - 191 followed for 2 or 3 years
- Control group vs. active treatment group

**PAT Study - Decreased Asthma Symptoms after AIT**

![Graph showing asthma symptoms pre-treatment and after 1 and 2 years of AIT]


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**Changing Environment in Allergy & Immunology**

**The 5 W's**

- Who
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- Why
Changing Environment in Allergy & Immunology
The Where (& How)- Routes

Efficacy and safety of intralymphatic immunotherapy in allergic rhinitis: A systematic review and meta-analysis

- Safe
- Not more effective than placebo
- High variation in trials
- More data needed
Changing Environment in Allergy & Immunology
The Where (& How)- Mixing Allergen Extracts

• Mixing Locations
  – Manufacturer
  – Pharmacy
  – Physician Office

• Regulatory Environment
  – FDA
  – USP
  – Joint Commission
  – CMS

Changing Environment in Allergy & Immunology
The Where (& How)- Mixing Environment Guidance

USP <797>
• ISO 5 PEC (Primary Engineering Control) OR Allergenic extract compounding area (AECA)
  – Away from
    • unsealed windows/doors leading outdoors or high traffic
    • restrooms, warehouses, food prep areas
    • sinks (1 meter)
  – Visible perimeter
  – Well lit w/ controlled temp/humidity
  – Restricted access
  – Dedicated use
  – Clean & intact surfaces (no carpets)
  – Frequent surface disinfection
  – Vial stopper disinfection

Joint Commission (5/11/2020)
• Outside ISO 5 environment if
  – Simple sterile transfers
  – Contain antimicrobials
  – Staff Preparers
    • Hand hygiene
    • Garb
    • Ampule & stopper disinfection
  – Labels
    • BUD, temp, single pt name, guidelines
  – No single dose storage/re-use
Changing Environment in Allergy & Immunology
The Where (& How)- 2022 CMS Proposed Rule Changes

- **RVU multiplier** -3.8%
  - Congressional mandate
  - 2021 +3.75% offset
  - 2022?

- Expanding BH & Telehealth

- Higher QPP incentive performance thresholds

- **2022 overall allergy services impact of -5.3%**

### Allowable Charges ($mil)

<table>
<thead>
<tr>
<th>Allowed Charges (mil)</th>
<th>wRVU Impact</th>
<th>PE RVU Impact</th>
<th>MP RVU Impact</th>
<th>Overall Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>$220</td>
<td>0%</td>
<td>-2%</td>
<td>0%</td>
<td>-2%</td>
</tr>
</tbody>
</table>

### Table: CMS 2022 Proposed Changes

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>2021 RVU</th>
<th>2021 Pay</th>
<th>% Change 2022</th>
<th>2022 RVUs (Prop)</th>
<th>2022 Pay (Prop)</th>
</tr>
</thead>
<tbody>
<tr>
<td>95115</td>
<td>AIT, one injection</td>
<td>0.27</td>
<td>$9.42</td>
<td>14.1%</td>
<td>0.32</td>
<td>$10.75</td>
</tr>
<tr>
<td>95117</td>
<td>AIT, two or more injections</td>
<td>0.33</td>
<td>$11.51</td>
<td>10.9%</td>
<td>0.38</td>
<td>$12.76</td>
</tr>
<tr>
<td>95144</td>
<td>Antigen therapy services (single dose vial)</td>
<td>0.48</td>
<td>$16.75</td>
<td>-7.8%</td>
<td>0.46</td>
<td>$15.45</td>
</tr>
<tr>
<td>95145</td>
<td>Antigen therapy services (1 venom)</td>
<td>1.00</td>
<td>$34.89</td>
<td>-16.3%</td>
<td>0.73</td>
<td>$29.22</td>
</tr>
<tr>
<td>95146</td>
<td>Antigen therapy services (2 venoms)</td>
<td>1.84</td>
<td>$64.20</td>
<td>-15.8%</td>
<td>1.61</td>
<td>$54.07</td>
</tr>
<tr>
<td>95147</td>
<td>Antigen therapy services (3 venoms)</td>
<td>1.82</td>
<td>$63.51</td>
<td>-16.6%</td>
<td>1.54</td>
<td>$51.72</td>
</tr>
<tr>
<td>95148</td>
<td>Antigen therapy services (4 venoms)</td>
<td>2.66</td>
<td>$92.82</td>
<td>-17.9%</td>
<td>2.27</td>
<td>$76.24</td>
</tr>
<tr>
<td>95149</td>
<td>Antigen therapy services (5 venoms)</td>
<td>3.54</td>
<td>$123.52</td>
<td>-17.9%</td>
<td>3.02</td>
<td>$101.43</td>
</tr>
<tr>
<td>95165</td>
<td>Supervision, prep &amp; provision of antigens (specify #)</td>
<td>0.46</td>
<td>$16.05</td>
<td>-12.1%</td>
<td>0.42</td>
<td>$14.11</td>
</tr>
<tr>
<td>95170</td>
<td>Whole body extract - insect/arthropod (specify #)</td>
<td>0.34</td>
<td>$11.86</td>
<td>-12.2%</td>
<td>0.31</td>
<td>$10.41</td>
</tr>
<tr>
<td>95180</td>
<td>Rapid desensitization procedure, each hour</td>
<td>3.95</td>
<td>$137.83</td>
<td>1.9%</td>
<td>4.18</td>
<td>$140.38</td>
</tr>
</tbody>
</table>
Changing Environment in Allergy & Immunology
The 5 W’s

- Who
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Changing Environment in Allergy & Immunology
The Why- Simple

Chance
FOR
A
Cure
"Advances in allergen immunotherapy have depended on the improved understanding of IgE-mediated immunologic mechanisms, the characterization of specific antigens and allergens, and the standardization of allergen extracts."

Summary Statement 1:
- The immunologic response to subcutaneous immunotherapy is characterized by decreases in the sensitivity of end organs and changes in the humoral and cellular responses to the administered allergens.

Summary Statement 6:
- Immunotherapy is effective for the treatment of allergic rhinitis, allergic conjunctivitis, allergic asthma, and stinging insect hypersensitivity. Therefore immunotherapy merits consideration in patients with these disorders as a possible treatment option.

Cox L et al. JACI 2011;127(1):S1-55.

Changing Environment in Allergy & Immunology

SUMMARY

- 5W’s
- 5R’s

5 Rights of Medication
Changing Environment in Allergy & Immunology

SUMMARY

• Who
  – Precision Med, Care Disparities
• What
  – Old & new extracts, diagnostics
• When
  – Treatment vs Prevention
• Where
  – Routes, Regulatory environment
• Why
  – Cure

Right patient
• Right drug
• Right dose
• Right route
• Right time

Personalizing Allergen Immunotherapy Treatments: The Field of Possibilities
Allowing the healthcare professional to adapt treatments to the profile and preferences of each allergic patient thanks to the...

Incorvaia C et al (Canonica)
Clin Mol Allergy 2021;19:10
# Thank You!!!

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 AM</td>
<td>Welcome and Introductions</td>
<td>Maureen M. Petersen, MD, FACAAI</td>
</tr>
<tr>
<td>9:35 AM</td>
<td>The Changing Environment in Allergy and Immunology</td>
<td>Michael R. Nelson, MD, PhD, FACAAI</td>
</tr>
<tr>
<td>9:55 AM</td>
<td>Allergens and Standardization</td>
<td>Maureen M. Petersen, MD, FACAAI</td>
</tr>
<tr>
<td>10:15 AM</td>
<td>Future Trends in Allergy Immunotherapy</td>
<td>Ignacio Ansotegui, MD, PhD</td>
</tr>
<tr>
<td>10:35 AM</td>
<td>The Media Fill Test and Glove Tip Test Explained</td>
<td>Tara Doran, RN, MHA</td>
</tr>
<tr>
<td>10:55 AM</td>
<td>Questions and Discussion</td>
<td></td>
</tr>
<tr>
<td>11:00 AM</td>
<td>Adjourn</td>
<td></td>
</tr>
<tr>
<td>11:30 AM</td>
<td>Welcome and Introductions</td>
<td>Bryan Martin, DO, FACAAI</td>
</tr>
<tr>
<td>11:35 AM</td>
<td>USP 797 and the Current Regulations Regarding Mixing</td>
<td>James L. Sublett, MD, FACAAI</td>
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<tr>
<td>11:55 AM</td>
<td>Understanding Potential Safety Issues in the Mixing Room</td>
<td>Bryan Martin, DO, FACAAI</td>
</tr>
<tr>
<td>12:15 PM</td>
<td>Experiences within a Large Mixing Practice</td>
<td>David J. Schwartz, MD</td>
</tr>
<tr>
<td>12:35 PM</td>
<td>The Allergenic Extracts Compounding Area (AECA)</td>
<td>Sarah Spriet DO, FACAAI</td>
</tr>
<tr>
<td>12:55 PM</td>
<td>Questions and Discussion</td>
<td></td>
</tr>
<tr>
<td>1:00 PM</td>
<td>Adjourn</td>
<td></td>
</tr>
</tbody>
</table>
Allergen Immunotherapy Standardization

Maureen M. Petersen, MD

ACAAI Allergen Extract Mixing Toolkit

http://college.acaai.org/toolkits/allergen-extract-mixing-toolkit/
Objectives

- The Basics of AIT
- Standardization of Prescription
- Standardization of Allergen Inclusion
- Standardization of Labeling
- Standardization of mixing

WHY?

- Effective for treatment of allergic conditions in adults and children
  - Allergic rhinitis
  - Allergic conjunctivitis
  - Allergic asthma
  - Atopic dermatitis
  - Insect allergy (Hymenoptera)
- Contamination is prevented by adequate training and the use of using aseptic technique
- Use of quality assurance checks throughout the mixing process is highly recommended
Extracts

- Liquid solutions containing dissolved allergenic proteins from pollens, dust mites, animal dander, molds, and insects.
  - Aqueous
  - Glycerinated
  - Lyophilized
  - Acetone-precipitated
  - Alum

- Manufactured by crushing raw material and “extracting” allergenic proteins by adding solvents
  - Purification steps follow resulting in liquid solution

Extracts: Aqueous

- Liquid-based extracts
  - Saline
  - Buffers
  - Liquid diluents
Extracts: Glycerinated
- Contain 50% glycerin

Extracts: Lyophilized
- Freeze dried aqueous extracts with increased stability
- Reconstituted with diluent to become aqueous
- Example: Hymenoptera venom extracts
Extracts: Acetone-precipitated

- Extra processing step of acetone precipitation
  - Acetone squeezes proteins of interest out of liquid into a solid form that is then re-dissolved in a diluent
- High concentration of stock solution
- Example: AP Dog

Extracts: Alum

- Extra processing step of adding aluminum hydroxide
- Allergens combine with alum and form complexes
- Slow release of allergens on injection
- Not appropriate for testing
- Larger dose at less frequent intervals
- Delayed reactions can occur
- Extracts require shaking
- Dilute with only certain diluents (do not use 10% glycerol-saline or HSA)
- NO FILTERING!
Diluents

- Keep allergens in suspension
- “Liquid backbone”
- Used to reconstitute lyophilized extracts and dilute extracts for diagnostic use and treatment
- Stabilizer
  - maintain the structure of the allergen in solution
  - Prevent sticking to the glass
- Preservative
  - Prevent microbial growth of bacteria and fungi

Diluents

- Dilutions can be made with one of several diluents:
  - Saline with 0.4% phenol
  - Saline with 0.4% phenol and 10% glycerin
  - Saline with 0.4% phenol and 0.03% human serum albumin (HSA)

- The allergenic proteins degrade more rapidly with saline alone compared with saline with added HSA or glycerin.
**Diluents: Glycerin**

- Preservative and stabilizer
- Bacteriostatic agent and inhibits proteolytic activity in fungal and cockroach extract at concentrations >20%
- SPT contains 50% glycerin (extract for intradermal testing is less concentrated)
  - Irritating at higher concentrations
- 50% glycerin causes injection site pain

**Diluents: Phenol**

- Bacteriostatic preservative
- Final concentration of 0.4%
- May denature proteins
  - HSA protects against this occurrence
Diluents: Human Serum Albumin (HSA)

- Stabilizer
- May protect against the negative effects of phenol on some extracts
- Prevents the allergenic protein from adhering to the surface of the vial

Standardization of Prescription

Each prescription / immunotherapy record should contain:

- Two patient identifiers (i.e., Name and Date of Birth or Medical Record Number)
- Patient contact information
- Name of prescriber
- Date of prescription
- Name, concentration, and volume for each allergen
- Name and volume of diluents
- Schedule for administration (including adjustments for interruptions and reactions)
Standardized Allergens

- Standardized based on allergen content by comparison of content to that of a US reference standard
  - Cat Hair
  - Cat Pelt
  - Dust Mite (D. farinae & D. pteronyssinus)
  - Grass: Bermuda Grass, Kentucky Bluegrass (June), Meadow Fescue Grass, Orchard Grass, Redtop Grass, Perennial Ryegrass, Sweet Vernal Grass, Timothy Grass
  - Short Ragweed
  - Hymenoptera: Honey Bee Venom, Wasp Venom, White Faced Hornet Venom, Yellow Hornet Venom, Yellow Jacket Venom, and Mixed Vespid Venom

Standardization of Allergen Inclusion

- Use relevant allergens for each patient
- Dose allergen extracts within minimum effective dose ranges
- Avoid combining extracts that may adversely affect overall potency
- Separate high protease extracts (mold, cockroach) from pollens
- Avoid mixing venom extracts with aeroallergen extracts
- Select and adjust doses of allergens using knowledge of cross-reactivity
Appendix 1. Effective Dose Range for Allergen Extracts, US Standardized Units

<table>
<thead>
<tr>
<th>Allergenic extract</th>
<th>Labeled potency or concentration</th>
<th>Proven effective dose range</th>
<th>Range of estimated major allergens isolated in US licensed extract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dust mite (Dermatophagoides pteronyssinus)</td>
<td>3,000, 5,000, 10,000, and 50,000 ALU/mL</td>
<td>5,500-2,000 AU</td>
<td>10,000 ALU/mL, 20-100,000 AU (day 1, day 1-5, day 1-5, 2-100,000 AU (day 2, day 2-5) 10-250,000 AU (day 3, day 3-5) 15-500,000 AU (day 4, day 4-5)</td>
</tr>
<tr>
<td>Cat hair</td>
<td>5,000 and 10,000 Bacterial Units</td>
<td>1,000-4,000 AU</td>
<td>10,000 ALU/mL, 20-100,000 AU (day 1) 2-100,000 AU (day 2) 7-8,000 AU (day 3, day 4) 15-150,000 AU (day 5)</td>
</tr>
<tr>
<td>Grass, standard</td>
<td>100,000 AU/mL</td>
<td>1,000-3,000 AU</td>
<td>10,000 ALU/mL, 20-100,000 AU (day 1) 2-100,000 AU (day 2)</td>
</tr>
<tr>
<td>Bermuda</td>
<td>10,000-40,000 AU/mL</td>
<td>100,000 AU/mL</td>
<td>10,000-40,000 AU/mL</td>
</tr>
<tr>
<td>Short ragweed</td>
<td>200-1,000 AU/mL</td>
<td>6-32 AU</td>
<td>150-1,000 AU/mL, 1-4,000 AU/mL</td>
</tr>
<tr>
<td>Naturalized</td>
<td>1-400 AU/mL</td>
<td>15-320 AU</td>
<td>80-400 AU/mL, 100-500 AU/mL</td>
</tr>
<tr>
<td>Naturalized extract, dog</td>
<td>1100-3200 AU/mL</td>
<td>15-320 AU</td>
<td>10-300 AU/mL, 100-500 AU/mL</td>
</tr>
<tr>
<td>Naturalized extract, environmental</td>
<td>110-3200 AU/mL</td>
<td>115-320 AU</td>
<td>10-300 AU/mL, 100-500 AU/mL</td>
</tr>
</tbody>
</table>

NA: Information not available.
ALU: ALU/mL, USA
Allergen Extracts: USA
AToA: Allergen Total Immunoassay.
ERC: Enhanced Radioimmunoassay.
IAR: Immunological Research Associates.
IgE: EIA: Enzyme-Linked Immunoassay.
IgE: EIA: Enzyme-Linked Immunoassay.
IgE: EIA: Enzyme-Linked Immunoassay.

Appendix 3. Extract Volumes Needed for 5.0 ml Maintenance Vials with 0.5 ml injection volume

<table>
<thead>
<tr>
<th>Allergenic extract</th>
<th>Concentrate</th>
<th>Volume of concentrate needed per vial (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pollens, fungi, insects</td>
<td>1:10 w/v</td>
<td>0.25, 0.375, 0.50</td>
</tr>
<tr>
<td>Dog epithelia</td>
<td>1:10 w/v</td>
<td>0.25, 0.375, 0.50</td>
</tr>
<tr>
<td>Dust mitea</td>
<td>30,000 ALU/mL</td>
<td>0.17, 0.42, 0.67</td>
</tr>
<tr>
<td>Pasture grassa</td>
<td>100,000 ALU/mL</td>
<td>0.10, 0.25, 0.40</td>
</tr>
<tr>
<td>Bermuda grass</td>
<td>10,000 ALU/mL</td>
<td>1.0, 2.5, 4.0</td>
</tr>
<tr>
<td>Cat</td>
<td>10,000 ALU/mL</td>
<td>1.0, 2.5, 4.0</td>
</tr>
<tr>
<td>Dog AP</td>
<td>1:100 w/v</td>
<td>NA, 0.00, 1.00</td>
</tr>
<tr>
<td>Short ragweedb</td>
<td>200 AgF U/mL</td>
<td>0.30, 0.45, 0.60</td>
</tr>
</tbody>
</table>

Abbreviations: w/v, weight-to-volume ratio; AgF, Antigen E or Amb a 1; U Unit; ALU, Allergy Unit; BAU, Bioequivalent Allergy Unit; NA: Not applicable.
Minimum recommended dose was not specified for this extract category.
*Also applies to ragweed mix (short-giant) products at 1.25 w/v and approx. 100AgF U/mL.
*Also applies to dust mix and pasture grass mix (eg, KORPG grass) products at the same ALU/mL or BAU/mL strengths.
Beware!

- Mixing high-protease extracts with most other aeroallergens will result in a loss of potency that can affect immunotherapy efficacy.

- Aeroallergens with known high cross-reactivity allow prescribers to treat with fewer allergens while providing coverage for a large number of related allergens.
  - For example, treatment with one or two northern pasture grass allergen extracts should be sufficient to provide benefit for the more than 10 cross-reactive northern grass species.

Mixing recommendations from GREER Laboratories, Inc, Lenoir, NC
Standardization of Labeling

- Improves communication and prevents errors in extract administration
- Each patient’s treatment vial label should contain at minimum:
  - Patient name, plus a second identifier (e.g., date of birth)
  - Concentration in vol/vol (1:1 vol/vol representing the maintenance concentrate)
  - Color code and vial number
  - Expiration or beyond use date (BUD)
- All vials in the treatment set should be numbered and/or color coded as outlined in the most recent practice parameters
- Initial treatment sets consist of a maintenance vial and a series of 10-fold dilutions

Correct Labeling and Color Coding
Summary

- Remember the "WHY?" of AIT
- Write standard Prescription
- Include appropriate Allergens
- Use standard Labeling
- Pay attention to how to comply with standard mixing

Questions?

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