Asthma and Allergy Guidelines

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Disclosures

• I have no relevant financial relationships with the manufacturers of any commercial products and/or provider of commercial services discussed in this CME activity.

• I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

• I do discuss brand names of all epinephrine autoinjectors for purposes of identifying all types available but have no personal financial conflict of interest.
Outline

• Asthma
  – GINA Guidelines
  – Biologic Therapies

• Drug Allergy
  – Penicillin Allergy

• Food Allergy
  – Complementary Peanut Introduction

• Vaccine Allergy
  – Types of adverse reactions
  – Approach to patient with suspected vaccine allergy
  – COVID Vaccines

Updates in Asthma
GINA Guidelines

• The Global Initiative for Asthma (GINA) strives to increase awareness of asthma among health professionals, health authorities, and the general public

• GINA was launched in 1993 in collaboration with
  – National Heart, Lung, and Blood Institute
  – National Institutes of Health
  – World Health Organization

• They update their guidelines yearly

Concerns about SABA only treatment…

• Short acting beta agonist (SABA) as the only reliever is
  – based on older studies when asthma was thought to primarily be a disease of bronchoconstriction

• Now it is known that airway inflammation is found in most patients with asthma
  – even those with intermittent/infrequent symptoms

• Downsides of SABA only treatment
  – Regular use increases allergic responses and airways inflammation, as well as decreases response to SABA
  – Over-use of SABA (>= 3 canisters dispensed in a year) is associated with increased risk of severe exacerbations
  – Dispensing of >= 12 canisters / year is associated with increased risk of asthma related death

GINA 2019, 2020, 2021
GINA Guidelines

• No longer prefers rescue treatment with SABA alone

• For age 12 years and older:
  – ICS-LABA for as needed symptom relief in Intermittent Asthma
  – ICS-LABA as Single-Inhaler for Maintenance and Reliever Therapy (SMART) in Mild-Moderate Persistent Asthma

• For 6-11 years:
  – Take ICS whenever SABA is taken in Intermittent asthma
  – ICS-LABA as SMART in Mild-Moderate Persistent Asthma

Why the new GINA recs?

• Reduce risk of serious asthma related exacerbations and death
• Provide consistent messaging about aims of asthma treatment, including prevention of exacerbations, across whole spectrum of asthma severity
• Avoid establishing a pattern of patient reliance on SABA early in the course of the disease
• This represents the culmination of their 12-year campaign to improve treatment of mild asthma
Pharmacokinetics of B2 agonists

<table>
<thead>
<tr>
<th>B2 agonist</th>
<th>Onset of action</th>
<th>Duration of action</th>
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<tbody>
<tr>
<td>Albuterol/Salbutamol</td>
<td>5-8 min</td>
<td>4-6 hours</td>
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<tr>
<td>Levalbuterol</td>
<td>5-10 min</td>
<td>4-6 hours</td>
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<tr>
<td>Formoterol</td>
<td>2-3 min</td>
<td>12 hours</td>
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<tr>
<td>Salmeterol</td>
<td>30 min</td>
<td>12 hours</td>
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<tr>
<td>Indacaterol</td>
<td>5 min</td>
<td>24 hours</td>
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The goal of ICS-formoterol is to offer both quick relief to reverse airway smooth muscle constriction and allow ICS to treat underlying airway inflammation.

Usual doses for rescue asthma treatment in children

<table>
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<tr>
<th>Medication</th>
<th>Dose form</th>
<th>0 to &lt;4 yrs</th>
<th>4 to 11 yrs</th>
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</thead>
<tbody>
<tr>
<td>Albuterol HFA MDI</td>
<td>90 mcg/puff</td>
<td>2 puffs q4-6 hrs prn</td>
<td>2 puffs q4-6 hrs prn</td>
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<tr>
<td>Levalbuterol HFA MDI</td>
<td>45 mcg/puff</td>
<td>Safety/efficacy not established</td>
<td>2 puffs q4-6 hrs prn</td>
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<td>Albuterol breath-activated DPI</td>
<td>90 mcg/inhalation</td>
<td>Safety/efficacy not established</td>
<td>2 puffs q4-6 hrs prn</td>
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<tr>
<td>Albuterol nebulizer</td>
<td>0.63 mg/3 mL to 5 mg/mL (0.5%)</td>
<td>0.63 to 2.5 mg q4-6 hrs prn</td>
<td>1.25 to 5 mg q4-8 hrs prn</td>
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<tr>
<td>Levalbuterol nebulizer</td>
<td>0.31 mg/3 mL to 1.25 mg/0.5 mL</td>
<td>0.31 to 1.25 mg q4-6 hrs prn</td>
<td>0.31 to 0.63 mg q4-8 hrs prn</td>
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<tr>
<td>Budesonide-formoterol MDI (Combo ICS-LABA)</td>
<td>Budesonide 80 mcg-formoterol 4.5 mcg/puff</td>
<td>Safety/efficacy not established in &lt;6 years</td>
<td>1 to 2 puffs q4 hrs prn, in addition to 2 inhalations daily as maintenance (maximum total daily dose 8 puffs)</td>
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### STARTING TREATMENT

**in adults and adolescents 12+ years with a diagnosis of asthma**

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<th>FIRST ASSESS:</th>
<th>IF:</th>
<th>START WITH:</th>
<th>TRACK 1 (preferred)</th>
<th>OR</th>
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<td>Confirmation of diagnosis</td>
<td>NO</td>
<td>Yes</td>
<td>Daily symptoms, waking at night once a week or more and low lung function?</td>
<td>YES</td>
<td>Medium dose ICS-formoterol maintenance and reliever (MART)</td>
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<td>Low dose ICS-formoterol maintenance and reliever (MART)</td>
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<td>Medium/high dose ICS-LABA + as-needed SABA</td>
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</table>
6-11 years

**SUGGESTED INITIAL CONTROLLER TREATMENT**

*in children 6-11 years with a diagnosis of asthma*

**FIRST ASSESS:**
- Confirmation of diagnosis
- Symptom control & modifiable risk factors (including lung function)
- Comorbidities
- Inhaler technique & adherence
- Child and parent preferences and goals

**IF:**
- Symptoms most days, waking at night or once a week and low lung function?
- Symptoms most days or waking at right once a week?
- Symptoms twice a month or more?

**START WITH:**
- Medium dose ICS-LABA or low dose ICS
- Low dose ICS-LABA or medium dose ICS or very low dose ICS
- Daily low dose ICS
- Take ICS whenever SABA taken

**STEP 1**
- Short course OCS may also be needed for patients presenting with severely uncontrolled asthma

**STEP 2**
- Medium dose ICS-LABA or low dose ICS
- Low dose ICS-LABA or medium dose ICS or very low dose ICS

**STEP 3**
- Refer for expert advice

---

**6-11 years**

**STARTING TREATMENT**

Children 6-11 years with a diagnosis of asthma

**ASSESS:**
- Confirmation of diagnosis
- Symptom control & modifiable risk factors (including lung function)
- Comorbidities
- Inhaler technique & adherence
- Child and parent preferences and goals

**START HERE IF:**
- Symptoms less than twice a month
- Symptoms less than a month, but less than daily
- Symptoms most days or waking with airborne asthma when a week or less
- Symptoms most days, waking at night or once a week and low lung function

**PREFERRED CONTROLLERS**
- To prevent exacerbations and control symptoms

**STEP 1**
- Daily low dose inhaled corticosteroid (ICS) (e.g., SABA taken)

**STEP 2**
- Daily low dose ICS-LABA, or medium dose ICS (two tablets of ICS dose marm for children)

**STEP 3**
- Low dose ICS-LABA, or medium dose ICS, or very low dose ICS in children

**STEP 4**
- Refer for expert advice

**STEP 5**
- As-needed short-acting beta2-agonist or ICS/formoterol reliever for MALT as above

---

*Low dose: BUD-FORM 200/8 mcg; Very low dose: BUD-FORM 100/8 mcg (metered dose)
MALT: maintenance and reliever therapy (ICS-formoterol or as needed maintenance and reliever)
Overview of Biologics in Asthma

Updates in Drug Allergy
Hypersensitivity reactions

<table>
<thead>
<tr>
<th>Type I</th>
<th>Type II</th>
<th>Type III</th>
<th>Type IV a</th>
<th>Type IV b</th>
<th>Type IV c</th>
<th>Type IV d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune reactant</td>
<td>IgE</td>
<td>IgG</td>
<td>IgG</td>
<td>IgG, IgM, T lymphocytes</td>
<td>IL-3, IL-4, IL-10</td>
<td>IFN-γ, IL-23</td>
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<tr>
<td>Antigen</td>
<td>Soluble antigen</td>
<td>Cell or matrix-associated antigen</td>
<td>Soluble antigen</td>
<td>Antigen-presenting cell or direct T cell stimulation</td>
<td>Soluble antigen</td>
<td>Cell-associated antigen or direct T cell stimulation</td>
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<tr>
<td>Effector</td>
<td>Mast cell activation</td>
<td>FeRγ+ cells (macrophages, NK cells)</td>
<td>FeRγ+ cells</td>
<td>Macrophage activation</td>
<td>Eosinophils</td>
<td>T cells</td>
</tr>
</tbody>
</table>

Example of hypersensitivity reaction:
- Allergic rhinitis, asthma, systemic anaphylaxis
- Some drug allergies (e.g., penicillin)
- Serum sickness, Arthus reaction
- Tuberculosis reaction, contact dermatitis (with nickel)
- Chronic asthma, chronic allergic rhinitis, Maculopapular exanthema with eosinophilia
- Contact dermatitis, Maculopapular and bullous exanthema hepatitis, AGEP, Behcet disease

Important questions for drug allergy

- When was the reaction?
- What medication is suspected?
- What was the timing between taking the drug and symptom onset? Minutes, hours, days?
- What were the symptoms?
  - If a rash, did they take a picture?
- What treatment was used?
- How long did symptoms last?
- Have they had the drug or similar drugs since?
Penicillin Allergy

80% lose prior sensitivity within 10 years
Using a PCN product can reduce rate of broad-spectrum antibiotic use

Blanco 1999

Why test for PCN?

Patients with a PCN allergy are more likely to…
- Receive quinolones, clindamycin, and vancomycin
- Longer hospitalizations
- Higher prevalence of C difficile
- Higher prevalence of MRSA and VRE

Positive Impact
- Reducing cost
- Reducing use of broad-spectrum antibiotics
- Reducing length of hospital stay
- Reducing complications from alternative

Macy 2014
PCN Testing

- Low risk patients can be given the drug via oral challenge without skin testing
  - Delayed onset, benign, non-urticarial rashes
  - GI upset
  - Headaches
- High risk patients
  - Recommend evaluation by allergist
    - Skin testing with possible oral challenge to amoxicillin

Macy 2017

Intra-family Cross-Reactivity

- Penicillins
- Carbapenems
- Cephalosporins
- Monobactams
PCN Allergy in the Pregnant Patient

- Consider allergy testing for all patients with a history of a penicillin allergy
  - ACOG Committee Opinion report on Prevention of Group B Streptococcal Early-Onset Disease in Newborns

- In 2021, Wolfson et al., largest study on pregnant patients to date
  - 209 of 220 had their penicillin allergy label safely removed
  - Those who had an in-person evaluation by an allergist were less likely to receive alternative antibiotics (vancomycin, clindamycin, gentamicin) for GBS prophylaxis in the peripartum period

ACOG 2020
Wolfson 2021

---

**Flowchart:**

1. Prenatal assessment
2. Not allergic to penicillin
   - Penicillin G or Ampicillin
   - LOW risk
     - Cefazolin
   - If susceptible, Clindamycin
3. Allergic to penicillin
   - HIGH risk
     - Check clindamycin susceptibility
     - If susceptible, Clindamycin
     - If clindamycin-resistant, Vancomycin
   - Unknown risk
     - Options: 1) PCN allergy testing, 2) Cephalosporin, 3) Clindamycin if susceptible 4) Vancomycin if not susceptible to clindamycin

ACOG 2020
Management of Type I IgE Mediated Hypersensitivity

- What happens if the patient is determined to be penicillin allergic?
  - History of type 1 IgE mediated hypersensitivity and/or positive allergic sensitization
- Need to determine if
  - 1) there is no other alternative agent to use
  - 2) urgency to use penicillin products
- If yes to above, then the allergist will consider a drug desensitization to the desired penicillin product

Updates in Food Allergy
Food Reactions

- Intolerance – your body cannot break down the food for some reason
  - GI symptoms (pain, cramping, vomiting, or diarrhea)
  - Eat small amounts – do okay

- Allergy – your body mistakes that food for something harmful, IgE-mediated
  - Immune response – localized or systemic reaction
  - Can be triggered by eating a microscopic amount or even with touch or inhalation of the particles

- Eight types of food account for > 90% of allergic reactions:
  - milk, eggs, peanuts, tree nuts, fish, shellfish, soy, and wheat

- This is consistent with the finding that allergens belong to a very restricted number of protein families
- Prevalence in children is 7-8%

Who is high risk?

- The following are at high risk of developing allergic disease:
  - A patient with family history of atopy
  - A patient with personal history of atopy
    - Especially with moderate-severe eczema

- How can we prevent these patients from developing a food allergy?
  - Introduction of highly allergenic foods in infancy

Gupta 2013
Togias 2017
Fleischer 2021
Prevention of Peanut Allergy

<table>
<thead>
<tr>
<th>Addendum guideline</th>
<th>Infant criteria</th>
<th>Recommendations</th>
<th>Earliest age of peanut introduction</th>
</tr>
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</table>
| 1                 | Severe eczema, egg allergy, or both             | - Strongly consider evaluation by sIgE measurement and/or SPT and, if necessary, an OFC.  
|                   |                                                 | - Based on test results, introduce peanut-containing foods.                     | 4-6 months                          |
| 2                 | Mild-to-moderate eczema                         | Introduce peanut-containing foods                                              | Around 6 months                     |
| 3                 | No eczema or any food allergy                  | Introduce peanut-containing foods                                              | Age appropriate and in accordance with family preferences and cultural practices |

Peanut introduction during infancy

Togias 2017
Updates in Vaccine Allergy

Safety monitoring systems

Get vaccinated. Get your smartphone. Get started with v-safe. v-safe is a smartphone-based tool that checks in on you after your COVID-19 vaccination. Your participation helps keep COVID-19 vaccines safe — for you and everyone. If you get vaccinated in the last 6 weeks, you can participate in v-safe. It takes just a few minutes to register and get started. All you need is your smartphone and a little extra time to recall the COVID-19 vaccine you received. This tool is not based on your medical history or personal health. If you cannot find your code, please contact your healthcare provider.

Register for v-safe

For more information about yourself and follow the prompts to set up your account.

CDC 2020
Adverse effects by immunologic mechanism

<table>
<thead>
<tr>
<th>Mechanism Category</th>
<th>Antibody mediated</th>
<th>T cell mediated or mixed</th>
<th>Immune deficiency</th>
<th>Normal Response</th>
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</thead>
<tbody>
<tr>
<td>Antigen</td>
<td>Excipient, vaccine</td>
<td>Vaccine</td>
<td>Vaccine</td>
<td>Vaccine</td>
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<tr>
<td>Adverse event (mechanism)</td>
<td>Immediate hypersensitivity (IgE mediated)</td>
<td>Local vasculitis (IgG immune complexes)</td>
<td>Delayed hypersensitivity</td>
<td>Mixed - CD4+ CD8+ T &amp; B cell mediated inflammation</td>
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<tr>
<td>Examples</td>
<td>Egg, gelatin, or alpha-gal immediate hypersensitivity</td>
<td>Arthus Reaction</td>
<td>Metal, antimicrobial contact allergy</td>
<td>Delayed smallpox reaction</td>
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<tr>
<td>Predispensing factors</td>
<td>Pre-existing allergy to component of vaccine (see table 3)</td>
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<td>Possible genetic variation in antigen presentation/processing</td>
<td>Pre-existing primary or secondary immunodeficiency</td>
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<tr>
<td>Evaluation</td>
<td>Thorough history and causality assessment</td>
<td>Stone 2019</td>
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What are the expected side effects from vaccination?

- Usually occur within a few hours of vaccination
- Resolve within minutes-hours-days
- Local
  - Pain, swelling, redness at site of injection
- Systemic
  - Fever, chills, malaise, headache, muscle pain
- Treatment:
  - Supportive: rest, hydration, Tylenol or NSAIDs
Delayed Adverse Effects

Delayed reactions

- Several hours-days after administration
- Often T-cell mediated (Rarely IgE mediated)
- All vaccines can cause minor, self-limited side effects
  - Reflective of a normal immune response
  - Not a contraindication to receiving further doses of the vaccine
- Rare sequelae
  - Serum sickness and SSLR
  - Papular rash, SJS, TEN, EM Major, AGEP, Erythema nodosum, Granuloma annulare, Bullous pemphigoid
  - Pruritic persistent nodules with aluminum containing vaccines, due to delayed Type IV hypersensitivity
  - Guillain Barre Syndrome, Encephalopathy

Johansson 2004
Stone 2019
Non-IgE mediated reactions

- Arthus reaction
  - A localized type III hypersensitivity reaction
  - Painful local swelling and erythema
  - Can start a few hours-days after
  - Risk factors: shallow injection, previously vaccinated
  - Reported with tetanus, diphtheria and hepatitis B vaccines

Minor delayed reactions due to SARS-CoV-2 vaccines

- “COVID vaccine arm”
- Delayed (several days) large local reaction
- Either a Type III or IV hypersensitivity
- Treatment:
  - supportive, oral antihistamines, topical steroids, Tylenol/NSAIDs
- Not a contraindication to second dose
  - May recur, may need supportive treatment
Minor delayed reactions due to SARS-CoV-2 vaccines

- Lymphadenopathy
  - Temporary, mild
  - Usually axillary or supraclavicular, typically same side as vaccine administration
  - Due to activation of adaptive immune system in local lymph notes (Not a Type I Hypersensitivity)
- Society of Breast Imaging stated:
  - For scheduling screening exams:
    - If possible, and when it does not unduly delay care, consider scheduling screening exams prior to the first dose of a SARS-CoV-2 vaccination or 4-6 weeks following the second dose of a SARS-CoV-2 vaccination.

Immediate Adverse Effects
Immediate reactions

• Symptoms within 4 hours of administration
• Typically IgE mediated
  – Often within minutes, almost always within 1 hour
  – Can involve various combinations of up to 40 symptoms and signs
    • Most common symptoms and signs are cutaneous (urticaria, angioedema), respiratory (wheezing), cardiovascular changes (hypotension)
    • Severe form is anaphylaxis
• Can be non-IgE mediated
• Can be non-immune

Anaphylactic reactions to vaccines

• Estimated rate of anaphylaxis is 1 per million doses in general for vaccines
  – About 220 million doses of vaccines are distributed in US per year
• Anaphylactic reactions to vaccines are rare, although potentially life-threatening
  – Immunoglobulin E (IgE)-mediated reactions
  – Often due to vaccine components rather than microbial products

Johansson 2004
Bohle 2003
McNeil 2016
Su 2019
Criteria for anaphylaxis

- Upper respiratory: Rhinorrhea, sneezing, hoarse voice, stridor
- Cardiovascular: Hypotension, vasodilatation, increased vascular permeability, syncope
- Digestive: Nausea, vomiting, abdominal pain, diarrhea
- Skin: Flushing, urticaria, angioedema, anaphylactic rash
- Cytokine/chemokines: interleukins, tryptase, prostaglandins, histamine

Anaphylaxis is highly likely when any ONE of the following three criteria is fulfilled:

1. Acute onset of an illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (e.g. generalized hives, pruritis or flushing, swelling lips, tongue, throat)

AND AT LEAST ONE OF THE FOLLOWING:

A. Respiratory compromise (e.g. dyspnea, wheeze-bronchospasm, stridor, hypoxemia)
B. Reduced BP* or associated symptoms of end-organ dysfunction (e.g. hypotonia, collapse, syncope, incontinence)

2. TWO or MORE of the following that occur rapidly after exposure to a LIKELY allergen for that patient (minutes to several hours):

A. Involvement of the skin mucosal tissue (e.g. generalized hives, itchy-rush, swollen lip, tongue, oral)
B. Respiratory compromise (e.g. dyspnea, wheeze-bronchospasm, stridor, hypoxemia)
C. Reduced BP* or associated symptoms (e.g. hypotonia, collapse, syncope, incontinence)
D. Persistent gastrointestinal symptoms (e.g. crampy abdominal pain, vomiting)

3. Reduced BP* after exposure to a KNOWN allergen for that patient (minutes to several hours):

A. Infants and children - Low systolic BP (age-specific)* or greater than 30% decrease in systolic BP
B. Adults - Systolic BP of less than 90 mmHg or greater than 30% decrease from that person's baseline

Sampson 2006
Reber 2017

CDC MMWR of SARS-CoV-2 vaccines

- Rate of reported anaphylaxis has been extremely rare
  - VAERS data from 7/31/2021:
    - 66 of 213 cases confirmed as post-vaccination anaphylaxis with day 0-1 ED visit
      - BNT162b2 vaccine (N=37): 5 per million doses
      - mRNA-1273 vaccine (N=26): 4.9 per million doses
      - Ad26.COV2.S vaccine (N=3): 7.6 per million doses
    - All cases fully recovered with treatment
  - Most occurred within 30 minutes of vaccine administration
  - Most had self-reported a history of allergies, but no consistent type of allergy

CDC 2021
Non-allergic reactions that mimic anaphylaxis

- In these situations, it can help to draw tryptase level within 2 hours of reaction to differentiate from anaphylaxis
- If not proven to be anaphylaxis, should consider getting 2nd dose

<table>
<thead>
<tr>
<th>Anxiety or Immune activation</th>
<th>Vasovagal reactions</th>
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<tbody>
<tr>
<td>Onset</td>
<td>Minutes - hours</td>
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<tr>
<td>Symptoms</td>
<td>Tachycardia, HTN, globus sensation, flushing without urticaria</td>
</tr>
<tr>
<td>Important Features</td>
<td>Can be due to anxiety or innate immune activation from vaccine</td>
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<tr>
<td>Treatment</td>
<td>Resolves with rest +/- supportive care</td>
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Acute Management of Vaccine Reactions
Example of a vaccine reaction protocol

**SEVERE Symptoms**

- **LUNG:** Shortness of breath, wheezing, severe cough
- **HEART:** Pale or bluish skin, fainting, convulsions
- **THROAT:** Tight or hoarse throat, trouble swallowing
- **MOUTH:** Significant swelling of the tongue or lips
- **SKIN:** Itchy or welts, rash, hives, body or facial edema
- **GUT:** Diarrhea, vomiting, abdominal pain
- **OTHER:** Coughing, something that is hard to swallow, anxiety, confusion

For a single mild symptom:

- Cetirizine HCl 10 mg, Fexofenadine 20 mg tablet
- Monitor vitals/supervise/skin exam every 15 minutes for at least 30 minutes and until resolution of symptoms.
- Consider H1 (1 mg, 5 mg, 10 mg, 20 mg, 30 mg, 50 mg, 100 mg), rescue of drowsiness.

- 

For ANY severe symptoms or MORE THAN ONE mild symptom:

- Inject 0.3 mg Epipen into thigh through clothing. May repeat in 5-10 minutes if worsening.
- Call Rapid Response at
- Lay the supine/evaluate legs (unless emesis/respiratory distress, then use upright position).
- Apply BP, HR, SPO2 monitor to take vitals every 2-5 minutes. Auscultate for stridor/wheezing.
- Administer adjuvants if possible
  - Cetirizine HCl 10 mg, Fexofenadine 20 mg tablet
  - Monitor vitals/supervise/skin exam every 15 minutes for at least 30 minutes and until resolution of symptoms.
  - Consider H1 (1 mg, 5 mg, 10 mg, 20 mg, 30 mg, 50 mg, 100 mg), rescue of drowsiness.
- Draw tryptase level (gold top tube) within 90 minutes
- Hand off to rapid response or EMS team. Communicate need for outpatient allergy referral.

**Injectable epinephrine**

**Intramuscular Epinephrine Tips**

- Remove blue safety release cap.
- “Blue to sky, Orange to thigh”
- Push firmly through clothes until click, hold firmly for 3 sec.
Assessing reactions to vaccines

- Detailed history to help determine causality
  - Signs and symptoms during the reaction with timing
  - Drugs or substances taken before vaccination
  - Medications needed to treat the reaction
  - Physical exam including vitals at the time of reaction

- Ancillary laboratory information
  - Within 30-90 minutes after an acute reaction
    - Serum tryptase level (mast cell marker)
    - SC5b-9 (terminal complement complex)

Follow up

- If symptoms fully resolve after first dose of epinephrine
  - Can discharge 4-8 hours after resolution of symptoms
  - Extended observation if multiple doses of epinephrine
    - To monitor for arrhythmias and late phase anaphylactic reactions

- Discharge with
  - Education on how to recognize and manage anaphylaxis
  - Potential prescription for epinephrine autoinjectors
  - Referral to allergist
Long Term Management of Vaccine Reactions

Who needs an evaluation by an allergist

- A patient who experienced...
  - An apparent allergic or other serious adverse reaction after receiving a vaccine OR
  - A suspected allergy to vaccine component
What will the allergist do?

Clinical History

Positive history of reactions after vaccine administration

Nonimmediate reaction

• In most cases, no allergy work-up
• If contact dermatitis or nodules, consider patch test

Immediate reaction

Positive history of reproducible allergy to vaccine excipient?

Yes - review vaccine excipient list and determine if allergy skin testing is necessary before vaccine administration

• Skin testing and/or in vitro IgE testing to vaccine and/or components

Positive

If additional doses required, vaccine may be given in graded doses

Negative

If additional doses required, vaccine can be given according to general recommendations

Vaccine Components

Active components

• Virus, bacteria, toxin

Culture media

• Hen's egg
• Horse serum
• Murine or simian cells
• Kidney cells of dog
• Yeast

Inactive residues

• Formaldehyde
• Beta-propiolactone
• Formalin
• Glutaraldehyde
• Casein

Contaminants

• Latex

Adjuvants

• Aluminum salts
• MF-59 (squalene salt)
• ASO4 (monophosphoryl lipid A and aluminum hydroxide)

Stabilizers

• Gelatin, Polgeline
• Human serum albumin
• Amino acid mix, Glycine
• Glutamate, MSG
• Sucrose, lactose, sorbitol
• Ascorbic acid
• Phosphatase
• Polysorbate 80/20

Antibiotics

• Neomycin, Gentamicin, Streptomycin, Kanamycin
• Chlortetracycline
• Erythromycin
• Polymyxin B
• Amphotericin B

Preservatives

• Thimerosal
• 2-phenoxyethanol
• Phenol
• Benzethonium chloride
Allergy testing

Examples of testing used to assess specific vaccines suspected of causing allergic reactions

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Skin testing</th>
<th>In vitro IgE testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP, Td, Tdap</td>
<td>DTaP, Td, Tdap, Tetanus toxoid, Gelatin, Milk</td>
<td>Gelatin, Milk</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Hepatitis B, Yeast</td>
<td>Yeast</td>
</tr>
<tr>
<td>Influenza</td>
<td>Influenza, Egg, Gelatin</td>
<td>Egg, Gelatin</td>
</tr>
<tr>
<td>MMR</td>
<td>MMR, Measles, Mumps, Rubella, Gelatin</td>
<td>Gelatin</td>
</tr>
<tr>
<td>Varicella or Zoster</td>
<td>Varicella or Zoster, Gelatin</td>
<td>Gelatin</td>
</tr>
<tr>
<td>Yellow fever</td>
<td>Yellow fever, Egg, Gelatin</td>
<td>Egg, Gelatin</td>
</tr>
</tbody>
</table>

- Whenever possible, the same vaccine from the same manufacturer that was given at the time of the reaction should be used for testing

Testing to vaccine

- Vaccine skin tests (not component testing)
  - Prick test with full strength vaccine
    - Consider dilution if history of life-threatening reaction
    - If prick test with full strength vaccine negative, move on to intradermal testing
  - Intradermal test with 0.02 mL vaccine 1:100
    - If negative, move on to challenge

- Limitations:
  - No formal studies to evaluate the positive and negative predictive values for vaccine skin tests
  - May cause irritant (false-positive), clinically irrelevant reactions
  - May not be available for certain vaccines (SARS-CoV2 vaccines)

Dreskin 2016

Kelso 2009
Vaccine graded challenge protocols

- Doses given at 15-minute intervals as tolerated
- Needs to be performed under direct medical supervision, equipped to handle anaphylaxis
  - Office/hospital setting, with/without IV line in place

SARS-CoV-2 Vaccines
I’m allergic to ___, should I still get the SARS-CoV-2 vaccine?

**Standard 15 min observation**
- Family history of severe allergies
- History of contact dermatitis
- Delayed reactions to drugs or vaccines
- Allergic rhinitis
- Asthma
- Mast cell disease

**30 min observation**
- History of potential anaphylaxis to:
  - Foods
  - Pollens, molds, dust mites
  - Latex
  - Insect venom
  - Drug
  - Radiocontrast dye
- History of idiopathic anaphylaxis

Refer to allergist
- Severe allergic reaction (anaphylaxis) to mRNA SARS-CoV-2 vaccine
- Allergic reaction to SARS-CoV-2 vaccine components
  - Immediate reaction to polysorbate or polyethylene glycol
- May also refer if history of allergic reaction to non-SARS-CoV-2 vaccine or injectable medication

*Banerji 2020
Castells 2020*
## SARS-CoV-2 vaccine components

<table>
<thead>
<tr>
<th>Vaccine Platform</th>
<th>Vaccine Name</th>
<th>Excipients</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNA based vaccine</td>
<td>BNT162b2</td>
<td>Polyethylene glycol 2000</td>
</tr>
<tr>
<td>RNA based vaccine</td>
<td>mRNA-1273</td>
<td>Polyethylene glycol 2000, Tromethamine</td>
</tr>
<tr>
<td>Adenovirus vector</td>
<td>AZD1222</td>
<td>Polysorbate 80 EDTA</td>
</tr>
<tr>
<td>Adenovirus vector</td>
<td>Ad26.COV2-S</td>
<td>Polysorbate 80</td>
</tr>
<tr>
<td>Protein subunit</td>
<td>NVX-CoV2373</td>
<td>Polysorbate 80 M1 adjuvant</td>
</tr>
<tr>
<td>Protein subunit</td>
<td>SCB-2019</td>
<td>Polysorbate 20</td>
</tr>
</tbody>
</table>

*Castells 2020
CDC 2021

## History of allergy to polyethylene glycol (PEG) or polysorbate allergy

- PEG is in mRNA SARS-CoV-2 vaccines
  - A possible antigen for severe allergic reaction to mRNA SARS-CoV-2 vaccines
- Polysorbate 20 or 80 are in non-mRNA SARS-CoV-2 vaccines
- Both act as a solvent, plasticizer, surfactant, base, lubricant. It stabilizes the vaccine.
Who should you refer?

- **Urgent**
  - Allergic reaction (severe/immediate) to SARS-CoV-2 vaccine
  - Allergic reaction to SARS-CoV-2 vaccine components and eligible to receive vaccine now

- **Routine**
  - Immediate allergic reaction to non-SARS-CoV-2 vaccine or injectable medication
  - Can consider referral of patient with multiple allergic conditions

Shared Decision Making

- We can help each individual patient identify their values and preferences to help guide decision making.
Thank you! If you have any questions, feel free to contact me at MLOVE2@kumc.edu.

References

References, continued


References, continued


