

The United Airway

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OBJECTIVES

- Describe the concept of the united airway
- Understand the linkage between upper and lower airway disease
- Describe prevalence of unified airway disease in asthmatic and rhinosinusitis patients
- Provide diagnostic and management options for your patients

The United Airways Concept

- Also known as the unified or integrated airway
- We know upper & lower airway diseases co-exist
- 60-80% of asthmatics have rhinitis
- 15% of allergic rhinitis patients have asthma
- Other allergic co-morbidities may include sinusitis, ocular allergy, lymphoid hypertrophy, chronic middle ear effusions, obstructive sleep apnea, disordered sleep, and consequent behavioral and educational effects

The United Airways Concept

- Rhinitis typically precedes the onset of asthma
- Upper airways symptoms contribute to unsatisfactory asthma control
- Asthma symptoms are influenced by duration and severity of allergic rhinitis
- Nasal symptoms, airflow, and nasal markers of inflammation directly correlate with lower airway involvement

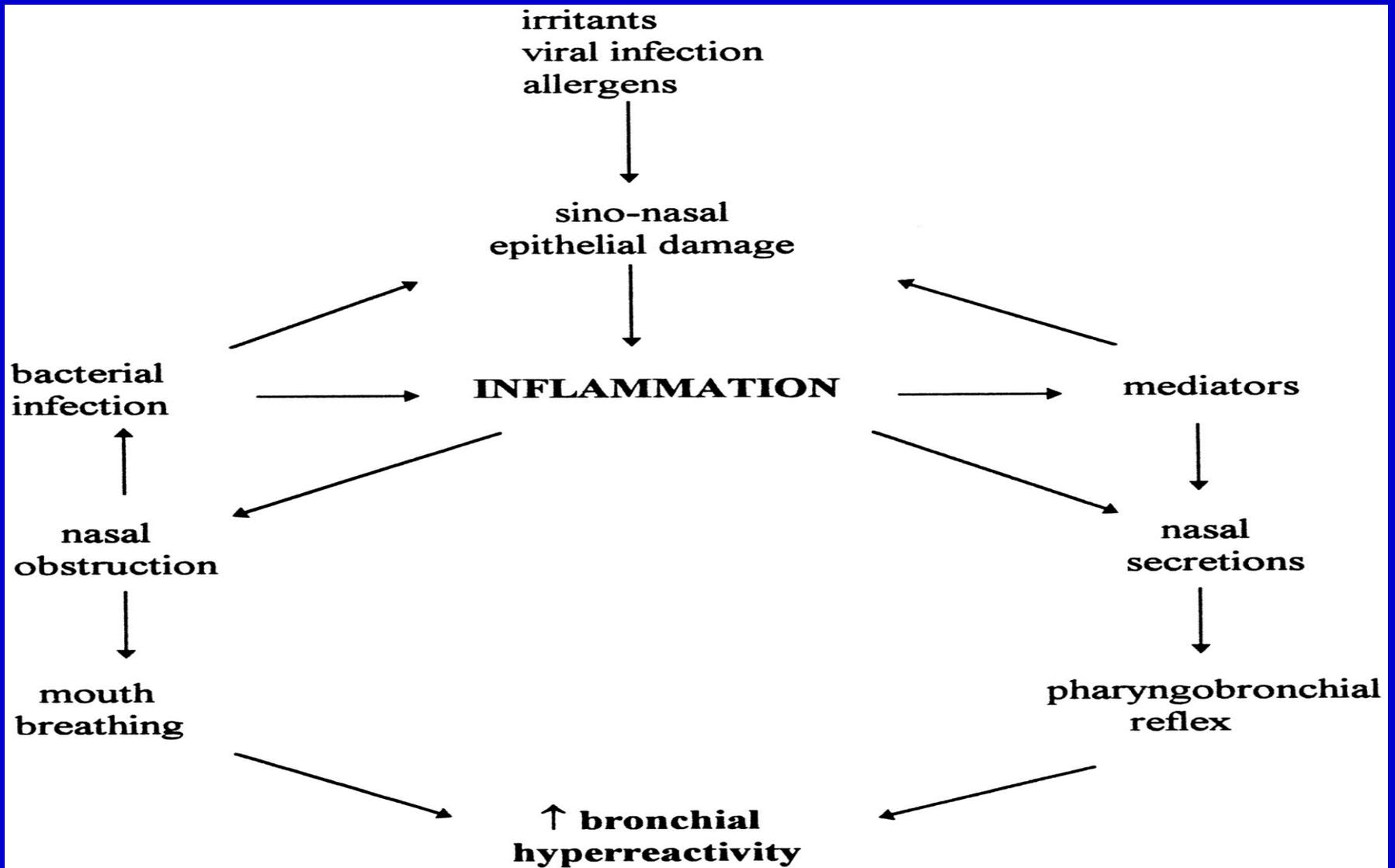
The United Airways Concept

- Relationship between upper & lower airways disease is complex
 - An accurate asthma diagnosis may be confused by cough secondary to rhinitis and postnasal drip
 - Sinusitis is a frequent extension of rhinitis, and difficult to distinguish, especially in children
 - Allergen exposure and release of histamine and other mediators may cause systemic inflammatory response
 - Mucosal inflammation extends thru the entire airway after nasal challenge of allergic rhinitis patients

The United Airways Concept

- Relationship between upper & lower airways disease is complex
 - Aspiration does not appear to be a major influence
 - Challenge studies have shown negative results when patients are asymptomatic, positive when symptomatic
 - This suggests a threshold level of nasal SX required
 - Studies suggest a sensory reflex arc originating in the oropharynx rather than the nose

The United Airways Concept

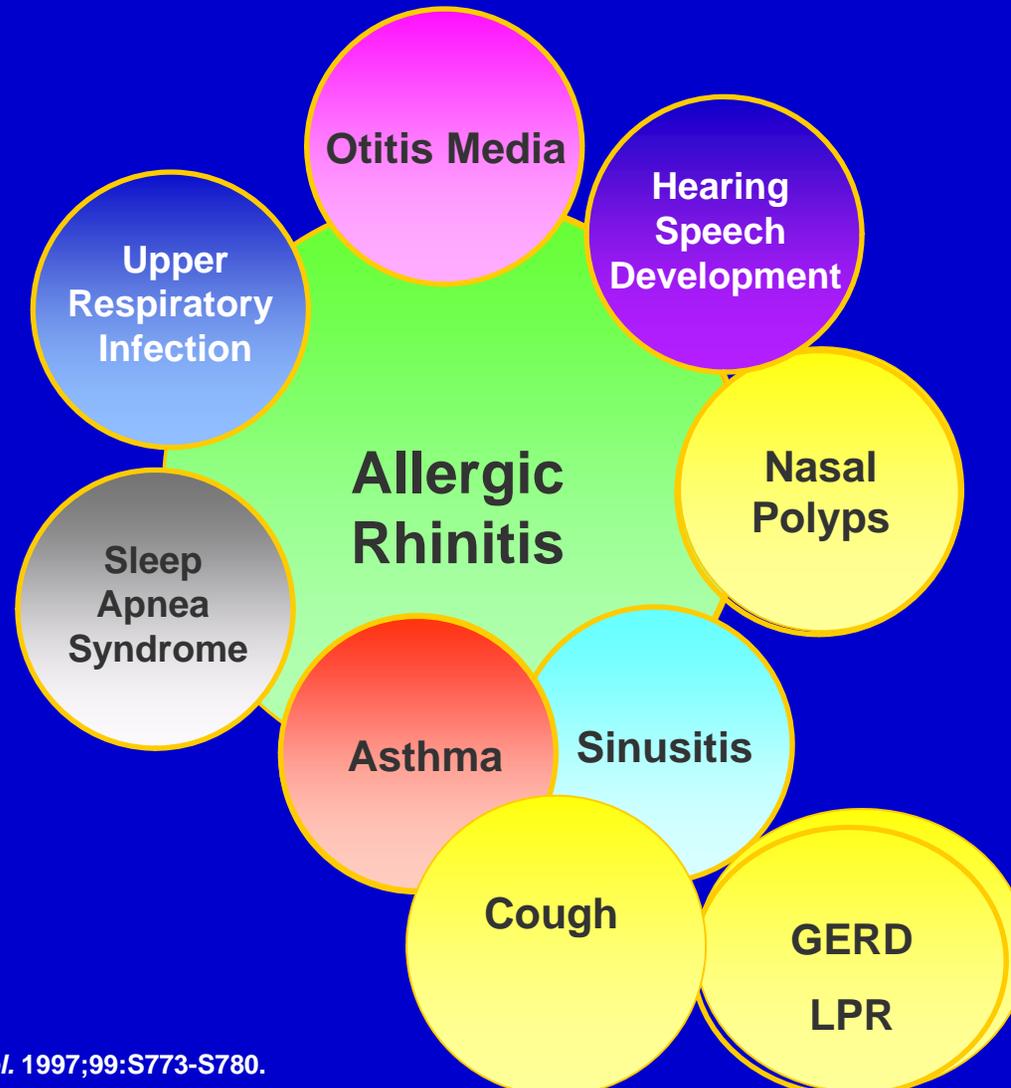


Impact of Allergic Rhinitis

- Affects over 40 million Americans¹
- Fifth most common chronic illness²
- Most prevalent chronic condition in patients under 18 years of age²
- Both physical and mental health status adversely affected¹
- 3.8 million lost work and school days annually³
- Total costs approximately \$8 billion/year³

American Academy of Allergy, Asthma and Immunology. *The Allergy Report*. 2000. Available at: <http://www.theallergyreport.org/reportindex.html>. Accessed

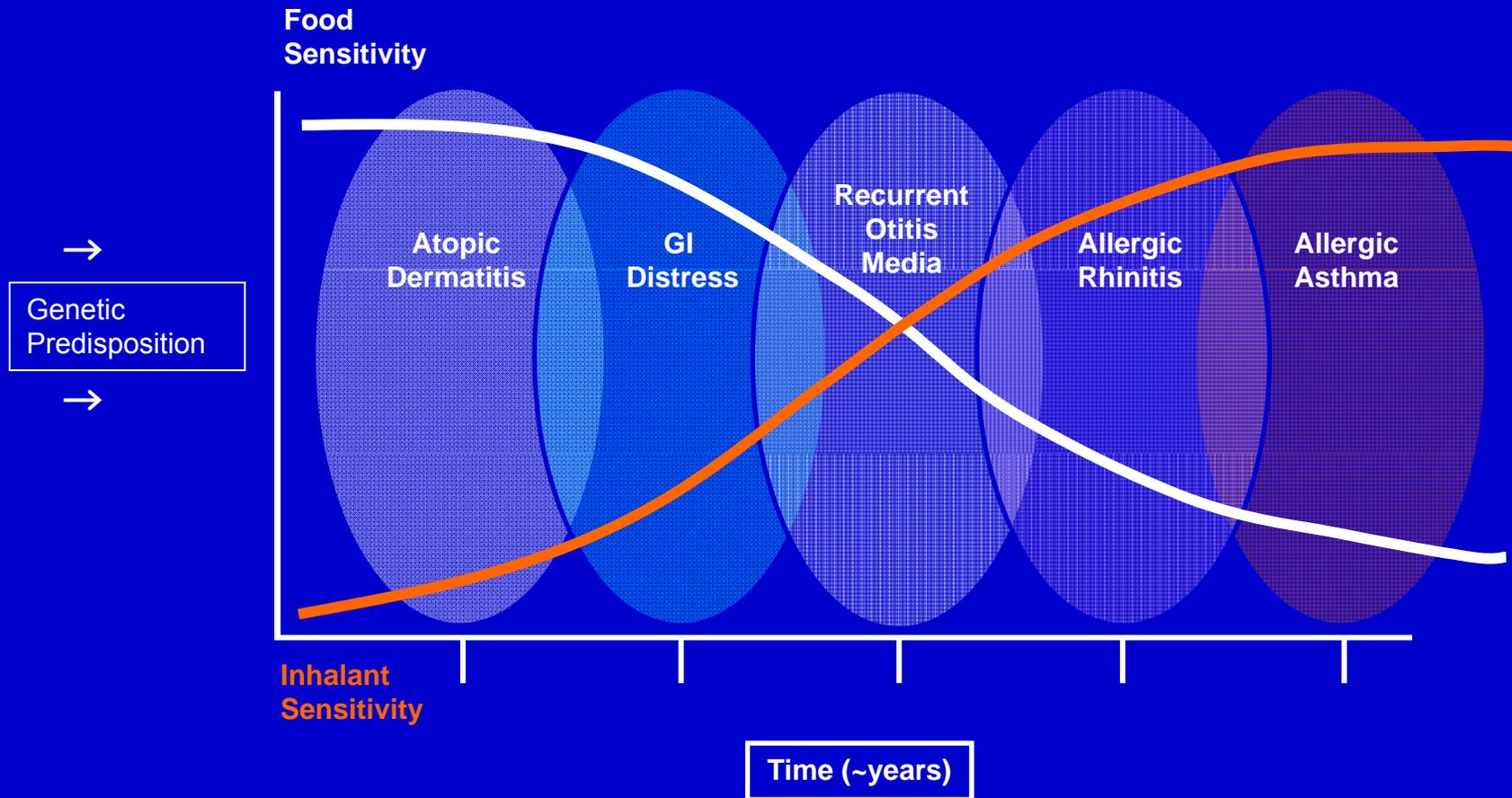
Allergic Rhinitis and Comorbid Airway Disease



Signs and Symptoms of Allergic Rhinitis

- Sneezing
- Itchy nose, eyes, throat, and/or ears
- Nasal congestion
- Clear rhinorrhea
- Conjunctival edema, itching, tearing, hyperemia
- Subocular edema and darkening (“shiners”)
- Loss of taste and smell sensations

The Allergy March: A Progression of Seemingly Unrelated Diseases



Diagnosis of Allergic Rhinitis: Medical History and Physical Exam

- Detailed and accurate history *critical* to proper diagnosis and successful treatment
 - Time course: onset, pattern
 - Symptoms
 - Effect of treatments tried (Rx and OTC)
 - Sequelae and co-morbidities
 - Family history
- Physical exam: More than the nose

Physical Exam

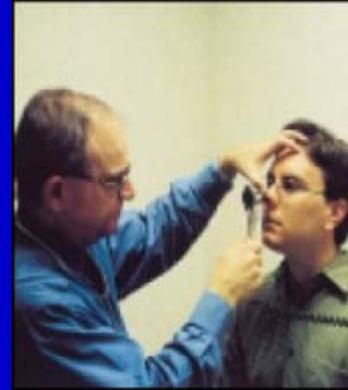
- **Skin:** eczema, excoriation, shiners, Dennie-Morgan lines
- Eyes: injection, discharge, chemosis
- Ears: air fluid level, retraction
- **Nose:** transverse crease, turbinates, mucosa, discharge, nasal polyp
- Oropharynx: mouth breathing, palatal arch, post nasal drainage, cobblestoning
- Chest: wheezing

Why Should You Test?

- History and physical alone yield a correct diagnosis only 50% of the time¹
- Different etiologies demand different treatment approaches
- Testing for specific IgE levels can rule in/out atopy
- If atopic:
 - NSAs probably drug of choice
 - Testing can help clinician pinpoint offending allergens
- If non-atopic:
 - Results will allow you to focus on other etiologies
 - Drugs of choice may include decongestants/steroids
 - Patient can avoid unnecessary/ineffective treatment

Diagnostic Tests for Allergic Rhinitis

- General ENT examination
- Allergy tests
 - skin tests
 - serum specific IgE (ImmunoCap-RAST)
- Endoscopy
 - rigid, flexible
- Nasal secretions
 - cytology



Diagnostic Testing

- Skin tests for specific IgE antibodies¹
 - Identify allergens suspicious by history
 - Antihistamine use can suppress results²
- Serum-specific IgE tests² (ImmunoCap-RAST)
 - Correlate well with skin tests
 - Acceptable substitute for skin tests in certain patients

*Nonallergic rhinitis with eosinophilia syndrome.

1. Cook PR, et al. *Otolaryngol Clin North Am.* 1996;29:39-56. 2. Skoner DP. *J Allergy Clin Immunol.* 2001;108:S2-S8.
3. Dykewicz MS, et al. *Ann Allergy Asthma Immunol.* 1998;81(5, pt 2):478-518.

ImmunoCAP: Gain Knowledge to Guide Treatment

- FDA-cleared quantitative measure of specific IgE
- Only a single blood draw required
- Covered under most insurance plans
- Accuracy superior to RAST^{TM*1}
 - Next-generation assay offers consistently improved sensitivity²
 - *De facto* standard, documented in >2,000 peer-reviewed publications³
- *In vitro* blood testing and skin prick testing (SPT) viewed as interchangeable⁴
- ImmunoCAP is available throughout the nation from clinical laboratories

* RAST is a trademark of Pharmacia Diagnostics.

1. Williams PB, et al. *J Allergy Clin Immunol*. 2000;105:1221-1230.

2. Szeinbach SL, et al. *Ann Allergy Asthma Immunol*. 2001;86:373-381.

3. Johansson SGO. *Expert Rev Mol Diagn*. 2004;4:273-279.

4. Hamilton RG. In: *Pediatric Allergy: Principles and Practice*. Mosby-Year Book, Inc; 2003:233-242.

ALLERGIC RHINITIS TREATMENT OPTIONS

- Environmental control
 - Avoidance of “triggers”
- H₁ antagonists
 - Cornerstone of treatment for AR
 - Oral and intranasal
- Oral and nasal decongestants
 - Effectively reduce nasal congestion
- Nasal corticosteroids
 - Indicated for moderate to severe AR
- Immunotherapy
 - Indicated for severe AR, failure or intolerance of other treatments, prevention of onset or worsening of comorbid conditions

ALLERGY AVOIDANCE TECHNIQUES

Pollens

- Keep windows and doors closed, use air conditioning, stay indoors during times of high pollen counts

Molds, Fungi

- Avoid walking through uncut fields, working with compost or dry soil, raking leaves; keep windows and doors closed; use air conditioning
- Clean moldy surfaces, wash swamp coolers, fix water leaks, use dehumidifier and air conditioning to reduce humidity to <50% if possible

Cockroaches

- Keep food and trash in closed containers, don't keep paper bags, newspapers, or cardboard boxes, use boric acid traps or hypdromethanon

Dust Mites

- Put allergen-impermeable covers on pillows, mattress, box springs, wash bedding weekly in water $\geq 130^{\circ}\text{F}$; reduce humidity in home to <50%, if possible, remove stuffed toys from bedroom

Pet Dander

- Remove pets from home
- If removal is not possible, keep pets out of bedroom and keep door closed, wash pets weekly, keep pets away from upholstered furniture and rug, use a HEPA-type air cleaner in the bedroom above the floor, close air ducts in the bedroom

Smoke

- Discourage smoking around patient, including in home and car; minimize use of fireplaces and wood-burning stoves

Allergen Avoidance

- Should be a key for the successful management of AR¹

BUT...

- Often difficult to implement²
- May be impractical^{2,3}
- Restricts daily social activities/children's play²

1. Dykewicz MS, Fineman S. *Ann Allergy Asthma Immunol.* 1998;81(5 pt 2):463-468.

2. Meltzer EO. *Allergy Asthma Proc.* 2006;27(1):2-8.

3. van Cauwenberge P et al. *Allergy.* 2000;55(2):116-134.

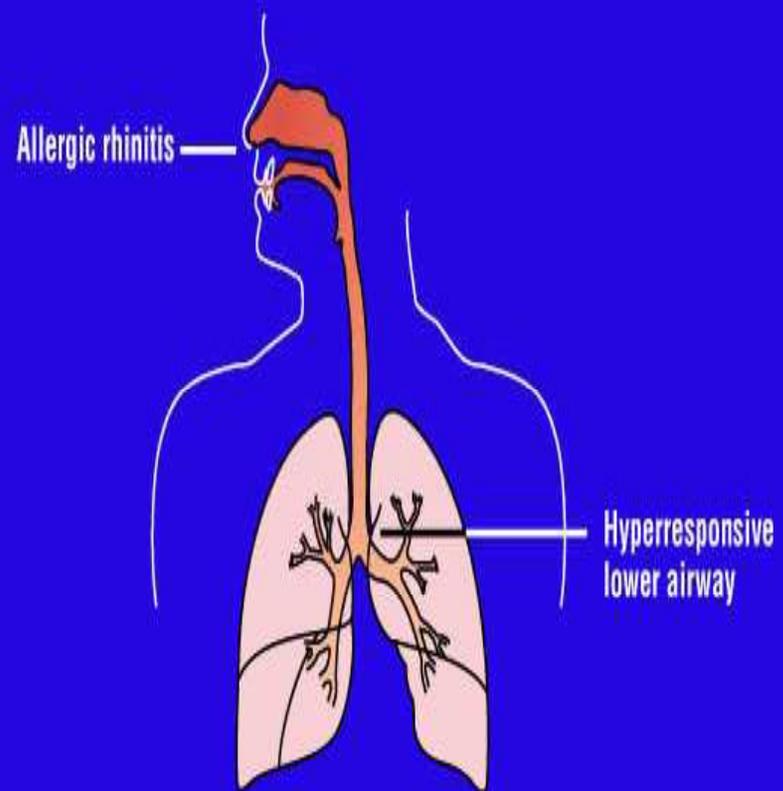
Environmental Control Measures: House Dust Mites



- Vigorous methods necessary
 - Ordinary vacuuming/dusting have little effect
 - wash bedding weekly in water $\geq 130^{\circ}\text{F}$
- Simple furnishings without carpeting
 - Especially bedroom, family room, etc
 - Plastic, leather, wood are best

Asthma and Allergic Rhinitis

- Allergic rhinitis has been shown to exist in $\geq 85\%$ of patients with asthma
- Studies show that allergic rhinitis is a risk factor for developing asthma
- Treatments of allergic rhinitis that modulate various aspects of the inflammatory cascade also lead to improvement in concomitant asthma

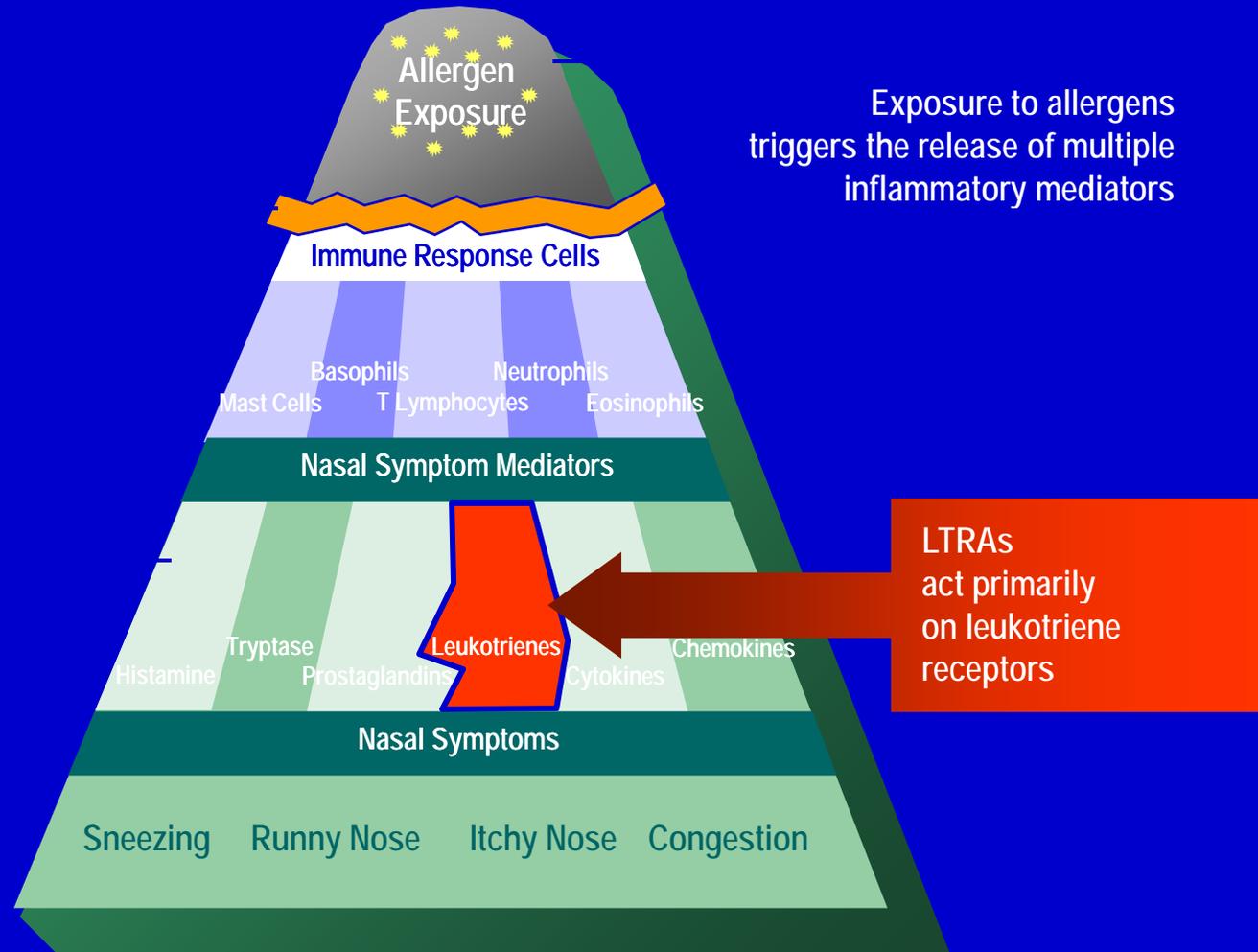


Role of Allergy in Asthma

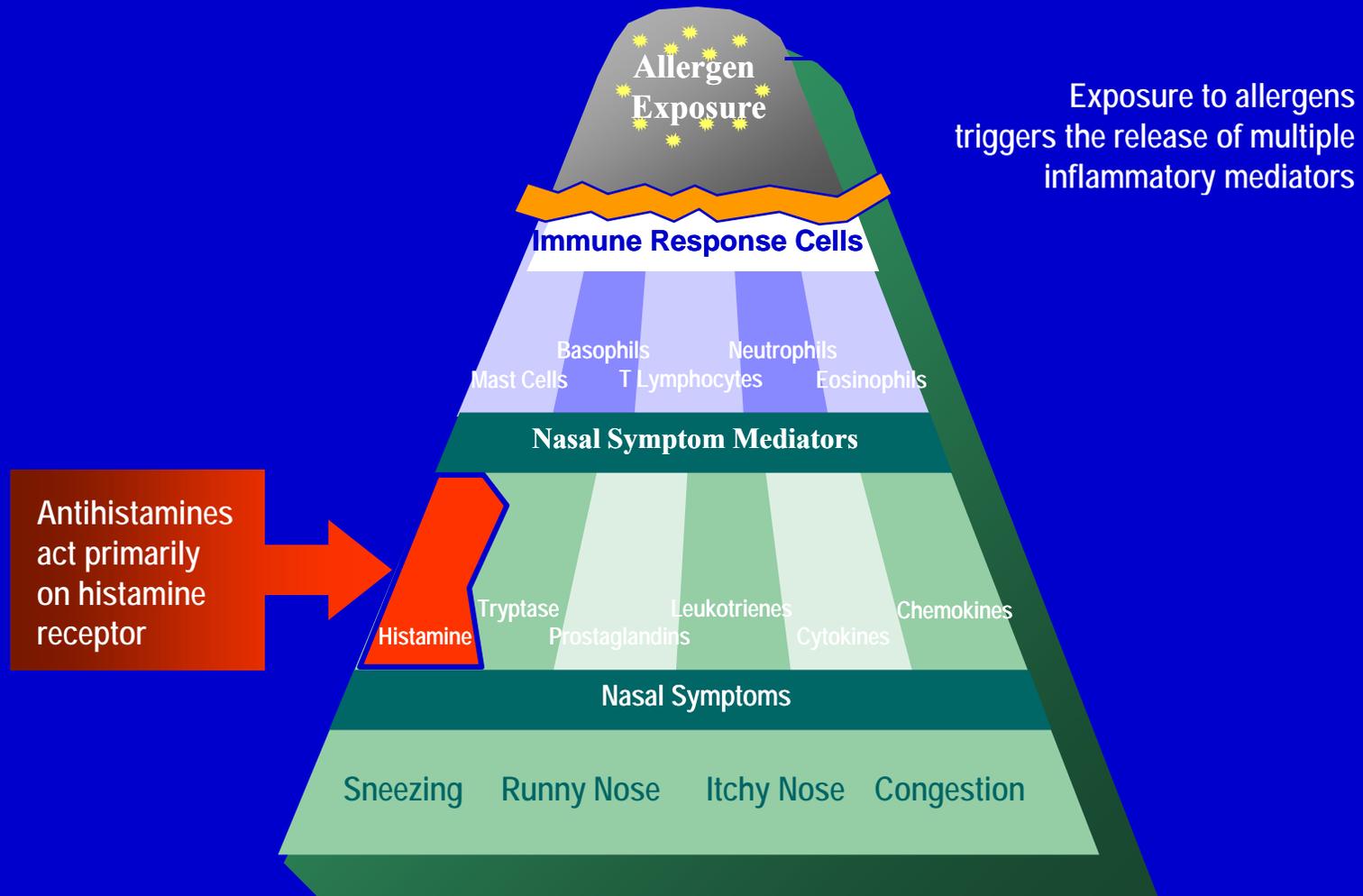
- Allergy is common in children
 - 80%–90% of school-aged children with asthma
 - “Treat the sneeze-prevent the wheeze” -E. Bronsky
- Presence of allergy is associated with more severe and persistent asthma
- Allergen exposure is associated with
 - Increased risk of developing asthma
 - Increased asthma morbidity
 - “Allergic March”

Allergen avoidance can reduce airway hyperreactivity and asthma morbidity

LTRAs: Mechanism of Action*



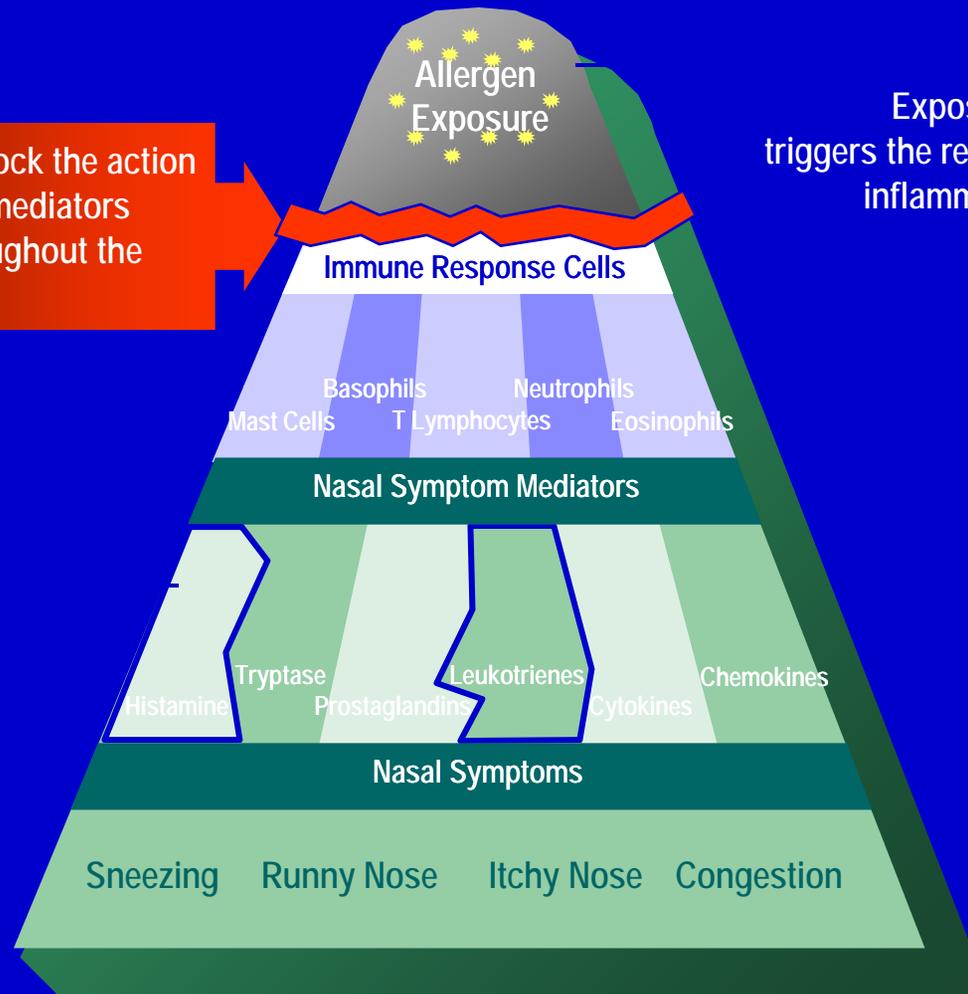
NSAs: Mechanism of Action*



INs: Mechanism of Action*

Nasal steroids block the action of inflammatory mediators early in and throughout the allergic response

Exposure to allergens triggers the release of multiple inflammatory mediators



Intranasal Corticosteroids

- Recommended as first-line therapy^{1,2}
- **Most efficacious therapy for treating AR³**
- Important in the treatment of comorbid asthma⁴
BUT...
- Apparently not leading to complete relief of nasal symptoms⁵
- Only partially effective for ocular symptoms³

1. van Cauwenberge P et al. *Allergy*. 2000;55(2):116-134.

2. Bousquet J et al. *J Allergy Clin Immunol*. 2001;108(5 suppl):S147-S334.

3. Bousquet J et al. *Allergy*. 2003;58(3):192-197.

4. Adams RJ et al. *J Allergy Clin Immunol*. 2002;109(4):636-642.

5. Allergies in America™ Executive Summary. Available at: <http://www.myallergiesinamerica.com>. Accessed February 23, 2007.

Targeting Allergic Rhinitis Nasal Symptoms With Medications

Agent	Sneezing	Congestion	Rhinorrhea
Intranasal corticosteroids	++	++	++
Oral antihistamines	++	+/-	++
Nasal antihistamines	+	+/-	+
Oral decongestants	-	+	-
Intranasal decongestants	-	++	-
Intranasal mast cell stabilizers	+	+	+
Topical anticholinergics	-	-	++

- = provides no benefit

+/- = provides little or minimal benefit

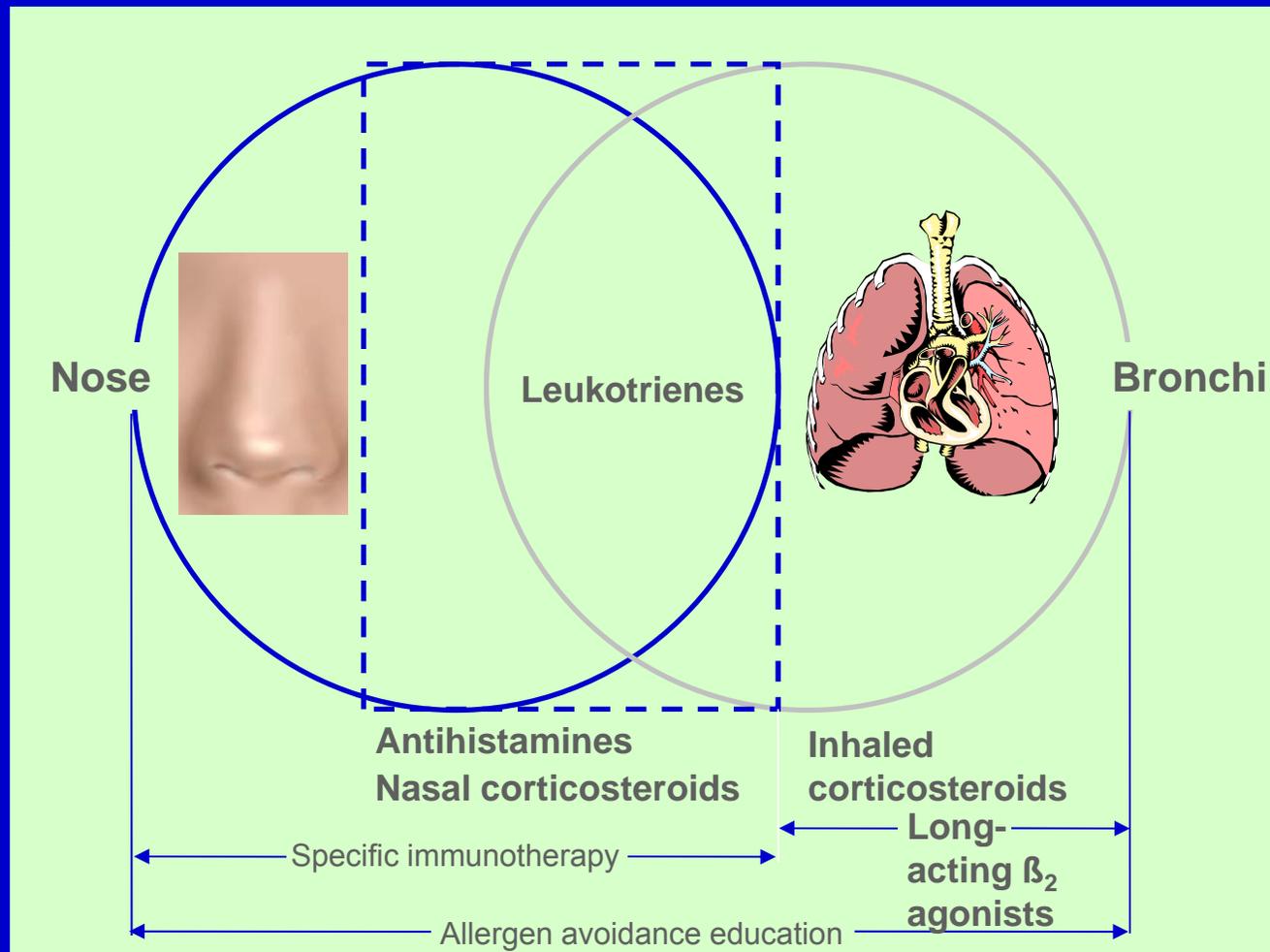
+ = provides modest benefit

++ = provides substantial benefit American Academy of Allergy, Asthma, and Immunology. *The Allergy Report*. Vol 1. Milwaukee, Wis: 2000.

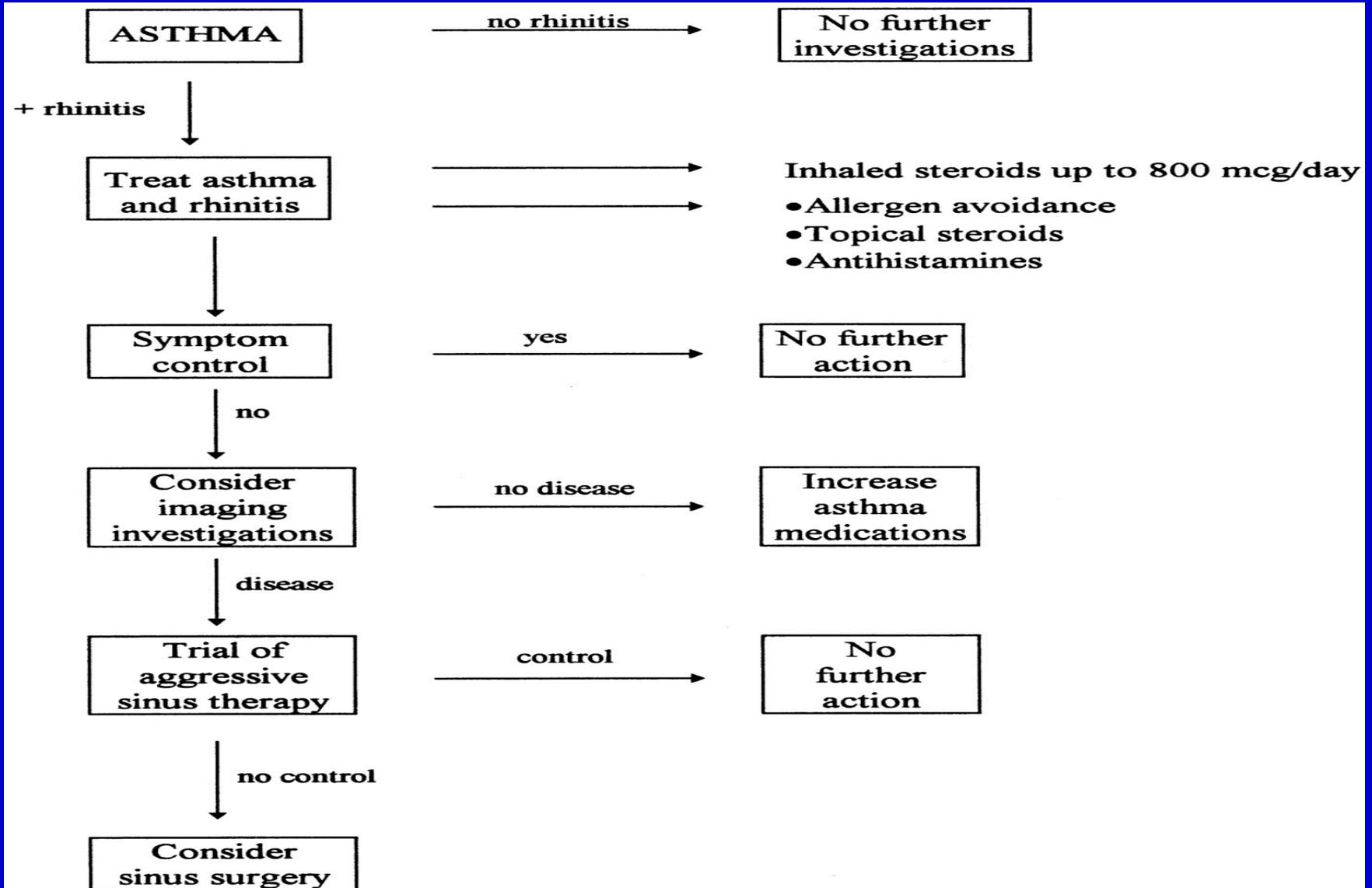
Immunotherapy for Allergic Rhinitis: An Overview

Benefits	Drawbacks
<ul style="list-style-type: none">• Especially effective for grass pollen, ragweed pollen, and house-dust mites• Improvement of childhood allergies in children• May prevent progression of rhinitis to asthma• May reduce need for symptomatic pharmacotherapy	<ul style="list-style-type: none">• Must be administered in facilities equipped to handle adverse reactions (urticaria, laryngeal edema, bronchospasm, and anaphylaxis)• Requires high level of patient compliance

Treatment of the United Airway



Asthma/Rhinitis Algorithm

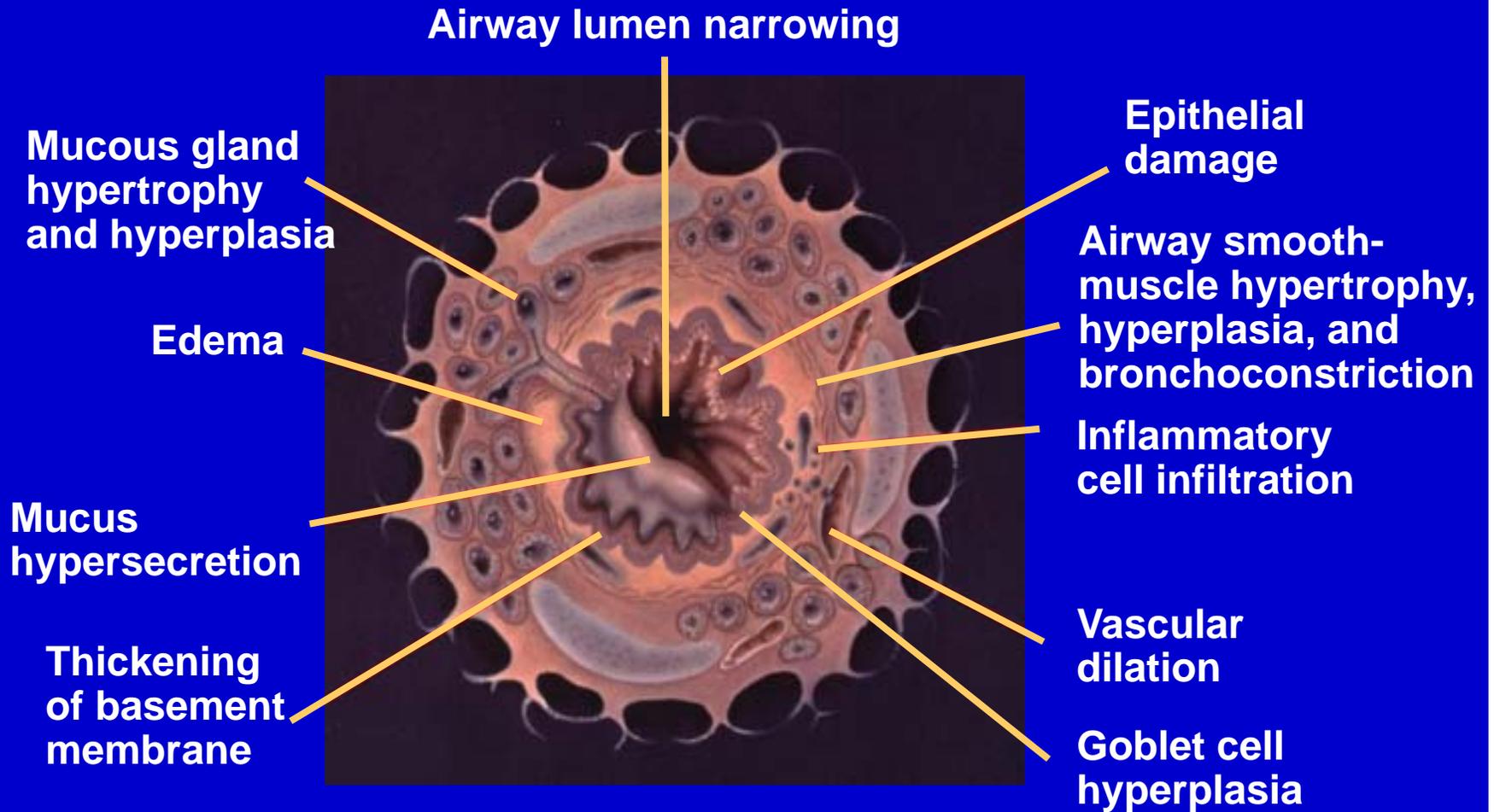


Asthma Triggers

- Allergen exposure
- Respiratory infections
- Strong expressions of emotion (laughing, crying)
- Vigorous exercise
- Cold air
- Dust
- Air pollution
- Cigarette smoke
- Household products
- Drugs
- Pets

National Asthma Education and Prevention Program (NAEPP). *Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma*. National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH). August 2007.

Asthma: Pathophysiologic Features and Changes in Airway Morphology



Adapted from *Expert Panel Report 3. Guidelines for the Diagnosis and Management of Asthma*. NIH, NHLBI. 2007.

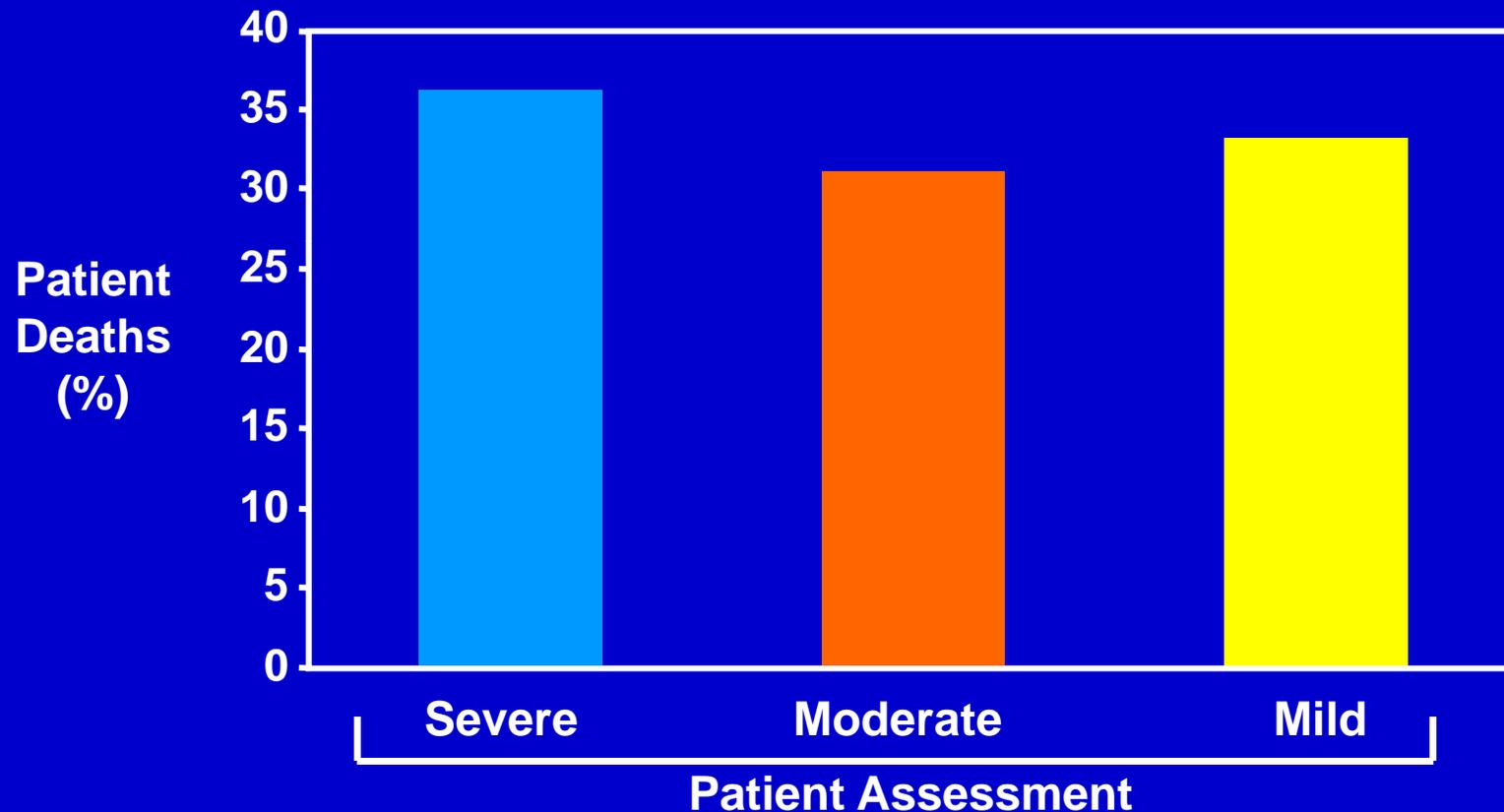
Classification of Severity: Clinical Features Before Treatment

	Symptoms	Nocturnal Symptoms	Lung Function
Step 4 Severe Persistent	<ul style="list-style-type: none"> ◆ Continuous symptoms ◆ Limited physical activity ◆ Frequent exacerbations 	Frequent	<ul style="list-style-type: none"> ◆ FEV₁ or PEF ≤60% predicted ◆ PEF variability >30%
Step 3 Moderate Persistent	<ul style="list-style-type: none"> ◆ Daily symptoms ◆ Daily use of inhaled β₂-agonist ◆ Exacerbations ≥2x/wk 	>1x/wk	<ul style="list-style-type: none"> ◆ FEV₁ or PEF >60%–<80% predicted ◆ PEF variability >30%
Step 2 Mild Persistent	<ul style="list-style-type: none"> ◆ Symptoms >2x/wk but <1x/day 	>2x/mo	<ul style="list-style-type: none"> ◆ FEV₁ or PEF ≥80% predicted ◆ PEF variability 20%–30%
Step 1 Mild Intermittent	<ul style="list-style-type: none"> ◆ Symptoms ≤2x/wk ◆ Asymptomatic and normal PEF between exacerbations 	≤2x/mo	<ul style="list-style-type: none"> ◆ FEV₁ or PEF ≥80% predicted ◆ PEF variability <20%

Asthma Variability

- Asthma is a variable condition
- Patients frequently move between severity categories
- Asthma severity cannot be determined in many patients based upon discrete, point-in-time assessments of lung function, frequency of SABA use, or asthma symptoms

Pediatric Asthma Deaths: Patients With Mild Asthma Are Also at Risk



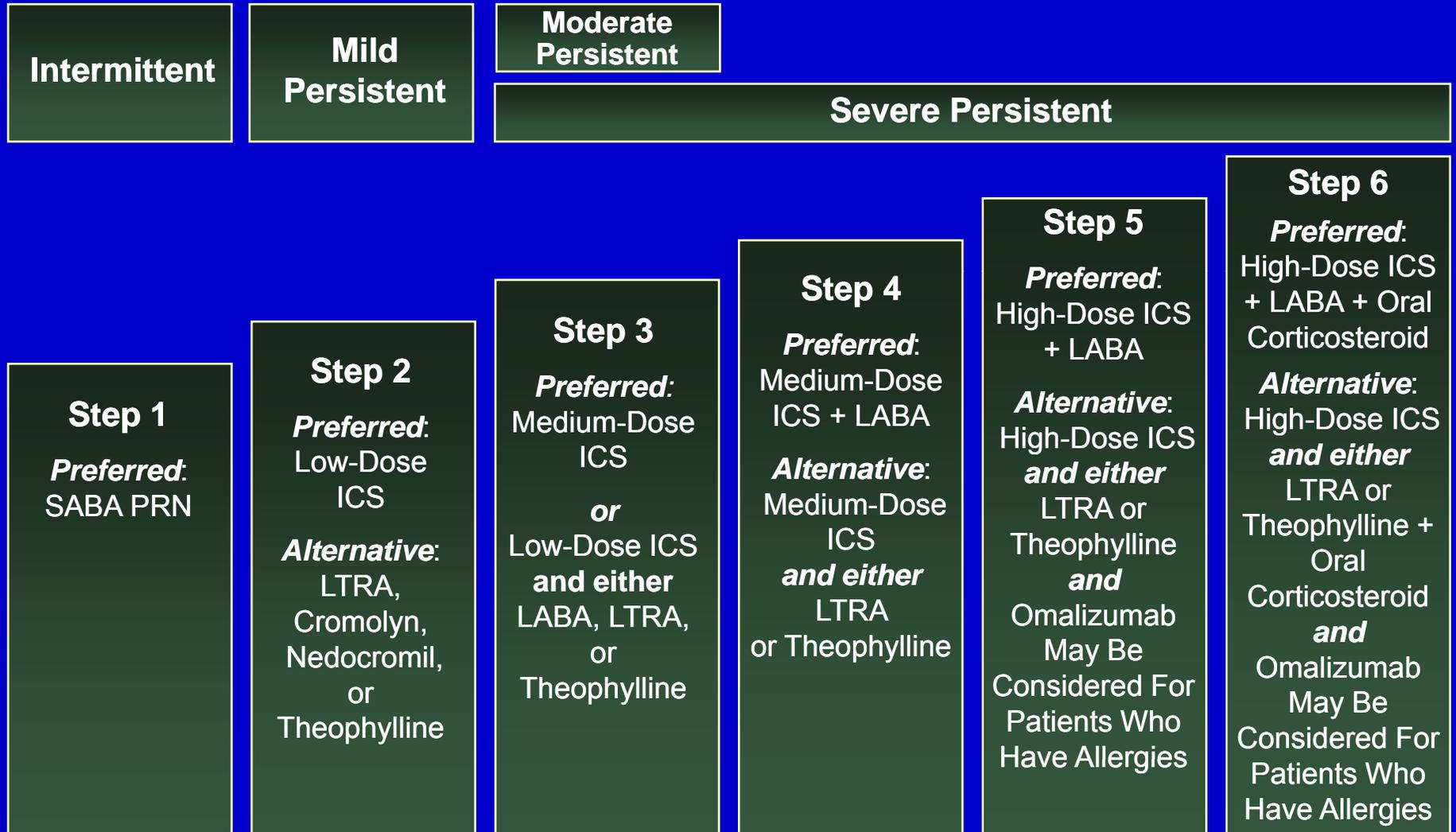
Findings from a cohort study reviewing all pediatric asthma-related deaths (n=51) in the Australian state of Victoria from 1986 to 1989.

Robertson et al. *Pediatr Pulmonol.* 1992;13:95-100.

National Asthma Education and
Prevention Program (NAEPP) Guidelines
for the Treatment of Asthma

3rd Expert Panel Report (EPR-3)

Stepwise Approach for Managing Asthma in Children Aged 5 to 11 Years



LTRA = leukotriene receptor antagonist.

Stepwise Approach for Managing

Asthma in Patients Aged ≥ 12 Years:

Intermittent

Mild
Persistent

Moderate
Persistent

Severe Persistent

Step 1

Preferred:
SABA PRN

Step 2

Preferred:
Low-Dose
ICS
Alternative:
Cromolyn,
Nedocromil,
LTRA,
or
Theophylline

Step 3

Preferred:
Medium-Dose
ICS
or
Low-dose ICS +
LABA
Alternative:
Low-Dose ICS
and either
LTRA,
Theophylline, or
Zileuton

Step 4

Preferred:
Medium-Dose
ICS + LABA
Alternative:
Medium-Dose
ICS
and either
LTRA,
Theophylline,
or Zileuton

Step 5

Preferred:
High-Dose ICS
+ LABA
and
Consider
Omalizumab
For Patients
Who Have
Allergies

Step 6

Preferred:
High-Dose ICS
+ LABA
+ Oral
Corticosteroid
and
Consider
Omalizumab
For Patients
Who Have
Allergies

Goal of Asthma Therapy: Achieve Control

Reduce Impairment

- Prevent chronic and troublesome symptoms
- Require infrequent use of inhaled SABA (≤ 2 days/week)
- Maintain (near) “normal” pulmonary function
- Maintain normal activity levels
- Meet patients’ expectations of, and satisfaction with, asthma care

Reduce Risk

- Prevent recurrent exacerbations
- Minimize need for emergency department visits or hospitalizations
- Prevent progressive loss of lung function
- Provide optimal pharmacotherapy, with minimal or no adverse effects

Asthma Control Test™ (ACT)

1. In the past **4 weeks**, how much of the time did your **asthma** keep you from getting as much done at work, school or at home?

Score

All of the time **1** Most of the time **2** Some of the time **3** A little of the time **4** None of the time **5**

2. During the past **4 weeks**, how often have you had shortness of breath?

More than once a day **1** Once a day **2** 3 to 6 times a week **3** Once or twice a week **4** Not at all **5**

3. During the past **4 weeks**, how often did your **asthma** symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night, or earlier than usual in the morning?

4 or more nights a week **1** 2 or 3 nights a week **2** Once a week **3** Once or twice **4** Not at all **5**

4. During the past **4 weeks**, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

3 or more times per day **1** 1 or 2 times per day **2** 2 or 3 times per week **3** Once a week or less **4** Not at all **5**

5. How would you rate your **asthma** control during the past **4 weeks**?

Not controlled at all **1** Poorly controlled **2** Somewhat controlled **3** Well controlled **4** Completely controlled **5**

Childhood Asthma Control Test

Questions Completed by Child Age 4-11 Years

1. How is your asthma today?

SCORE



0
Very bad



1
Bad



2
Good



3
Very Good

2. How much of a problem is your asthma when you run, exercise or play sports?



0

It's a big problem, I can't do what I want to do.



1

It's a problem and I don't like it



2

It's a little problem but it's okay.



3

It's not a problem.

3. Do you cough because of your asthma?



0

Yes, all of the time.



1

Yes, most of the time.



2

Yes, some of the time.



3

No, none of the time.

4. Do you wake up during the night because of your asthma?



0

Yes, all of the time.



1

Yes, most of the time.



2

Yes, some of the time.



3

No, none of the time.

Childhood Asthma Control Test

Questions Completed by Parent/Caregiver

5. During the last 4 weeks, on average, how many days per month did your child have any daytime asthma symptoms?

5

Not at all

4

1-3 days/mo

3

4-10 days/mo

2

11-18 days/mo

1

19-24 days/mo

0

Everyday

6. During the last 4 weeks, on average, how many days per month did your child wheeze during the day because of asthma?

5

Not at all

4

1-3 days/mo

3

4-10 days/mo

2

11-18 days/mo

1

19-24 days/mo

0

Everyday

7. During the last 4 weeks, on average, how many days per month did your child wake up during the night because of asthma?

5

Not at all

4

1-3 days/mo

3

4-10 days/mo

2

11-18 days/mo

1

19-24 days/mo

0

Everyday

TOTAL

Expanded Rules of Two®

Long term controller therapy is needed if your patient

- **Uses SABA >2 times/week**
- **Awakens at night >2 times/month**
- **Refill SABA >2 times/year**
- **2 or more unscheduled visits/year**
- **2 or more courses of oral corticosteroid/year**

Overview of Asthma Medications

Long-Term Control

- Corticosteroids (inhaled)
- Long-acting beta₂-agonists
- Cromolyn/nedocromil
- Methylxanthines-**Theophylline**
- Leukotriene modifiers
- Anti-IgE therapy
- Allergen Immunotherapy

Quick Relief

- Short-acting inhaled beta₂-agonists
- Anticholinergics
- Systemic corticosteroids

National Asthma Education and Prevention Program (NAEPP). *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma*. National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

ICS + LABA Combinations

- **Greater efficacy in combination products versus ICS alone:**
 - Improved daytime and nighttime symptoms
 - Improved lung function
 - Decreased SABA need
 - Reduced frequency of exacerbations
 - Improved asthma control
 - Reduced ICS dose
- **Increased convenience**
- **May improve adherence**
- **U.S. combinations:**
 1. **Budesonide + formoterol (HFA)**
 2. **Fluticasone + salmeterol (DPI & HFA)**
 3. **Mometasone+formoterol (HFA)**

Long-Term Control Medications

- EPR-3 recommends long-term control medications be taken on a daily basis for treatment of persistent asthma
- Inhaled corticosteroids
- Inhaled long-acting bronchodilators (LABA)
- Leukotriene modifiers (Singulair)
- Mast cell stabilizers (Cromolyn and nedocromil or Tilade)
- Theophylline
- Immunomodulators

LABAs: Where Do We Stand?

- FDA Black Box Warning
 - “These medicines may increase the chance of severe asthma episodes, and death when those episodes occur”
- SMART Study was not designed to assess the effect of ICS on the endpoints
- At this point, guidelines and clinical trial data continue to support the use of LABAs *ONLY* as add-on to ICS

The **NEW ENGLAND**
JOURNAL *of* **MEDICINE**

**Step-up Therapy for Children with Uncontrolled Asthma
While Receiving Inhaled Corticosteroids**

Robert F. Lemanske, Jr., M.D., David T. Mauger, Ph.D., Christine A. Sorkness, Pharm.D., Daniel J. Jackson, M.D.,
Susan J. Boehmer, M.S., Fernando D. Martinez, M.D., Robert C. Strunk, M.D., Stanley J. Szeffler, M.D.,
Robert S. Zeiger, M.D., Ph.D., Leonard B. Bacharier, M.D., Ronina A. Covar, M.D., Theresa W. Guilbert, M.D.,
Gary Larsen, M.D., Wayne J. Morgan, M.D., Mark H. Moss, M.D., Joseph D. Spahn, M.D.,
and Lynn M. Taussig, M.D., for the Childhood Asthma Research and Education (CARE)
Network of the National Heart, Lung, and Blood Institute

nejm.org

N Engl J Med 2010;362:975-985.

BADGER: Research Question

- In children not satisfactorily controlled on low dose ICS (fluticasone 100 µg BID) therapy, what is the next best treatment approach?
 - Increased doses of ICS (fluticasone 250 µg BID)?
 - Add a LABA (salmeterol/fluticasone combination)?
 - Add a LTRA (montelukast)?

BADGER: Novel Trial Design

- Each participant would receive all 3 treatment options
- Determine the presence or absence of a differential response among those treatments using a composite outcome that evaluated 3 components in defining asthma control:
 - Impairment domain
 - Asthma control days
 - Pulmonary function (FEV₁)
 - Risk domain
 - Asthma exacerbations

Differential Response



- At the end of the study, each child was identified as either a **differential** or **non-differential** treatment responder.
- A **differential responder** was someone who exhibited significantly better outcomes on one treatment than on another.
- Effective treatment response was based on (in order of importance):
 1. Asthma exacerbations
 2. Asthma control days (ACD)
 3. Change in FEV₁

BADGER: Outcome measures to determine differential response

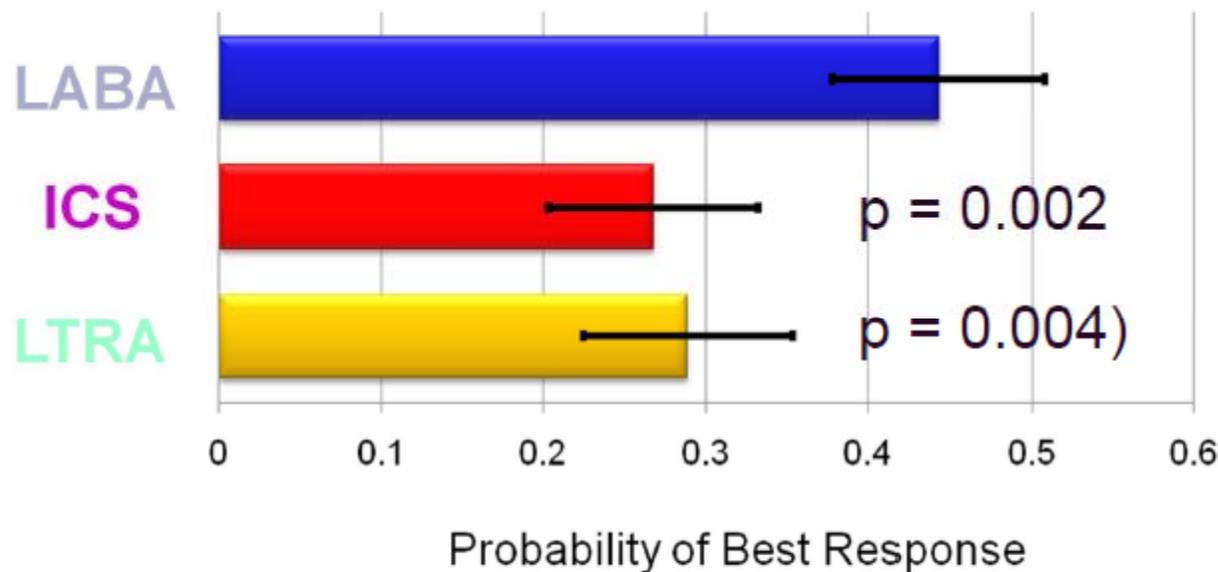
- 3 outcome measures:
 - Exacerbations:
 - occurs when the total amount of prednisone prescribed to control asthma symptoms is at least 180 milligrams less on one treatment than on either of the other two treatments
 - FEV₁:
 - occurs when the FEV1 change is at least 5.0% higher on one treatment than on either of the other two treatments
 - Asthma Control Days:
 - occurs when the number of annualized ACD (AACD) achieved is at least 31 days more on one treatment than on either of the other two treatments

Results: Differential Response

- Differential response occurred in
161/165 participants (98%)
($p < 0.0001$)

Primary Outcome: Probability of BEST Response Based on Composite Outcome*

LABA step-up was more than 1.5 times as likely to produce the best response

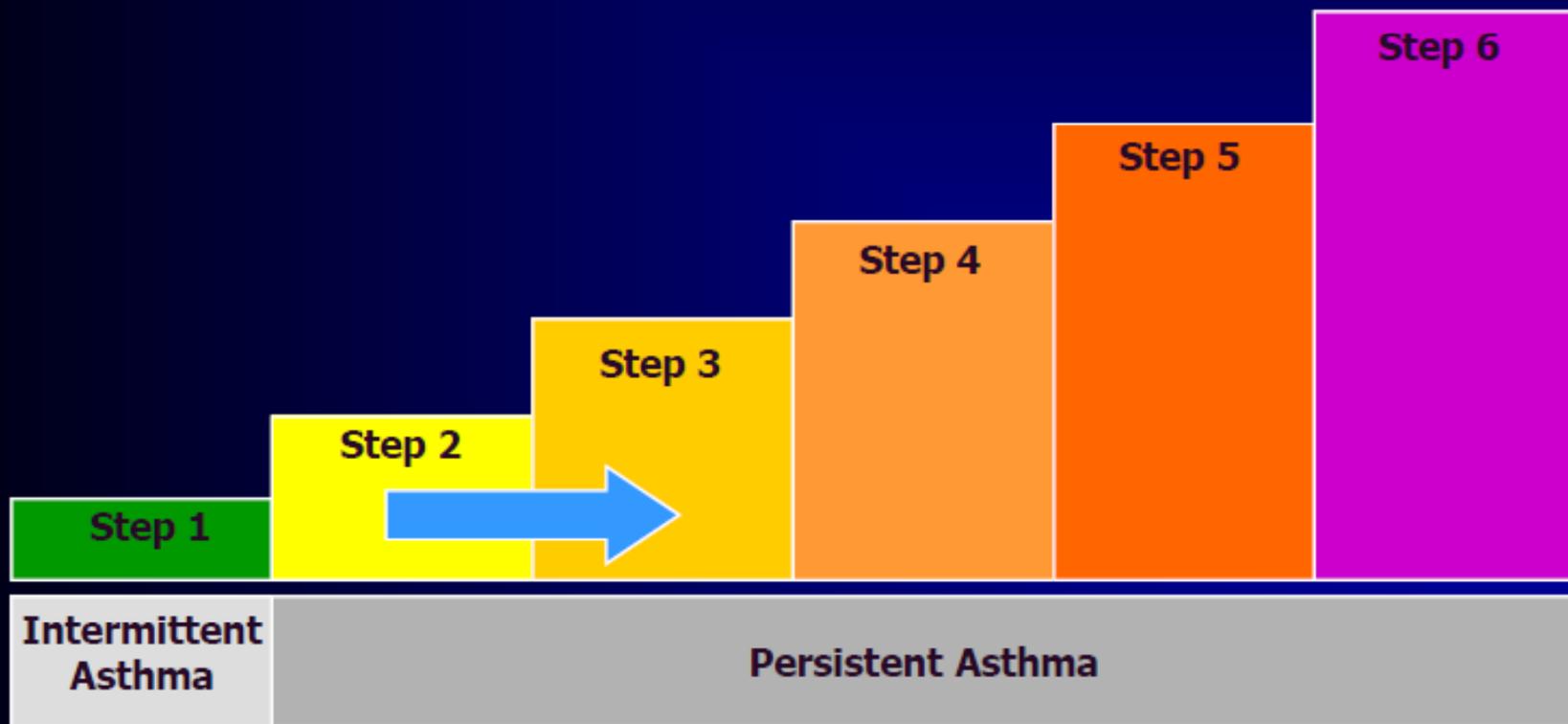


*Covariate adjusted model Ref. Lemanske R and CARE Network NEJM 2010;362:975-985.
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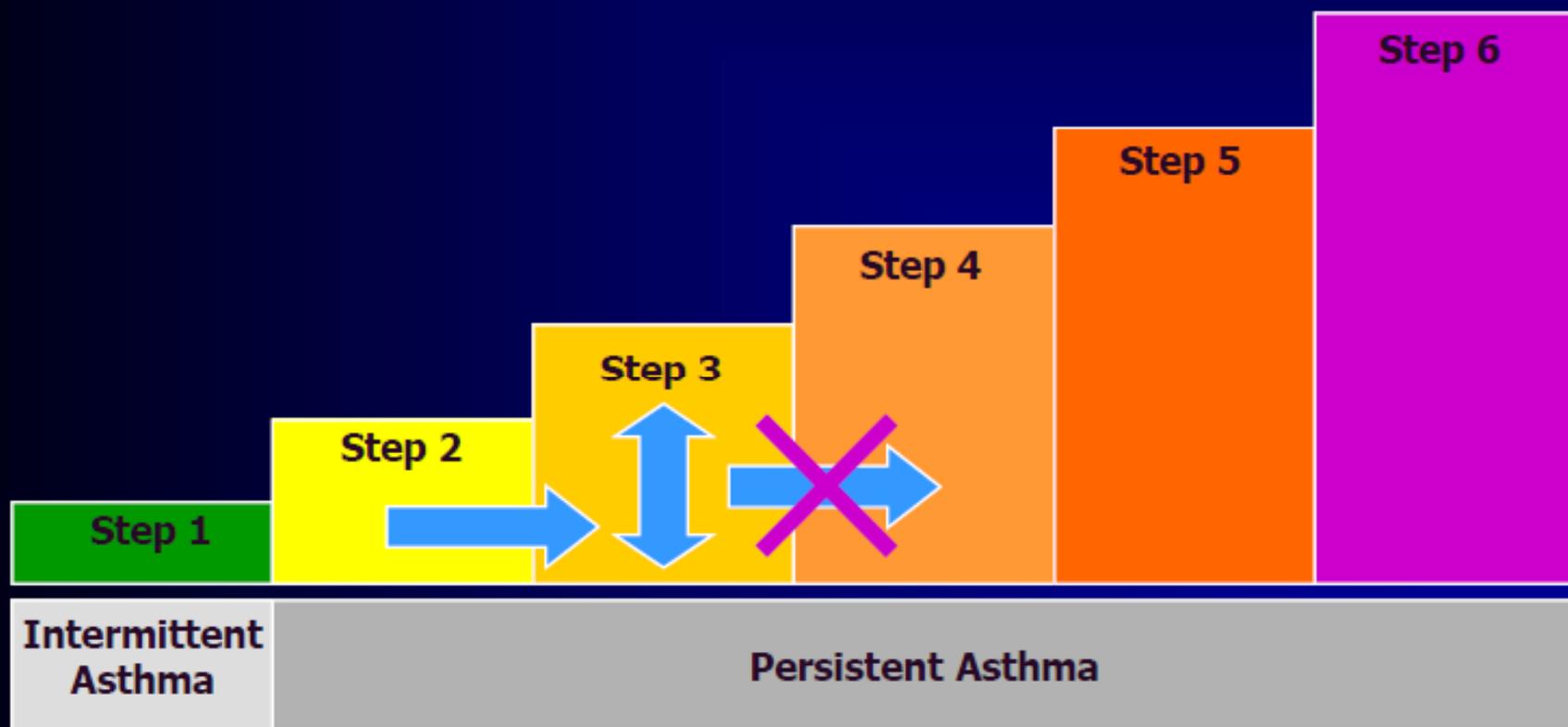
BADGER: Conclusions

The probability of experiencing the best overall response was more than 1.5 times as likely with LABA step-up.



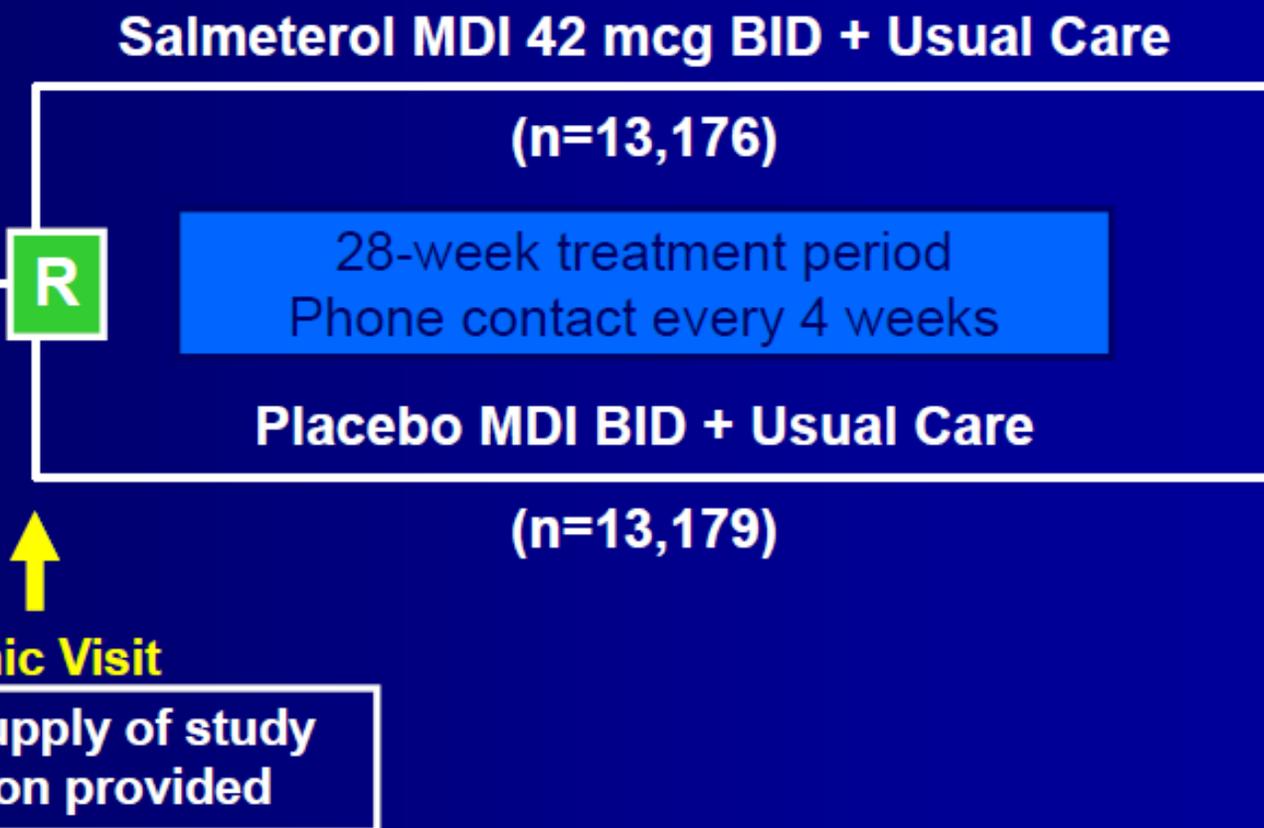
BADGER: Conclusions

Many children demonstrated a best response to either ICS or LTRA step-up, highlighting the need to regularly monitor and appropriately adjust each child's asthma therapy.



SMART Study Design

- No inhaled long-acting beta₂-agonist
- ≥12 years of age



SMART Study Endpoints

- Primary Endpoint
 - Combined respiratory-related deaths or life-threatening experiences (intubation and ventilation)
- Key Secondary Endpoints
 - Respiratory-related deaths
 - Combined asthma-related deaths or life-threatening experiences
 - Asthma-related deaths

Baseline Characteristics

	Salmeterol (n=13,176)	Placebo (n=13,179)
Age, mean	39.2	39.1
Sex, n (%)		
Female	8334 (64)	8337 (64)
Male	4703 (36)	4686 (36)
Ethnic origin, n (%)		
Caucasian	9281 (71)	9361 (72)
African American	2366 (18)	2319 (18)
Hispanic	996 (8)	999 (8)
Asian	173 (1)	149 (1)
Other	230 (2)	224 (2)
Peak expiratory flow (% predicted)	84.0	83.8

Nelson HS et al. *Chest*. 2006;129:15-26. Adapted with permission.

Baseline Asthma Characteristics in Caucasians and African Americans

	Caucasian (n=18,642)	African American (n=4685)
Peak expiratory flow (% predicted)	85%	78%
Nocturnal symptoms present	59%	67%
≥ 1 ER visit last 12 months	22%	41%
≥ 1 ER visit lifetime	59%	72%
≥ 1 hospitalization last 12 months	6%	15%
≥ 1 hospitalization lifetime	30%	44%
≥ 1 intubation for asthma lifetime	4%	8%
Baseline ICS use	49%	38%

Nelson HS et al. *Chest*. 2006;129:15-26. Adapted with permission.

Asthma-Related Deaths in the 28-Week Salmeterol Multicenter Asthma Research Trial (SMART)

	Salmeterol n (%)	Placebo n (%)	Relative Risk (95% confidence interval)	Excess Death Exp. Per 10,000 pts. (95% confidence interval)
Population Salmeterol: N = 13,176 Placebo: N = 13,179	13 (0.10%)	3 (0.02%)	4.37 (1.25, 15.34)	8 (3,13)
Caucasian Salmeterol: N = 9281 Placebo: N = 9361	6 (0.7%)	1 (0.01%)	5.82 (0.70, 48.37)	6 (1,10)
African American Salmeterol: N = 2366 Placebo: N = 2319	7 (0.31%)	1 (0.04%)	7.26 (0.89, 58.94)	27 (8,46)

LABA's or NOT?

- FDA Black Box Warning provides another scare for asthmatics, and parents of asthmatic children to not use ICS
- Pre-emptive and proactive discussion of the pros and cons of LABA use in combination with long-term controller meds is appropriate
- Developing that collaborative, mutually agreed upon treatment plan with patients is crucial

The United Airway

Questions?

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