Overview of Asthma: Treatment Guidelines

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Objectives

- Review of Guidelines
- Pediatric Asthma Management Tools
- Techniques for successful control
- Review devices for administration and management of asthma

National Heart, Lung and Blood Institute Guidelines

- Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma
- www.NHLBI.NIH.gov
- 1991 Guidelines
- 1997 Guidelines
- 2002 Update
## Key Points to Guideline Changes

- **Monitoring**
  - Definition of Spirometry and Peak Flow Use
- **Medication Management**
  - Effective strategies to control chronic inflammation
- **Social**
  - Inclusion of Patient and Family Expectations
- **Environment Control**

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## 2007 Guidelines

- **Diagnostic Criteria**
  - Episodic airflow obstruction
  - At least partial reversibility
  - Alternative diagnoses are excluded
  - Obstructive sleep apnea
  - GERD

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## 2007 Guidelines

- **Diagnostic Criteria**
  - Following indicators combined with spirometry
- **Wheezing**
- **History of:**
  - Cough, worse at night
  - Recurrent wheeze
  - Recurrent difficulty breathing
  - Recurrent chest tightness
2007 Guidelines

- Diagnostic Criteria
  - Following indicators combined with spirometry

- Symptoms occur or worsen with:
  - Exercise
  - Viral infection
  - Animals
  - Dust mites
  - Menstrual cycles
  - Airborne chemicals/dust
  - Mold
  - Smoke
  - Change of weather
  - Pollen
  - Emotional outburst

2007 Guidelines

- Differential Diagnosis
  - Other diagnoses to consider

- Allergic rhinitis and sinusitis
- Foreign body
- Vocal cord dysfunction
- Lymph node enlargement
- Viral bronchiolitis
- Cystic fibrosis
- COPD
- GERD
- Pulmonary embolism
- Iatrogenic cough (ACE-i)

2007 Guidelines

- Components to Asthma Care
  - Measures for assessment and monitoring (physical, pt Hx, pt report)
  - Pharmacologic Management
  - Education for a partnership in asthma care
  - Control of environmental factors and comorbid conditions
### 2007 Guidelines

- **Measures for assessment and monitoring** (physical, pt Hx, pt report)
  - Severity - baseline
  - Control - intensity of exacerbation
  - Responsiveness - reversibility

### 2007 Guidelines

- **Inflammatory process**
- **Early recognition of disease**
  - Atopy
  - Rhinitis
- **Category Changes**
  - Intermittent instead of “mild intermittent”

### 2007 Guidelines

- **Address impairment and risk**
  - Effect on QOL
  - Risk of exacerbations and effect on pulmonary function
- **FEV₁ / FVC added as diagnostic indices in children**
- **Influenza vaccination recommendations**
### Quality of Life

- **HRQoL**
  - Measures evaluated
    - Asthma symptoms,
    - Health care utilization
    - And school absences
    - Caregiver emotional distress
  - Comparison
    - Spirometry

### 2007 Guidelines

- **Factors describing Impairment**
  - Symptoms:
    - Nocturnal awakenings
    - Need for short acting beta agonist
    - Work/school days missed
    - Ability to perform normal/desired activities
    - QoL assessments
  - PFT’s

### 2007 Guidelines

- **Factors describing Risk**
  - Adverse effects
  - Exacerbations
    - Frequency
    - Severity
### Classification of Asthma Severity Children age 0-4 years

<table>
<thead>
<tr>
<th>Component of Severity</th>
<th>Classification</th>
<th>Intermittent</th>
<th>Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment</td>
<td></td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Symptoms</td>
<td>&lt;2 days/wk</td>
<td>&lt;2 days/week, not daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Nighttime Awakenings</td>
<td>0</td>
<td>1-2/week, not QD</td>
<td>3-4/week</td>
</tr>
<tr>
<td>SABA Relief</td>
<td>&lt; 2 days/wk</td>
<td>&gt; 20 days/week, not QD</td>
<td>Daily</td>
</tr>
<tr>
<td>Interference w/norm. activity</td>
<td>None</td>
<td>Minor limitation</td>
<td>Some limitation</td>
</tr>
<tr>
<td>Risk</td>
<td>Exacerbations needing PO Steroids</td>
<td>0-1/year</td>
<td>&gt;2x/6 mos OR &gt;4 wheezing episodes/year AND risk factors for asthma</td>
</tr>
</tbody>
</table>

### Lung Function

<table>
<thead>
<tr>
<th>FEV1</th>
<th>FEV1/FVC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;60% pred</td>
<td>&lt;75%</td>
</tr>
<tr>
<td>FEV1 60-80% pred</td>
<td>FEV1/FVC 75-80%</td>
</tr>
<tr>
<td>&gt;80% pred</td>
<td>FEV1/FVC &gt;85%</td>
</tr>
</tbody>
</table>

### Symptoms Impact

- Extremely limited
- Some limitation
- Minor limitation
- None
- Interference w/normal activity

### Nighttime Awakenings

- Several times per day
- Daily
- >2 Days/week, not QD
- QD

### SABA Relief

- <2 Days/wk
- >20 Days/wk, not QD

### Effect on Normal Activity

- Several times per day
- Daily
- >2 Days/week, not QD
- QD

### Classification of Asthma Severity Children 5-11 years old

<table>
<thead>
<tr>
<th>Component of Severity</th>
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<th>Intermittent</th>
<th>Persistent</th>
</tr>
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<tbody>
<tr>
<td>Impairment</td>
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<td>Symptoms</td>
<td>&lt; 2 days/wk</td>
<td>&gt; 2 days/week, not daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Nighttime Awakenings</td>
<td>&lt; 2x/mo</td>
<td>3-4x/mo</td>
<td>5-8x/mo</td>
</tr>
<tr>
<td>SABA Relief</td>
<td>&lt; 2 days/wk</td>
<td>&gt; 20 days/week, not QD</td>
<td>Daily</td>
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<tr>
<td>Effect on Normal Activity</td>
<td>None</td>
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<td>Some limitation</td>
</tr>
<tr>
<td>Lung Function</td>
<td>FEV1 &lt;80% pred</td>
<td>FEV1/FVC &gt;80%</td>
<td>FEV1 60-80% pred</td>
</tr>
<tr>
<td>Risk</td>
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<td>0-1/year</td>
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### Symptoms Impact

- Extremely limited
- Some limitation
- Minor limitation
- None
- Interference w/normal activity

### Nighttime Awakenings

- Several times per day
- Daily
- >2 Days/week, not QD
- QD

### SABA Relief

- <2 Days/wk
- >20 Days/wk, not QD

### Classification of Asthma Severity 12 years and older

<table>
<thead>
<tr>
<th>Component of Severity</th>
<th>Classification</th>
<th>Intermittent</th>
<th>Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment</td>
<td></td>
<td>Mild</td>
<td>Moderate</td>
</tr>
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<td>Symptoms</td>
<td>&lt; 2x/wk</td>
<td>&gt; 2 days/week, not daily</td>
<td>Daily</td>
</tr>
<tr>
<td>Nighttime Awakenings</td>
<td>&lt; 2x/mo</td>
<td>1-4x/mo</td>
<td>5-8x/mo</td>
</tr>
<tr>
<td>SABA Relief</td>
<td>&lt; 2 days/wk</td>
<td>&gt; 20 days/week, not QD</td>
<td>Daily</td>
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<tr>
<td>Effect on Normal Activity</td>
<td>None</td>
<td>Minor limitation</td>
<td>Some limitation</td>
</tr>
<tr>
<td>Lung Function</td>
<td>FEV1 &lt;80% pred</td>
<td>FEV1/FVC &gt;80%</td>
<td>FEV1 60-80% pred</td>
</tr>
<tr>
<td>Risk</td>
<td>Exacerbations needing PO Steroids</td>
<td>0-1/year</td>
<td>&gt;2x/yr</td>
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### Nighttime Awakenings

- Several times per day
- Daily
- >2 Days/week, not QD
- QD

### SABA Relief

- <2 Days/wk
- >20 Days/wk, not QD
### Classification of Asthma Control

#### Age 0-4 yrs

<table>
<thead>
<tr>
<th>Component of Control</th>
<th>NHLBI 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment</td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>&lt;2x/wk</td>
</tr>
<tr>
<td>&gt;2x/wk, not QD</td>
<td></td>
</tr>
<tr>
<td>&gt;2x/wk, not QD</td>
<td></td>
</tr>
<tr>
<td>Nighttime Awakenings</td>
<td>1x/night</td>
</tr>
<tr>
<td>&gt;2x/night</td>
<td></td>
</tr>
<tr>
<td>&lt;2x/night</td>
<td></td>
</tr>
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<td>Effect on Normal Activity</td>
<td>None</td>
</tr>
<tr>
<td>Short Acting Beta Agonist Use</td>
<td>&lt; 2 days/wk</td>
</tr>
</tbody>
</table>

| Risk                  | Exacerbations needing PO Steroids | 0-1x/yr | 2-3x/yr | >3 x/yr |

#### Age 5-11 yrs old

<table>
<thead>
<tr>
<th>Component of Control</th>
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</thead>
<tbody>
<tr>
<td>Impairment</td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>&lt;2x/wk</td>
</tr>
<tr>
<td>&gt;2x/wk, or multiple times</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Nighttime Awakenings</td>
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</tr>
<tr>
<td>&gt;2x/night</td>
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| Risk                  | Exacerbations needing PO Steroids | 0-1x/yr | >2 x/yr |

#### Age >12 years of age

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<tr>
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<th>NHLBI 2007</th>
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<tbody>
<tr>
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<td>Effect on Normal Activity</td>
<td>None</td>
</tr>
<tr>
<td>Short Acting Beta Agonist Use</td>
<td>&lt; 2 days/wk</td>
</tr>
<tr>
<td>FEV1 or Peak Flow</td>
<td>&gt;80% predicted / personal best</td>
</tr>
<tr>
<td>Validated questionnaires</td>
<td>ATAQ</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>&gt;20</td>
</tr>
<tr>
<td></td>
<td>&gt;19</td>
</tr>
</tbody>
</table>

| Risk                  | Exacerbations needing PO Steroids | 0-1x/yr | >2 x/yr |
Long-Acting Beta-Agonists

- Formal FDA Warnings Feb 18, 2010
  - Safety Guidelines
    - Not to be used as monotherapy
    - Long-term use for patients without control on other therapy
    - Shortest duration during step-up therapy
    - Use combination products to ensure adherence


2007 Guidelines

Pediatric Stepped Therapy

0-4 years

<table>
<thead>
<tr>
<th>Low-Dose ICS</th>
<th>Medium Dose LABA, LABA or LTRA or Xanthine</th>
<th>High Dose ICS + LABA + Oral CS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent</td>
<td>Persistent Environment control / Pt Education</td>
<td>Referral Asthma Specialist</td>
</tr>
</tbody>
</table>

5-11 years

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Intermittent</td>
<td>Persistent Environment control / Pt Education</td>
<td>Referral Consider Immunotherapy Asthma Specialist</td>
</tr>
</tbody>
</table>
2007 Guidelines

- Adult Stepped Therapy
  - Beta-Agonist prn
  - Low-Dose ICS
    - Low Dose ICS
    - Medium Dose ICS
      - Medium Dose ICS
        - High Dose ICS
          - High Dose ICS
            - High Dose ICS
  - Medium Dose ICS
    - LABA
    - High Dose ICS
      - LABA
      - Oral CS
        - May add Omalizumab

Asthma as an Inflammatory Disease

- Key point as parents' treatment contrasts with current therapy
- Reversible remodeling spontaneously or with treatment
- Poorly controlled asthma may result in irreversible damage

Allergic Rhinitis and Asthma

- Incidence with asthma increased 41% to 77% over 20 years (1983-1995)
- Effective management reduces ER visits for asthma
Overview of Classification

Symptoms

Nighttime

Lung Function

Severe Persistent

Continual Frequent < 60% of predicted

Variability > 30%

Moderate Persistent

Daily

Daily use of rescue medication

Activity affected

Attacks > 2x/wk > 1x/wk 60-80% of predicted

PEF Variability >30%

Mild Persistent

Sx > 2x/wk, < daily

May affect activity

> 2x/mo 80-100% of predicted

20-30% variability

Mild Intermittent

Sx < 2x/wk

Asymptomatic between episodes

Brief duration of episodes

< 2x/mo 80-100% of predicted

<20% variability

NHLBI 1997

Diversity in the Patient Population

Diversity

- Age, Gender, Cultural, Socioeconomic status, Religion, Race, Sexual orientation, Disability, Veteran status, National origin, Gender identity, or any other protected status.

Adjust your interview as needed

- Posture
- Position
- Dress

Instructional Materials

- Video resources
- Patient education

Patient Instructions

- Provide in patient's native language
- Parent, caregiver
Opportunities: Pro-Active Office Encounters

- Screening for all patients with asthma Dx
  - Frequency of nocturnal episodes
  - Frequency of immediate albuterol need

Opportunities: Asthma Screening

- Asthma Control Test
  - Validated survey instrument for asthma
  - Scores less than 20 indicate need to re-evaluate therapy
  - Flaws:
    - Need to specify that questions refer to period without acute asthma flare
    - Need to assess each question individually

Opportunities: Asthma Screening

- Asthma Control Test
  - Interference with daily activities
  - SOB frequency
  - AM/Hs asthma Sx
  - Rescue med use
  - Self rating of asthma control
**When to Review Asthma**

- Physical Exams
- Refill requests for inhalers
- Urgent care clinic visits for asthma or respiratory-related problems

**Evaluate Data**

- Medication refill rates
  - What is refilled
  - How often is it refilled
  - Date (Sold or Ordered)
    - 5/1/09 (S) Albuterol
    - 5/1/09 (O) Qvar 80 mcg
- Frequency of Oral Steroid Bursts

**Follow-Up Appointment Questions**

- Beta-Agonist Refill Rate
- Participation in regular activities / exercise
Using Healthconnect as an Asthma Tool

- Develop your preferred medication list for asthma
  - ICS with common sigs
    - Include "to control asthma" as part of the sig
    - Default to multiple refills
    - Example: Qvar 80 # 3 sig: 1 puff twice a day to control asthma, 2 puffs twice a day with colds, brush teeth after use (3 refills)

Using Healthconnect as an Asthma Tool

- Develop your preferred medication list for asthma
  - Beta-Agonists
    - Include pre-medication for exercise
    - Include "for asthma attacks"
    - Example: Albuterol Inhaler #2 sig: 2 puffs every 4 hours as needed, twice a day with colds, 15 minutes before exercise (0 refills)

Using Healthconnect as an Asthma Tool

- Albuterol for Nebulizer
  - Default is now for 2 boxes of 2.5 mg/3 mL (equal to 150 mL) with 1 refill
    - Old default was 3 boxes (225 mL) with 3 refills
  - Delete old rx's
Using Healthconnect as an Asthma Tool

- Smartphrases for progress notes
  - Triggers for asthma
    - Irritants: Dust, smoke, chemicals/cleaners/perfume, weather changes
  - Impairment measures: Exercise limitations, nocturnal awakening, missed school days
  - Risk measures: frequency of PO steroid use, albuterol need, risk of airway remodeling “scarring” as a result of repeated episodes

Using Healthconnect as an Asthma Tool

- Smartphrases for progress notes
  - Assess degree/severity of asthma
    - Consider “seasonal” asthma
  - Assess use of medications and services

Using Healthconnect as an Asthma Tool

- Smartphrases for progress notes
  - Plan
    - Medication plan
    - Advice on dust control
    - Advice on smoking cessation
    - Follow-up date
Using Healthconnect as an Asthma Tool

- Patient Instructions – After Visit Summary
  - Include preventive and contingency plans of action (dose changes, seasonal plans, when to seek help)

Using Healthconnect as an Asthma Tool

- Post-Hospital Follow-up
  - PCP visit within 3 days
  - Appropriate referrals placed prior to discharge
  - Albuterol q4h while awake until visit
  - Start inhaled CS prior to discharge and through PO steroids

Managing Pediatric Asthma: Practical Use of Guidelines and Devices

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Asst. Prof. of Clinical Pharmacy,
University of California, San Francisco
Immediate Past-President, California Society of Health-Systems Pharmacists
### Pediatric Asthma

- Most common disease in childhood
  - Missed school days
  - Probable work days lost by parents
  - Lack of participation in physical activities

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### Pediatric Asthma

- 50-80% of Childhood asthma develops before age 5
- Underdiagnosed
  - Chronic bronchitis, wheezy bronchitis, recurrent pneumonia, GERD, URI
- Differential Diagnosis
  - CF, primary immunodeficiency, foreign body, congenital heart disease, parasitic disease

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### Pediatric Asthma

- Contributing factors
  - Tobacco Use by Family or patient
  - Rhinitis
  - GERD
Pediatric Asthma

- Objective measurements difficult
- PFT’s variable in pediatrics
- Diagnosis by
  - Physical exam
  - Hx of disease
  - Hx of symptoms
  - Quality of Life

Pediactic Asthma

- Diagnosis Strongly suspected if:
  - 3 or more episodes in the last 12 mos - lasts for more than 1 day and interrupts sleep
  - Parental Hx of asthma
  - Atopic dermatitis
  - Allergic Rhinitis
  - Eosinophilia
  - Wheeze apart from URI

Concerns in Pediatrics

- Chronic Medication Use in Children
  - Many parents reluctant
  - Steroid-phobia
- Perception
  - Continuum of disease
  - Parents were treated as attack to attack
**Pediatric Asthma**

- Quality of Life
  - Participation in activities
  - Missed school days for patient
  - Missed work days for parents
  - Length of URI Sx

**When to Review Asthma**

- Physical Exams
- School physicals
- Refill requests for inhalers
- Urgent care clinic visits for asthma or respiratory-related problems

**Follow-Up Appointment Questions**

- Beta-Agonist Refill Rate
- Participation in regular activities / exercise
### Introducing Patients to Asthma

- Chronic disease
- Combination of constrictive and inflammatory processes
- Linked to allergies

### Interviewing the Patient

#### Family History of Asthma & Allergies
- Siblings
- Mother
- Father
- Maternal & Paternal

#### Social/Environmental Exposures
- Smokers at home or work
  - Indoors or outdoors
  - Personal Smoking History (Adolescent & Adult)
- Pets at home
  - Indoors or outdoors
- Work environment
### Interviewing the Patient

- Other chronic medical problems
  - Condition
  - Medications
  - Discussion of "sensitive" subjects
    - Smoking History
    - Weight loss
    - Catching patient's misperceptions

### Interviewing the Patient - Triggers

<table>
<thead>
<tr>
<th>URI-Colds</th>
<th>Seasonal variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weather changes</td>
<td>Dust</td>
</tr>
<tr>
<td>Exercise</td>
<td>Chemicals</td>
</tr>
<tr>
<td>Smoke</td>
<td>Nocturnal Episodes</td>
</tr>
<tr>
<td>Plants/flowers</td>
<td>- Frequency</td>
</tr>
<tr>
<td></td>
<td>- Severity</td>
</tr>
</tbody>
</table>

### Interviewing the Patient - Triggers

- Food Allergies
  - Food
  - Nature of reaction
  - Severity of reaction

- Medication Allergies
  - Medication
  - Nature of reaction
  - Severity of reaction

- Anaphylaxis
  - Contact Allergy or
  Primary Care re:need
  for epinephrine
Evaluate Data

- Frequency of emergent care services
  - Emergency Room
  - Hospitalization

- Multiple prescribers

Evaluate Data

- Hospitalization
  - Most episodes handled in the Emergency Room or Urgent Care Setting
  - Hospitalization intensity
    - Use of oxygen to drive nebulizer
    - Continuous albuterol nebulized
    - Beta-agonist infusion (terbutaline)
    - Intubation

Evaluate Data

- Medication refill rates
  - What is refilled
  - How often is it refilled

- Frequency of Oral Steroid Bursts
Impact on Quality of Life

- Missed days from School (Work)
- Lack of restful sleep
- Inability or limited ability to exercise
- Incentives or expectations does the patient want to fulfill

Formulate Treatment Plan

- Good Medications need a Good Plan
- Environmental interventions
  - Dust control
  - Avoidance of “triggers”
  - Use of OSHA-approved safety devices

Formulate Treatment Plan

- Medications
- Peak Flow Monitoring
  - Recommended for Moderate and Severe Persistent Asthma
  - Patient-Provider Communication
  - Patient-Parent agreement on symptoms
  - Patient Control of disease
Formulate Treatment Plan

- **Maintenance Medications**
  - Inhaled route preferred
  - Leukotriene modifiers

- **Acute Episode Management**
  - Short-acting beta-agonist inhaler
  - Short-acting beta-agonist nebulizer
  - Short-acting beta-agonist oral solution/tablet

Formulate Treatment Plan

- **Plan around patient/parent’s schedule**
  - BID dosing preferred
    - Before brushing teeth at AM and Hs
  - TID preventive therapy
    - Before school, After school, Nighttime

- **Provide School Forms**
  - Most common school districts forms

Formulate Treatment Plan

- **Exercise-induced bronchospasm**
  - Short-acting or Long Acting beta-agonist

- **Onset of URI/Colds**
  - Increase frequency of inhaled corticosteroid and pre-medicate with beta-agonist
  - Increase “as needed” use of beta-agonist
  - Continuation after most symptoms resolve
  - Seek Medical Attention for fever or failure to improve
Formulate Treatment Plan

- Seasonal Changes
  - May require modification of treatment plan
- Removal of Irritants
  - Smoking cessation
  - Dust Control
  - Pet Dander

Formulate Treatment Plan

- Smoking Cessation
  - Parents to quit to help children
  - Patient to quit to help themselves
  - $$$ factor
  - Worst-case scenarios

Formulate Treatment Plan

- FOLLOW-UP
  - Primary Care Provider
    - Within 1 week of flare
    - 3 days of hospitalization
  - Schedule before leaving the office!!!
Prescriber Habits

- Cross-sectional, random-sample survey
- Standardized case vignettes.
  - Acute health care use (hospitalized 6 months ago)
  - Bother (parent bothered by the child’s asthma status)
  - Control (frequency of symptoms and albuterol use)
  - Direction (qualitative change in symptoms)
  - Wheezing during physical examination

Pediatrics 2008;122:e195–e201

Prescriber Habits

- Observations on likeliness to increase dosage
- Observations on likeliness to reduce dosage
- Compared to patient with well-controlled symptoms

Pediatrics 2008;122:e195–e201

“Selling” Preventive Therapy to Parents

- Reduce frequency of PO Steroid Bursts
- Improved exercise tolerance
- Reduce days missed from school
- Reduce days parents miss work
- “Topical” steroid administration
- Reduce hospital and urgent clinic appointments
Impact on Quality of Life OR
What's this patient’s carrot?

- Missed days from School (Work)
- Lack of restful sleep
- Inability or limited ability to exercise
- Incentives or expectations does the patient want to fulfill

Asthma Impact on Growth and Development in Pediatrics

- Long-term studies in children 5 to 12 years of age at the time of enrollment conclude that inhaled corticosteroids improve health outcomes for children with mild or moderate persistent asthma and that the potential albeit small risk of delayed growth from the use of inhaled corticosteroids is well balanced by their effectiveness (CAMP 2000).
- Further, available long-term data indicate that most children treated with recommended doses of inhaled corticosteroids achieve their predicted adult heights (Agertoft and Pedersen 2000).

Referral Points

- Allergist/Primary Care Physician Referral
  - History of Intubation
  - Anaphylactic Reactions
  - History of rapidly escalating symptoms
  - Severe Persistent Asthma
Updates on Medications & Devices

- Medications
  - Ciclesonide (Alvesco)
  - Omalizumab (Xolair)
  - Budesonide nebulized steroid suspension
  - New Propellants / Delivery Devices

- Devices

Medguides and Asthma

- FDA required patient information
  - "FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that:
    - certain information is necessary to prevent serious adverse effects
    - patient decision-making should be informed by information about a known serious side effect with a product, or
    - patient adherence to directions for the use of a product are essential to its effectiveness."

Medguides and Asthma

- Advair
- Foradil
- Serevent
- Symbicort
- Xolair
### Updates on Medications & Devices

<table>
<thead>
<tr>
<th>Ciclesonide (Non-Formulary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Pro-drug: active topical corticosteroid on the surface of the lung</td>
</tr>
<tr>
<td>- Poorly absorbed via GI tract</td>
</tr>
<tr>
<td>- Head to Head comparisons with Budesonide and Fluticasone</td>
</tr>
<tr>
<td>- No less effective compared to beclomethasone</td>
</tr>
</tbody>
</table>

*Drugs 2008; 68 (12): 1741-1770*

### Updates on Medications & Devices

<table>
<thead>
<tr>
<th>Ciclesonide (Non-Formulary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Avelco 80 mcg or 160 mcg per inhalation</td>
</tr>
<tr>
<td>- 80 mcg BID, 160 mcg BID, 320 mcg BID</td>
</tr>
<tr>
<td>- HFA Propellant</td>
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<tr>
<td>- Approved for age 12 and over</td>
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<tr>
<td>- Used in Switzerland for ages 6 and over</td>
</tr>
</tbody>
</table>

*Drugs 2008; 68 (12): 1741-1770*

### Updates on Medications & Devices

<table>
<thead>
<tr>
<th>Omalizumab (Xolair) (Non-Formulary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- IgE Blockade agent</td>
</tr>
<tr>
<td>- Administered by subcutaneous injection</td>
</tr>
<tr>
<td>- Stable for 6 hours after reconstitution</td>
</tr>
<tr>
<td>- Potential for anaphylactic reactions</td>
</tr>
<tr>
<td>- Murine component to recombinant DNA process in manufacture</td>
</tr>
</tbody>
</table>

*Drugs 2008; 68 (12): 1741-1770*
**Omalizumab (Xolair)**

- **Dosing**
  - Dosage based on algorithm based on weight and IgE levels
  - Approved for 12 yo and older
  - Persistent symptoms while taking controller therapy
- **Adverse Drug Reactions**
  - Higher incidence of cancer in pt with Hx Ca
  - Anaphylaxis

### Omalizumab (Xolair) every 4 weeks

<table>
<thead>
<tr>
<th>Serum IgE</th>
<th>Weight 30-60 Kg</th>
<th>Weight 60-70 Kg</th>
<th>Weight 70-90 Kg</th>
<th>Weight 90-150 Kg</th>
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<tr>
<td>100-200</td>
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<td>600-700</td>
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### Omalizumab (Xolair) every 2 weeks

<table>
<thead>
<tr>
<th>Serum IgE</th>
<th>Weight 30-60 Kg</th>
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<tr>
<td>100-200</td>
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<td>200-300</td>
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<td>600-700</td>
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<td>375</td>
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</table>
Omalizumab (Xolair)

- Side effects
  - Headache
  - Injection site
  - Upper respiratory tract infections / sore throat
  - Sinusitis

---

Omalizumab (Xolair)

- Recent FDA press release

**FDA Proposes to Strengthen Label Warning for Xolair**

Today the Food and Drug Administration (FDA) announced that it has requested Genentech, Inc. add a boxed warning to the product label for omalizumab, marketed as Xolair. The boxed warning emphasizes that Xolair, used to treat patients with asthma related to allergies, may cause anaphylaxis. Anaphylaxis may include trouble breathing, chest tightness, dizziness, fainting, itching and hives, and swelling of the mouth and throat. In addition, FDA has asked Genentech to revise the Xolair label and provide a Medication Guide for patients to strengthen the existing warning for anaphylaxis.

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Omalizumab (Xolair)

- Recent FDA press release

Also, anaphylaxis after administration of Xolair may be delayed up to 24 hours after the dose is given. Health care providers should be prepared to manage life-threatening anaphylaxis following Xolair administration and observe patients for at least two hours after an injection. Following administration of Xolair, patients should also carry and know how to initiate emergency self-treatment for anaphylaxis.
Omalizumab (Xolair)

- Recommendations and considerations
  - Cost
  - Administration in controlled clinic environment
  - Limited efficacy information
  - For moderate to severe persistent asthma
  - Return to baseline after discontinued

Selected Medications

- Mometasone Inhaled
  - Once to Twice daily dosing
  - Dry Powder Delivery System
  - Counter on device
  - Humidity Dependent Expiration

Selected Medications

- Pulmicort Respules
  - First nebulized corticosteroid
  - Suspension
  - Delivery Device needed for safe administration
### Leukotriene Inhibitors

- **Reported neuropsychiatric events:**  
  - Agitation, Aggression, Anxiousness, Dream abnormalities, Hallucinations, Depression, Insomnia, irritability, Restlessness, Suicidal thinking and behavior (including suicide), and Tremor.

- **Advice to patients and healthcare professionals**  
  - Patients and healthcare professionals should be aware of the potential for neuropsychiatric events with these medications.  
  - Patients should talk with their healthcare providers if these events occur.  
  - Healthcare professionals should consider discontinuing these medications if patients develop neuropsychiatric symptoms.

### Leukotriene Inhibitors

- **Background**  
  - In April 2009, FDA completed its review of neuropsychiatric events, (mood and behavioral changes) possibly related to drugs that act through the leukotriene pathway (montelukast, zafirlukast, zileuton). As part of its review, FDA reviewed post-marketing reports and also requested that manufacturers submit all available clinical trial data for these products.  
  - The post-market reports of patients on these medications included cases of neuropsychiatric events. Some reports included clinical details consistent with a drug-induced effect. In the clinical trial data submitted by manufacturers, neuropsychiatric events were not commonly observed. However, the available data were limited because the trials were not designed to look for neuropsychiatric events. Sleep disorders (primarily insomnia) were reported more frequently with all three products compared to placebo.

### New Propellants

- **Removal of Chlorinated Fluorocarbons by end of 2008**
- **Effect on Ozone**
- **Transition for albuterol - shortage 2006**
### New Propellants

- Hydrofluoroalkane as one alternative
  - Lower vapor pressure
  - Soluble for beclomethasone
  - Smaller particle size
  - Lower velocity
  - Does not require spacer, can still use spacer

### New Propellants

- Considerations and impact
  - Different taste
  - All inhalers are now brand-name

### Innovative Delivery Devices

- Diskus
- Twisthaler
- Aerolizer
- Turbuhaler
- Handihaler
- HFA propellants
<table>
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<tr>
<th>Diskus Device</th>
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<table>
<thead>
<tr>
<th>Twisthaler</th>
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</table>
**Turbuhaler - Pulmicort**
*(Budesonide)*

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**Turbuhaler - Detail**

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**Spacer Devices**

- Holding chamber for inhaled medications
- Features
  - Valve at mouthpiece
  - Reed
  - Antistatic coating or static-free material
### Spacer Device Instructions

- Shake canister
- Insert pressurized MDI mouthpiece into device
- Exhale completely
- Spray once
- Inhale slowly, breath hold, then exhale
- Brush teeth or rinse mouth after inhaled corticosteroids

### Spacer Device Instructions

- Wait 1-2 minutes between inhalations
- Allows canister to warm to room temperature
- May allow bronchodilation to allow deeper airway penetration

### Spacer Devices
Aerochamber Max

Aerochamber Max w/ mask

Spacer Device - Flexible Bag
- Shake canister
- Insert pressurized MDI canister into device
- Exhale completely
- Spray once
- Inhale slowly, breath hold, then exhale
- Brush teeth or rinse mouth after inhaled corticosteroids
- Bag will collapse as the patient inhales, continue until full breath taken

Bag will collapse as the patient inhales, continue until full breath taken
<table>
<thead>
<tr>
<th><strong>Spacer Device - Flexible Bag</strong></th>
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<tbody>
<tr>
<td><strong>Pro’s</strong></td>
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<tr>
<td>- Compact</td>
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<tr>
<td>- Visual cue for the patient</td>
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<tr>
<td><strong>Cons’s</strong></td>
</tr>
<tr>
<td>- Breaks easily</td>
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<thead>
<tr>
<th><strong>Spacer Device - EZ Spacer</strong></th>
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<tr>
<th><strong>Nebulized Medication</strong></th>
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Nebulized Medication

- When to use
  - Patient not able to use other delivery systems
  - Patient adheres to scheduled appointments

Nebulized Medication

Nebulizer components
- Air compressor with room air filter
- Tubing
- Nebulizer cup
- Mouthpiece or mask

Nebulizers

- Pro’s
  - Easy to inhale – not technique dependent
  - Higher dose can be administered
- Con’s
  - Higher dose – more side effects
  - Bulky
  - Expensive
  - Time consuming
Nebulizer Vendor

- Respironics

Nebulizers

- Breath-actuated device
  - Less medication wastage
  - Relative larger dose given
  - Usually more rapid administration times
  - More expensive

Nebulizer - Pari LC Jet
Nebulizers

- Battery-Powered
  - Not covered by most DME Plans
  - Convenient
  - Some are rechargeable
  - Coverage depends on durable medical equipment
  - Indicator that asthma may need better management

Nebulizer - Micro Air

- Micro Air

Nebulizer - Micro Air

- Micro Air
Peak Flow Meters

- Useful as predictors for asthma control
- Helps mediate disagreements
- Consider using when patient able to use MDI
- Use practically (guidelines vs practice)

Peak Flow Meter - Tru Zone

Peak Flow Meter - Mini-Wright
### Other Considerations

- Emergency Treatment
  - Epinephrine injector
    - Particularly for food allergy

### Epinephrine Injector

### Dust/ Allergen Control
### Resources and Reference

- National Heart, Lung and Blood Institute  
  - http://www.nhlbi.nih.gov/
- American Lung Association  
  - http://www.lungusa.org
- American Academy of Allergy, Asthma and Immunology  
  - http://www.aaaai.org/

### Questions