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INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:

Diagnosis and Management of Asthma

Eighth Edition
January 2008

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- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;

- health care teaching institutions;

- health care information technology departments;

- medical specialty and professional societies;

- researchers;

- federal, state and local government health care policy makers and specialists; and

- employee benefit managers.

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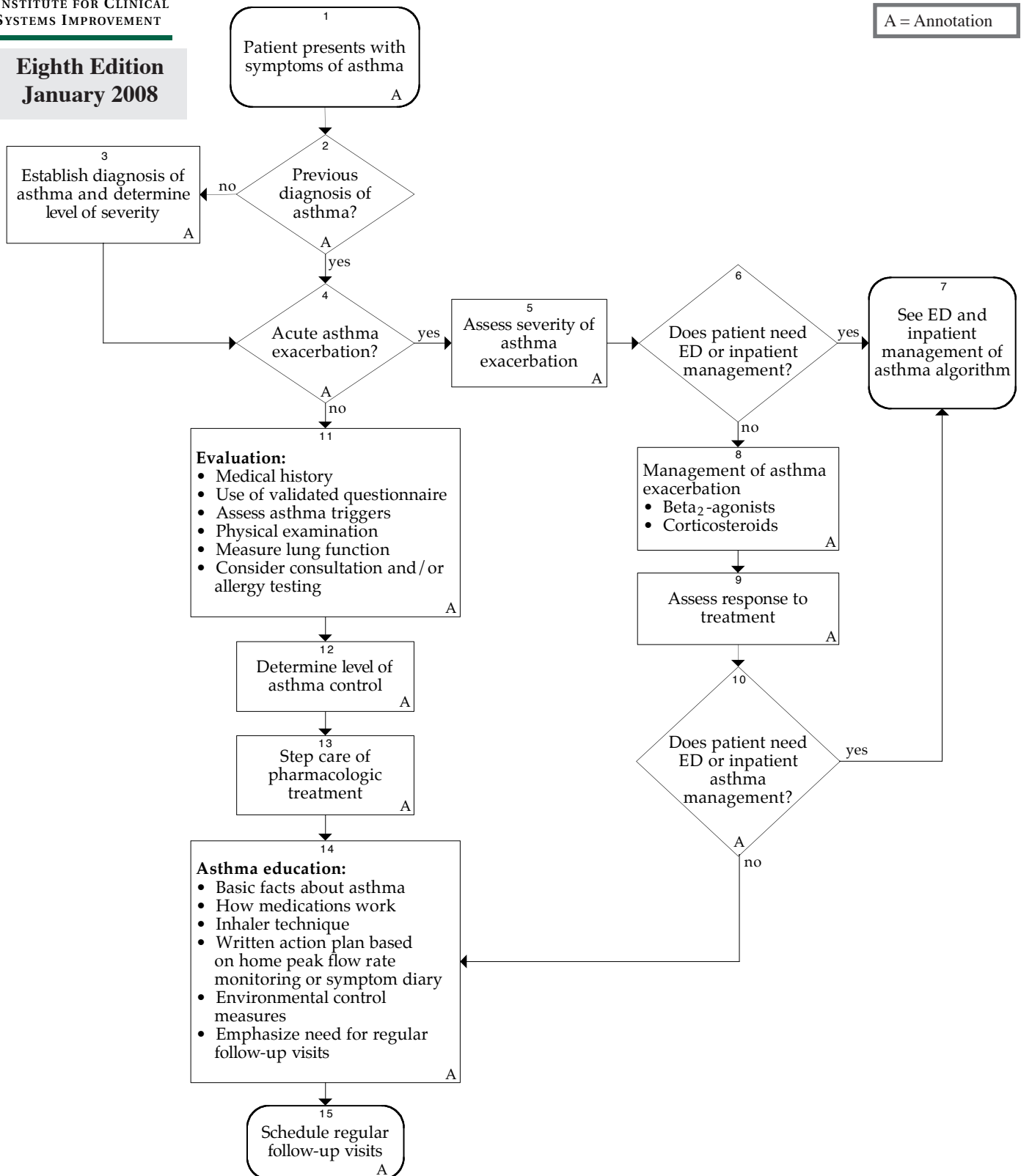
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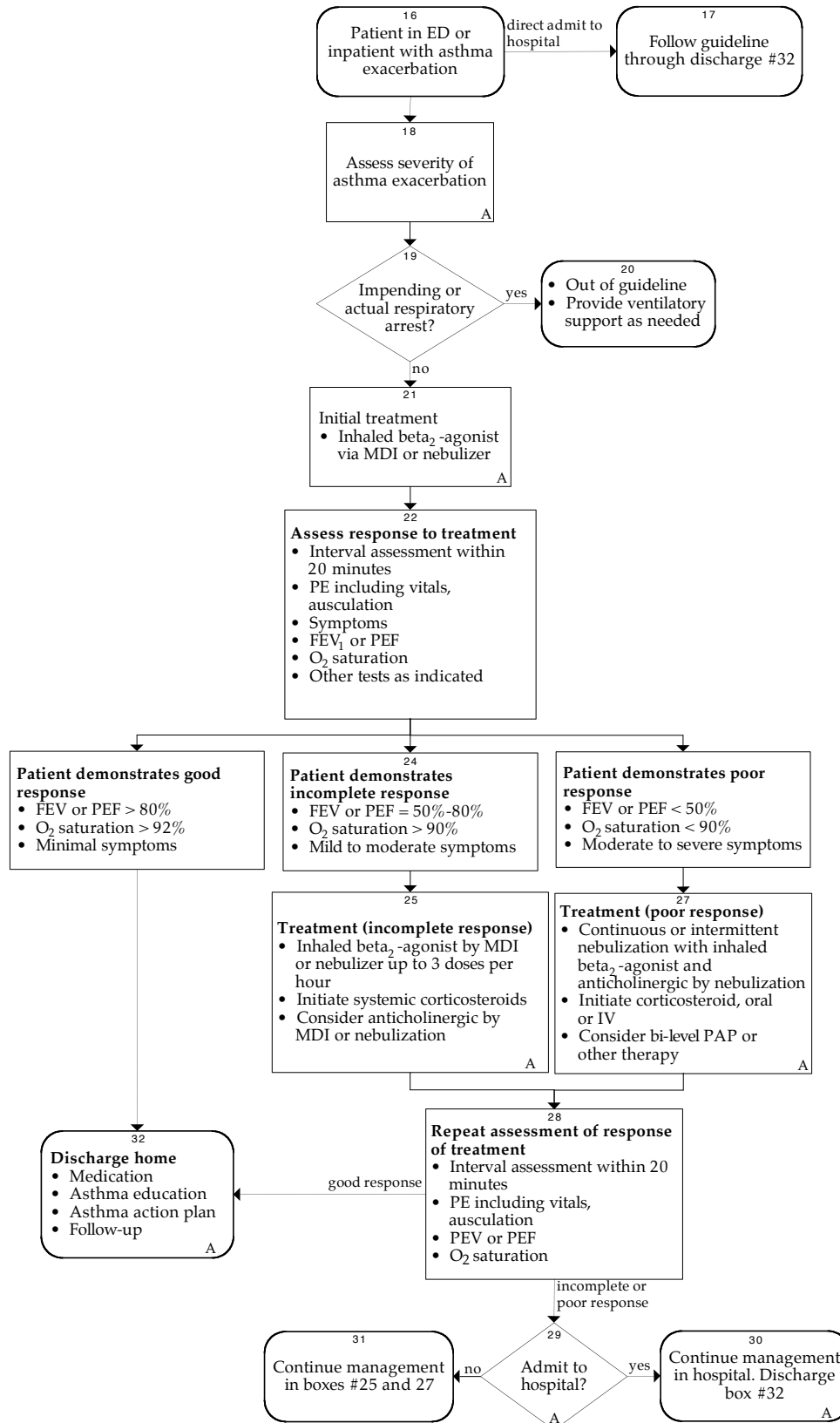
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Eighth Edition
January 2008

A = Annotation

1
Patient presents with symptoms of asthma
A

2
Previous diagnosis of asthma?
A

no →

3
Establish diagnosis of asthma and determine level of severity
A

yes

4
Acute asthma exacerbation?
A

yes →

no

5
Assess severity of asthma exacerbation
A

6
Does patient need ED or inpatient management?

yes →

no

7
See ED and inpatient management of asthma algorithm

8
Management of asthma exacerbation
• Beta$_2$-agonists
• Corticosteroids
A

9
Assess response to treatment
A

10
Does patient need ED or inpatient asthma management?
A

yes →

no

11
Evaluation:
• Medical history
• Use of validated questionnaire
• Assess asthma triggers
• Physical examination
• Measure lung function
• Consider consultation and/or allergy testing
A

12
Determine level of asthma control
A

13
Step care of pharmacologic treatment
A

14
Asthma education:
• Basic facts about asthma
• How medications work
• Inhaler technique
• Written action plan based on home peak flow rate monitoring or symptom diary
• Environmental control measures
• Emphasize need for regular follow-up visits
A

15
Schedule regular follow-up visits
A

Emergency Department or Inpatient Management Algorithm

16
Patient in ED or inpatient with asthma exacerbation

→ direct admit to hospital →

17
Follow guideline through discharge #32

18
Assess severity of asthma exacerbation
A

A = Annotation

19
Impending or actual respiratory arrest?

→ yes →

20
- Out of guideline
- Provide ventilatory support as needed

no
↓

21
Initial treatment
- Inhaled beta$_2$-agonist via MDI or nebulizer
A

22
Assess response to treatment
- Interval assessment within 20 minutes
- PE including vitals, ausculation
- Symptoms
- FEV$_1$ or PEF
- O$_2$ saturation
- Other tests as indicated

Patient demonstrates good response
- FEV or PEF > 80%
- O$_2$ saturation > 92%
- Minimal symptoms

24
Patient demonstrates incomplete response
- FEV or PEF = 50%-80%
- O$_2$ saturation > 90%
- Mild to moderate symptoms

Patient demonstrates poor response
- FEV or PEF < 50%
- O$_2$ saturation < 90%
- Moderate to severe symptoms

25
Treatment (incomplete response)
- Inhaled beta$_2$-agonist by MDI or nebulizer up to 3 doses per hour
- Initiate systemic corticosteroids
- Consider anticholinergic by MDI or nebulization
A

27
Treatment (poor response)
- Continuous or intermittent nebulization with inhaled beta$_2$-agonist and anticholinergic by nebulization
- Initiate corticosteroid, oral or IV
- Consider bi-level PAP or other therapy
A

28
Repeat assessment of response of treatment
- Interval assessment within 20 minutes
- PE including vitals, ausculation
- PEV or PEF
- O$_2$ saturation

← good response ←

32
Discharge home
- Medication
- Asthma education
- Asthma action plan
- Follow-up
A

incomplete or poor response
↓

29
Admit to hospital?

← no

31
Continue management in boxes #25 and 27

yes →

30
Continue management in hospital. Discharge box #32
A

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Foreword

Scope and Target Population

This guideline addresses the diagnosis, emergent, inpatient and outpatient management of acute and chronic asthma in all patients over five years of age who present with asthma-like symptoms or have been diagnosed with asthma.

Clinical Highlights and Recommendations

- Conduct interval evaluations of asthma including medical history and physical examination, assessment of asthma triggers and allergens, measurement of pulmonary function, and consideration of consultation and/or allergy testing. *(Annotation #11)*

- Assess control using objective measures and the asthma control test. *(Annotation #12)*

- Match medical intervention with asthma control and adjust to correspond with change over time. *(Annotation #13)*

- Provide asthma education to patients and parents of pediatric patients. Education should include basic facts about asthma, how medications work, inhaler technique, a written action plan including home peak flow rate monitoring or a symptom diary, environmental control measures, and emphasis on the need for regular follow-up visits. *(Annotation #14)*

- Patients should receive appropriate follow-up as per Diagnosis and Management of Asthma guideline. *(Annotation #15)*

- Early intervention with bi-level PAP may prevent mechanical intubations. *(Annotation #27)*

Priority Aims

1. Promote the accurate assessment of asthma severity and control through the use of objective measures of lung function and symptoms.

2. Promote long-term control of persistent asthma through the use of inhaled corticosteroid drug therapy.

3. Promote the partnership of patients with asthma and/or their parents with health care professionals through education and the use of written action plans.

4. Improve the timely and accurate assessment of patients presenting with an asthma exacerbation.

5. Improve the treatment and management of inpatient asthma.

6. Schedule follow-up visits to ensure asthma control is maintained and appropriate therapy is administered.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Facilitate timely and accurate diagnosis of asthma and asthma severity and control.

2. Educate providers in the use of spirometry as a diagnostic tool.

3. Educate providers and patients in the importance of developing and maintaining an asthma action plan and assessing adherence.

Related ICSI Scientific Documents

Related Guidelines

• Chronic Obstructive Pulmonary Disease

• Diagnosis and Treatment of Respiratory Disease in Children and Adults

Order Sets

• Admission for Asthma

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Richard Sveum has received less than $10,000 in speakers fees from Novartis, Merck and Schering.

David Lowe has received $10,000-$50,000 as a member of Speaker's Bureau for Glaxo and Schering.

No other work group members have potential conflicts of interest to disclose.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision as well as obtaining and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at http://www.icsi.org.

Evidence Grading System

A. Primary Reports of New Data Collection:

Class A: Randomized, controlled trial

Class B: Cohort study

Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study

Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis

Class R: Consensus statement
Consensus report
Narrative review

Class X: Medical opinion

Citations are listed in the guideline utilizing the format of *(Author, YYYY [report class])*. A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Algorithm Annotations

1. Patient Presents with Symptoms of Asthma

Definition of Asthma

Asthma is a chronic inflammatory disorder of the airways. It is characterized by:

- Airway inflammatory cells, including eosinophils, macrophages, mast cells, epithelial cells and activated lymphocytes that release various cytokines, adhesion molecules and other mediators.

- Inflammation resulting in an acute, subacute or chronic process that alters airway tone, modulates vascular permeability, activates neurons, increases secretion of mucus, and alters airway structure reversibly or permanently.

- Airway hyperresponsiveness in response to allergens, environmental irritants, viral infections and exercise.

- Airflow obstruction caused by acute bronchial constriction, edema, mucus plugs and frequently, permanent remodeling.

Symptoms

- Wheezing

- Breathlessness

- Cough, productive or dry

- Chest discomfort

Pattern of symptoms

- Perennial/seasonal

- Episodic/continual

- Diurnal

Severity of symptom classification

- Number of symptom episodes per week

- Number of nocturnal symptoms per month

- Objective measures of lung function (forced expiratory volume in one second [FEV_1], peak expiratory flow rate [PEFR], PEF variability)

Symptoms of Asthma

Symptoms suggestive of asthma include episodic wheezing and cough with nocturnal, seasonal or exertional characteristics. Infants and children with frequent episodes of "bronchitis" are likely to have asthma. Atopic and positive family histories for asthma, particularly when associated with previously mentioned symptoms, should encourage one to consider a diagnosis of asthma.

Eliciting symptoms should emphasize characterizing the current classification scheme that describes frequency per week, changes in physical activity, diurnal variation, and seasonal variation. It is important to recognize that patients with asthma are heterogeneous, falling into every age group, from infancy to older age, and

presenting a spectrum of signs and symptoms that vary in degree and severity from patient to patient, as well as within an individual patient over time *(National Heart, Lung, Blood Institute EPR-3, 2007 [R]).*

2. Previous Diagnosis of Asthma?

At each evaluation, it is important to consider whether or not a previous diagnosis was correct.

- History and physical consistent with diagnosis.

- Response to therapy consistent with symptoms.

3. Establish Diagnosis of Asthma and Determine Level of Severity

Key Points:

- The diagnosis of asthma is based on the patient's medical history, physical examination, pulmonary function tests and laboratory test results.

- Spirometry is recommended for the diagnosis of asthma.

- The level of asthma severity is determined by both impairment and risk.

Asthma triggers

- Viral respiratory infections

- Environmental allergens

- Exercise, temperature, humidity

- Occupational and recreational allergens or irritants

- Environmental irritants (perfume, tobacco smoke, wood-burning stoves)

- Drugs (aspirin, non-steroidal anti-inflammatory drugs [NSAIDs], beta-blocker) and food (sulfites)

Other historical components

- Emergency room visits and hospitalization

- Medication use (especially oral steroids)

- Lung function, PEFR variability

- Associated symptoms, e.g., rhinitis, sinusitis, gastroesophageal reflux (GERD)

Clinical testing

- Accurate spirometry is recommended in every patient five years of age or older at the time of diagnosis.

- Additional studies done, tailored to the specific patient.

  - Allergy testing (skin testing, in vitro specific IgE antibody testing)

  - Chest radiography, to exclude alternative diagnosis

  - Bronchial provocation testing if spirometry is normal or near normal

  - Sinus x-rays or CT scan

- GERD evaluation

- CBC with eosinophils, total IgE, sputum exam

Spirometry is the cornerstone of the laboratory evaluation that enables the clinician to demonstrate airflow obstruction and establish a diagnosis of asthma with certainty. Spirometry is essential for assessing the severity of asthma in order to make appropriate therapeutic recommendations. The use of objective measures of lung function is recommended because patient-reported symptoms often do not correlate with the variability and severity of airflow obstruction. Testing should be performed in compliance with the American Thoracic Society standards. Obstructive and restrictive ventilatory defects can generally be determined using forced expiratory volume in one second (FEV_1)/forced vital capacity (FVC) ratio *(American Thoracic Society, 1991 [R])*.

Spirometry is generally valuable in children five years of age or older; however, some children cannot conduct the maneuver, depending on developmental ability. Spirometry measurements (FEV_1, FVC, FEV_1/FVC) before and after the patient inhales a short-acting bronchodilator should be undertaken for patients in whom the diagnosis of asthma is being considered. Airflow obstruction is indicated by reduced FEV_1 and FEV_1/FVC values relative to reference or predicted values. Significant reversibility is indicated by an increase of 12 percent or greater and 200 mL in FEV_1, after inhaling a short-acting bronchodilator.

Investigation into the role of allergy, at least with a complete history, should be done in every patient, given high prevalence of positive skin tests among individuals with asthma and the benefits of limiting exposure to known allergens. History may help to distinguish seasonal allergies but may be inadequate for perennial allergies. Eosinophil count and IgE may be elevated in asthma; however, neither test has sufficient specificity or sensitivity to be used alone in a diagnosis. The chest x-ray and electrocardiogram are usually normal in asthma but may be useful to exclude other pulmonary or cardiac conditions. Sputum examination may be helpful if sputum eosinophilia or infection are suspected.

There are several clinical scenarios in children that have a frequent association with asthma and should strongly suggest asthma as a possible diagnosis. These include recurrent pulmonary infiltrates (especially right middle lobe infiltrates) with volume loss that clear radiologically within two to three days, and the diagnosis of pneumonia without fever. Asthma may cause some radiologic uncertainty since mucus plugging and atelectasis may be interpreted as infiltrates.

Diagnostic spirometry and a methacholine challenge test, if necessary, are important to clinching the diagnosis. The patient's history and response to therapy should guide other diagnostic tests when considering alternative diagnoses. Follow-up spirometry every one to two years in mild asthmatics will reconfirm the diagnosis and objectify serial change and level of control. More frequent monitoring should be considered for the moderate and severe persistent categories.

See Table 1, "Classifying Asthma Severity in Children 5-11 Years."

See Table 2, "Classifying Asthma Severity in Youths and Adults."

Differential Diagnostic Possibilities for Asthma

Upper airway disease

- Allergic rhinitis and sinusitis

Obstruction involving large airways

- Foreign body in trachea or bronchus

- Vocal cord dysfunction

- Vascular rings or laryngeal webs

- Laryngotracheomalacia, tracheal stenosis or bronchostenosis

- Enlarged lymph nodes or tumor (benign or malignant)

- Bronchiectasis of various causes, including cystic fibrosis

Obstruction of small airways

- Viral bronchiolitis or obliterative bronchiolitis

- Cystic fibrosis

- Bronchopulmonary dysplasia

- Pulmonary infiltrates with eosinophilia

- Chronic obstructive pulmonary disease (chronic bronchitis or emphysema)

Other causes

- Pulmonary embolism

- Congestive heart failure

- Cough secondary to drugs (angio-tension-converting enzyme [ACE] inhibitors)

- Aspiration from swallowing mechanism dysfunction or gastroesophageal reflux

- Recurrent cough not due to asthma

An important under-recognized alternative diagnosis is vocal cord dysfunction. Patients have recurrent breathlessness and wheezing, usually inspiratory, but they can also have expiratory wheezing. It is often monophasic and loud over the glottis. Respiratory failure can occur with alveolar hypoventilation, requiring emergent intubation. It also coexists in patients who have asthma. The flow-volume loop and video image can help make the diagnosis *(National Heart, Lung, Blood Institute EPR-2, 1997 [R])*.

Table 1. Classifying Asthma Severity in Children 5-11 Years

■ **Classifying severity in children who are not currently taking long-term control medication.**

Components of Severity		Classification of Asthma Severity (Children 5–11 years of age)			
		Intermittent	Persistent		
			Mild	Moderate	Severe
Impairment	Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout the day
	Nighttime awakenings	≤2x/month	3–4x/month	>1x/week but not nightly	Often 7x/week
	Short-acting beta$_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not daily	Daily	Several times per day
	Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
	Lung function	• Normal FEV$_1$ between exacerbations • FEV$_1$ >80% predicted • FEV$_1$/FVC >85%	• FEV$_1$ = >80% predicted • FEV$_1$/FVC >80%	• FEV$_1$ = 60–80% predicted • FEV$_1$/FVC = 75–80%	• FEV$_1$ <60% predicted • FEV$_1$/FVC <75%
Risk	Exacerbations requiring oral systemic corticosteroids	0–1/year (see note)	≥2 in 1 year (see note) ————————————→		
		←—— Consider severity and interval since last exacerbation. Frequency and severity may fluctuate over time for patients in any severity category. ——→			
		Relative annual risk of exacerbations may be related to FEV$_1$			

■ **Level of severity is determined by both impairment and risk. Assess impairment domain by patient's/caregiver's recall of the previous 2–4 weeks and spirometry. Assign severity to the most severe category in which any feature occurs.**

■ **At present, there are inadequate data to correspond frequencies of exacerbations with different levels of asthma severity. In general, more frequent and intense exacerbations (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) indicate greater underlying disease severity. For treatment purposes, patients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have persistent asthma, even in the absence of impairment levels consistent with persistent asthma.**

Source: National Heart, Lung, Blood Institute EPR-3, 2007.

Table 2. Classifying Asthma Severity in Youths and Adults

- **Classifying severity for patients who are not currently taking long-term control medications.**

Components of Severity		Classification of Asthma Severity (Youths ≥12 years of age and adults)			
			Persistent		
		Intermittent	**Mild**	**Moderate**	**Severe**
Impairment Normal FEV$_1$/FVC: 8–19 yr 85% 20–39 yr 80% 40–59 yr 75% 60–80 yr 70%	Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout the day
	Nighttime awakenings	≤2x/month	3–4x/month	>1x/week but not nightly	Often 7x/week
	Short-acting beta$_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not >1x/day	Daily	Several times per day
	Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
	Lung function	• Normal FEV$_1$ between exacerbations • FEV$_1$ >80% predicted • FEV$_1$/FVC normal	• FEV$_1$ ≥80% predicted • FEV$_1$/FVC normal	• FEV$_1$ >60% but <80% predicted • FEV$_1$/FVC reduced 5%	• FEV$_1$ <60% predicted • FEV$_1$/FVC reduced >5%
Risk	Exacerbations requiring oral systemic corticosteroids	0–1/year (see note)	≥2/year (see note) ⟶		
		⟵ Consider severity and interval since last exacerbation. Frequency and severity may fluctuate over time for patients in any severity category. ⟶			
		Relative annual risk of exacerbations may be related to FEV$_1$			

- Level of severity is determined by assessment of both impairment and risk. Assess impairment domain by patient's/caregiver's recall of previous 2–4 weeks and spirometry. Assign severity to the most severe category in which any feature occurs.
- At present, there are inadequate data to correspond frequencies of exacerbations with different levels of asthma severity. In general, more frequent and intense exacerbations (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) indicate greater underlying disease severity. For treatment purposes, patients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have persistent asthma, even in the absence of impairment levels consistent with persistent asthma.

Source: National Heart, Lung, Blood Institute EPR-3, 2007.

4. Acute Asthma Exacerbation?

Symptoms of an acute asthma episode include progressive breathlessness, cough, wheezing or chest tightness. An acute asthma episode is characterized by a decrease in expiratory airflow that can be documented and quantified by measurement of lung function (spirometry or peak expiratory flow rate [PEFR]). Indications for emergency care include:

- Peak flow less than 50% predicted normal
- Failure to respond to a beta$_2$-agonist
- Severe wheezing or coughing
- Extreme anxiety due to breathlessness
- Gasping for air, sweaty, or cyanotic
- Rapid deterioration over a few hours
- Severe retractions and nasal flaring
- Hunched forward

5. Assess Severity of Asthma Exacerbation

Key Points:

- Severity should be promptly assessed using objective measures of lung function.

- Patients experiencing an acute asthma exacerbation need a focused history and physical examination and measurement of airflow.

Patients presenting with an acute exacerbation of their asthma should receive prompt evaluation to assess the severity of their symptoms. Treatment should begin as rapidly as possible even while still assessing severity.

Assessment of asthma severity should include history, physical examination, an objective measure of lung function, either FEV_1 or PEFR, oxygen saturation and other tests as indicated.

History

- Symptoms consistent with asthma

- Severity of symptoms, limitations and sleep disturbance

- Duration of symptoms

- Current medical treatment plan

- Adherence to medical treatment plan

- Rescue medication use:

  - Recent use of short-acting $beta_2$-agonists

  - Number of bursts of oral steroids in past year

- Review Asthma Action Plan and daily charting of peak flows

- Previous emergency department (ED) visits or hospitalization

- Record triggers:

  - Upper respiratory infection (URI)

  - Bronchitis, pneumonia, sinusitis

  - Exposure to allergens or irritants

  - Exercise

  - GERD

Clinicians treating asthma exacerbations should be familiar with the characteristics of patients at risk for life-threatening deterioration.

See Table 3, "Risk Factors for Death from Asthma."

Table 3. Risk Factors for Death from Asthma

Past history of sudden severe exacerbations
Prior intubation for asthma
Prior admission for asthma to an intensive care unit
Three or more emergency care visits for asthma in the past year
Hospitalization or an emergency care visit for asthma within the past month
Use of more than two canisters per month of inhaled short-acting beta$_2$-agonist
Current use of systemic corticosteroids or recent withdrawal from systemic corticosteroids
Difficulty perceiving airflow obstruction or its severity
Serious psychiatric disease or psychosocial problems
Low socioeconomic status and urban residence
Illicit drug use
Sensitivity to alternaria

(National Heart, Lung, Blood Institute EPR-3, 2007 [R])

Lung Function

- Spirometry (FEV_1) – preferred, FEV_1/FVC

  or

- Peak expiratory flow rate (PEFR)

- Pulse oximetry

Physical Exam

- Vital signs: Temperature, blood pressure, pulse rate, respiratory rate, pulsus paradoxus

- Alertness

- Ability to talk

- Use of accessory muscles

- Auscultation of chest

- Color

Laboratory Studies

Treatment with bronchodilators should not be delayed for laboratory studies. Tests which may be useful include:

- Arterial blood gases (ABG's)

- Chest x-ray (CXR)

- Complete blood count (CBC)

- Electrocardiogram (EKG)

- Electrolytes

- Theophylline level (if appropriate)

Table 4. Assessment of Severity should be based on the following table.

Classifying Severity of Asthma Exacerbations				
	Mild	**Moderate**	**Severe**	**Respiratory Arrest Imminent**
Symptoms				
Breathlessness	While walking Can lie down	While at rest Prefers sitting	While at rest Sits upright	
Talks in	Sentences	Phrases	Words	
Alertness	May be agitated	Usually agitated	Usually agitated	Drowsy or confused
Signs				
Respiratory rate	Increased	Increased	Often > 30/min.	
Use of accessory muscles; suprasternal retractions	Usually not	Commonly	Usually	Paradoxical thoracoabdominal movement
Wheeze	Moderate, often only end expiratory	Loud; throughout exhalation	Usually loud; throughout inhalation and exhalation	Absence of wheeze
Pulse/minute	< 100	100-120	> 120 > 110 5-8 years old	Bradycardia
Pulsus paradoxus	Absent < 10 mmHg	May be present 10-25 mmHg	Often present > 25 mmHg (adult) 20-40 mmHg (child)	Absence suggests respiratory muscle fatigue
Functional Assessment				
FEV_1 or PEF % predicted or % personal best	> 70%	Approx. 40%-69% or response lasts < 2 hours	< 40% predicted or personal best	< 25% Note: PEF may not be needed in very severe attacks
PaO_2 (on air) and/or	Normal (test not usually necessary)	> 60 mmHg (test not usually necessary)	< 60 mmHg: possible cyanosis	
PCO_2	< 42 mmHg (test not usually necessary)	< 42 mmHg (test not usually necessary)	$\geq$ 42 mmHg: possible respiratory failure	
SaO_2 % (on air) at sea level	> 95% (test not usually necessary)	90%-95% (test not usually necessary)	< 90	
	Hypercapnia (hypoventilation) develops more readily in young children than in adults and adolescents.			
Note: • The presence of several parameters, but not necessarily all, indicates the general classification of the exacerbation. • Many of these parameters have not been systematically studied, so they serve only as general guides.				

Adapted from: National Heart, Lung, Blood Institute EPR-3, 2007

8. Management of Asthma Exacerbation

Key Points:

- Treatment is begun with inhaled short-acting beta$_2$-agonists administered by meter dose inhaler (MDI)/spacer or nebulizer.

- Further intensification of therapy is based on severity, response and prior history, but typically includes a short course of oral corticosteroids.

(McFadden, 2003 [R])

Treatment

Usual initial treatment is with short-acting beta$_2$-agonist (albuterol) administered by nebulizer or MDI/spacer.

Alternatives:

Epinephrine: (1:1,000)

Adult: 0.3-0.5 mg subcutaneous or IM every 20 minutes up to three doses

Pediatrics: 0.01 mg/kg up to 0.3-0.5 mg subcutaneous or IM every 20 minutes up to three doses

Ipratropium added to nebulized beta$_2$-agonist (albuterol)

- Nebulized dose for adults and those over 12 years of age is 0.5 mg every 4 hours. Not FDA approved for any indication in those under 12 years of age.

- Ipratropium is not currently FDA approved for use in asthma.

Levalbuterol

- Dose for adolescents 12 years of age and over and adults is 0.63 mg (via nebulizer) three times daily (every six to eight hours); may increase to 1.25 mg via neb three times daily (every six to eight hours) if patient does not exhibit adequate response.

- Dose for children 6-11 years of age is 0.31 mg (via nebulizer) three times daily. Routine dosing should not exceed 0.63 mg three times daily.

Corticosteroids

- Initiate or increase anti-inflammatory medication:

  - Inhaled corticosteroids

  - Cromolyn/nedocromil

  - Consider leukotriene modifiers

- Strongly consider systemic corticosteroids in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse *(Chapman, 1991 [A]; Fanta, 1983 [A]; Harris, 1987 [A]; Scarfone, 1993 [A]).*

Note: The Food and Drug Administration has reported that salmeterol monotherapy may be associated with an increased risk of death from asthma.

Antibiotics are not recommended for the treatment of acute asthma except for those patients with signs of acute bacterial infection, fever and purulent sputum.

9. Assess Response to Treatment

Good response:

- PEFR or FEV_1 greater than 70% predicted normal

- No wheezing on auscultation

Incomplete response:

- PEFR or FEV_1 50%-70% predicted normal

- Mild wheezing

- Consider hospitalization, particularly for high-risk patients (see chart in annotation #4)

Poor response:

- PEFR or FEV_1 less than 50% predicted

- No improvement in respiratory distress

- Strongly consider hospitalization

- Continue inhaled $beta_2$-agonist every 60 minutes

- Start oral prednisone unless contraindicated

    - Adult: short course "burst" 40-60 mg/day as single or two divided doses for 3 to 10 days.

    - Pediatric: short course "burst" 1-2 mg/kg day in two divided doses, maximum 60 mg/day for 3 to 10 days.

10. Does Patient Need ED or Inpatient Asthma Management?

A recent study suggests that most children who require hospitalization can be identified by a repeat assessment one hour after initial treatment *(Kelly, 2004 [D]; Wilson, 2003 [D])*. After one hour, those children who continue to meet the criteria for a severe exacerbation have greater than 86% chance of requiring hospitalization; those who meet the criteria for moderate exacerbation at one hour have an 84% chance of requiring hospitalization; and those whose assessment has remained the same or dropped to the mild level have only an 18% chance of requiring hospitalization. These severity assessment studies highlight the importance of regular, multifaceted assessments and close observation of children and adolescents who present to the office or ED with acute asthma exacerbations *(National Heart, Lung, Blood Institute EPR-3, 2007 [R])*.

11. Evaluation

Evaluation of asthma should include the following:

- Medical history

- Use of a validated asthma questionnaire

- Assess asthma triggers/allergens

- Physical examination

- Measure lung function

- Consider specialty consultation

Medical History

- Disruption of usual activities (work, school, home)

- Sleep disturbance

- Level of usage of short-acting $beta_2$-agonist

- Adherence to medical treatment plan

- Interval exacerbation of symptoms (either treated by self or a health care provider)

- Symptoms suggesting comorbid conditions or alternative diagnosis

- Side effects of medications

Reassessment of medical history can elicit factors that effect overall asthma control and sense of well-being *(Juniper, 1993 [D])*. The key symptoms that should alert the clinician include disruptive daytime symptoms and disturbances of sleep, and symptoms early in the morning that do not improve fifteen minutes after short-acting $beta_2$-agonist are a predictor of poor control. The quantity of short-acting $beta_2$-agonist that is being used should be discussed since overuse can be a marker of the potentially fatality-prone asthmatic *(Spitzer, 1992 [C])*. The use of a quality-of-life tool or questionnaire can assist to elicit history *(Juniper, 1992 [D])*.

Self-Assessment with a Validated Asthma Questionnaire

The self-assessment questionnaires that can be completed at office visits are intended to capture the patient's and family's impression of asthma control, self-management skills and overall satisfaction with care. Several multidimensional instruments have been developed to assess control. (http://www.nhlbi.nih.gov/guidelines/asthma/index.html)

(Skinner, 2004 [D])

Assess Asthma Triggers/Allergens

- Inquire about exposure to triggers and allergens (e.g., occupational, pets, smoke).

- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens.

Studies of emergency room visits and near death show allergens as a factor in asthma exacerbation. Asthma triggers in the workplace also need to be considered. About 15% of asthma in adults is work related *(Blanc, 1987 [C]; Malo, 1992 [C]; O'Hollaren, 1991 [D]; Pollart, 1988 [C])*.

The differential diagnosis, as previously discussed, can range from common to rare. The most common contributing disorders that exacerbate asthma are allergic rhinitis and sinusitis *(Corren, 1992 [A]; Rachelefsky, 1984 [D])*. Another common condition to consider is gastroesophageal reflux disease (GERD). Reflux is three times more common in asthmatics, and treating GERD leads to improved asthma control *(Harper, 1987 [D])*.

Physical Examination

- Assess signs associated with asthma, concurrent illness or medication side effects

- Height in children

- Head, eyes, ears, nose, throat, lungs, heart, skin

It is important to discuss any potential medication side effects as this often has a direct relationship to compliance. Common side effects from inhaled steroids include oral candidiasis and dysphonia. beta$_2$-agonists may cause tachycardia, tremor or nervousness. Individuals on long-term oral corticosteroids or frequent bursts of steroids need to be monitored for complications of corticosteroids use such as osteoporosis, hypertension, diabetes and Cushing's syndrome.

The height of individuals on corticosteroids should be monitored over time. The potential effect on linear growth in children is important because these drugs tend to be used over long periods of time. Cumulative data in children suggest that low-to-medium doses of inhaled corticosteroids may have the potential of decreasing growth velocity, but this effect is not sustained in subsequent years of treatment, is not progressive and may be reversible *(Childhood Asthma Management Program Research Group, The, 2000 [A]; National Heart, Lung, Blood Institute EPR-3, 2007 [R]).*

Inhaled glucocorticoids used to treat asthma have been shown to have deleterious effects on bone mineral density and markers of bone mineral metabolism. The risk of fracture attributable to inhaled or nasal glucocorticoids is uncertain *(Lung Health Study Research Group, The, 2000 [A]).*

The remainder of the physical exam either supports or refutes conditions and comorbidities discussed above (see history).

Measure Lung Function

It is important to measure lung function at each visit. The two main methods are spirometry and peak expiratory flow rate (PEFR). Spirometry is more precise and yields more information than PEFR. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of PEFR (example: very young or elderly, neuromuscular or orthopedic problems) *(Enright, 1994 [R]; Miles, 1995 [R]).*

Spirometry is recommended:

- for initial diagnosis or to reassess or confirm diagnosis;

- after treatment is initiated or changed, and once symptoms and PEFR have stabilized, to document attainment of "near normal pulmonary function"; and

- at least every one to two years to assess maintenance of airway function – more often as severity indicates.

Regular monitoring of pulmonary function is particularly important for asthma patients who do not perceive their symptoms until obstruction is severe *(Connolly, 1992 [C]; Kikuchi, 1994 [C]).*

PEFR

- Used for follow-up, not for diagnosis

PEFR provides a simple, quantitative and reproductive measure of severity of airflow obstruction. The results are more reliable if the same type of meter, and preferably the patient's own, is used.

During interval assessment, the clinician should question the patient and review records to evaluate the frequency, severity and causes of exacerbation. Triggers that may contribute should be reviewed. All patients on chronic maintenance medication should be questioned about exposure to inhalant allergens.

Consider Specialty Consultation

Referral is recommended for consultation or care to a specialist in asthma care (allergist or pulmonologist, or other physicians who have expertise in asthma management, developed through additional training and experience) *(Zieger, 1991 [C])* when:

- Patient has had a life-threatening asthma exacerbation.

- Patient is not meeting the goals of asthma therapy after three to six months of treatment. An earlier referral or consultation is appropriate if the physician concludes that the patient is unresponsive to therapy.

- Signs and symptoms are atypical, or there are problems in differential diagnosis.

- Other conditions complicate asthma or its diagnosis (e.g., sinusitis, nasal polyps, aspergillosis, severe rhinitis, VCD, GERD, chronic obstructive pulmonary disease [COPD]).

- Additional diagnostic testing is indicated (e.g., allergy skin testing, rhinoscopy, complete pulmonary function studies, provocative challenge, bronchoscopy).

- Patient requires additional education and guidance on complications of therapy, problems with adherence, or allergen avoidance.

- Patient is being considered for immunotherapy.

- Patient requires step 4 care or higher. Consider referral if patient requires step 3 care.

- Patient has required more than two bursts of oral corticosteroids in one year or has an exacerbation requiring hospitalization.

- Patient requires confirmation of a history that suggests that an occupational or environmental inhalant or ingested substance is provoking or contributing to asthma. Depending on the complexities of diagnosis, treatment or the intervention required in the work environment, it may be appropriate in some cases for the specialist to manage the patient over a period of time or to co-manage with the PCP.

12. Determine Level of Asthma Control

Key Points:

- The level of control is based on the most severe impairment or risk category.

- The level of asthma control (well controlled, not well controlled, or poorly controlled) is the degree to which both dimensions of the manifestations of asthma – impairment and risk – are minimized by therapeutic intervention.

- The level of control at the time of follow-up assessment will determine clinical actions – that is, whether to maintain or adjust therapy.

See Table 5, "Assessing Asthma Control in Children 5-11 Years of Age" and Table 6, "Assessing Asthma Control in Youths 12 Years of Age Through Adults."

Table 5. Assessing Asthma Control in Children 5-11 Years of Age

Components of Control		Classification of Asthma Control (Children 5–11 years of age)		
		Well Controlled	**Not Well Controlled**	**Very Poorly Controlled**
Impairment	Symptoms	≤2 days/week but not more than once on each day	>2 days/week or multiple times on ≤2 days/week	Throughout the day
	Nighttime awakenings	≤1x/month	≥2x/month	≥2x/week
	Interference with normal activity	None	Some limitation	Extremely limited
	Short-acting beta$_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week	Several times per day
	Lung function • FEV$_1$ or peak flow • FEV$_1$/FVC	>80% predicted/personal best >80%	60–80% predicted/personal best 75–80%	<60% predicted/personal best <75%
Risk	Exacerbations requiring oral systemic corticosteroids	0–1/year	≥2/year (see note)	
		Consider severity and interval since last exacerbation		
	Reduction in lung growth	Evaluation requires long-term followup.		
	Treatment-related adverse effects	Medication side effects can vary in intensity from none to very troublesome and worrisome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk.		

Key: EIB, exercise-induced bronchospasm; FEV$_1$, forced expiratory volume in 1 second; FVC, forced vital capacity; ICU, intensive care unit

Notes:

- The level of control is based on the most severe impairment or risk category. Assess impairment domain by patient's/caregiver's recall of previous 2–4 weeks and by spirometry/or peak flow measures. Symptom assessment for longer periods should reflect a global assessment, such as inquiring whether the patient's asthma is better or worse since the last visit.

- At present, there are inadequate data to correspond frequencies of exacerbations with different levels of asthma control. In general, more frequent and intense exacerbations (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) indicate poorer disease control. For treatment purposes, patients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have not-well-controlled asthma, even in the absence of impairment levels consistent with not-well-controlled asthma.

Source: National Heart, Lung, Blood Institute EPR-3, 2007

Table 6. Assessing Asthma Control in Youths 12 Years of Age Through Adults

Components of Control		Classification of Asthma Control (Youths ≥12 years of age and adults)		
		Well-Controlled	**Not Well-Controlled**	**Very Poorly Controlled**
Impairment	Symptoms	≤2 days/week	>2 days/week	Throughout the day
	Nighttime awakening	≤2x/month	1–3x/week	≥4x/week
	Interference with normal activity	None	Some limitation	Extremely limited
	Short-acting beta$_2$-agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week	Several times per day
	FEV$_1$ or peak flow	>80% predicted/ personal best	60–80% predicted/ personal best	<60% predicted/ personal best
	Validated Questionnaires ATAQ ACQ ACT	0 ≤0.75* ≥20	1–2 ≥1.5 16–19	3–4 N/A ≤15
Risk	Exacerbations	0–1/year	≥2/year (see note)	
		Consider severity and interval since last exacerbation		
	Progressive loss of lung function	Evaluation requires long-term followup care		
	Treatment-related adverse effects	Medication side effects can vary in intensity from none to very troublesome and worrisome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk.		

*ACQ values of 0.76–1.4 are indeterminate regarding well-controlled asthma.

Key: EIB, exercise-induced bronchospasm; FEV$_1$, forced expiratory volume in 1 second. See figure 3–8 for full name and source of ATAQ, ACQ, ACT.

Notes:

- The level of control is based on the most severe impairment or risk category. Assess impairment domain by patient's recall of previous 2–4 weeks and by spirometry/or peak flow measures. Symptom assessment for longer periods should reflect a global assessment, such as inquiring whether the patient's asthma is better or worse since the last visit.

- At present, there are inadequate data to correspond frequencies of exacerbations with different levels of asthma control. In general, more frequent and intense exacerbations (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) indicate poorer disease control. For treatment purposes, patients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have not-well-controlled asthma, even in the absence of impairment levels consistent with not-well-controlled asthma.

Source: National Heart, Lung, Blood Institute EPR-3, 2007

13. Step Care of Pharmacologic Treatment

The aim of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimize the risk for adverse effects. The stepwise approach to therapy – in which the dose and number of medications and frequency of administration are increased as necessary and decreased when possible – is used to achieve this control. Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations. See following tables for Management Approach for Asthma.

Based on data comparing leukotriene receptor antagonists (LTRAs) to inhaled corticosteroids, inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and by extrapolation until published data become available, for children. LTRAs are an alternative, although not preferred, treatment. *[Conclusion Grade I: See Conclusion Grading Worksheet A – Annotation #13 (Leukotriene Receptor Antagonists [LTRAs])]*

(Bleecker, 2000 [A]; Ducharme, 2002 [M]; National Heart, Lung, Blood Institute EPR-3, 2007 [R]; Szefler, 2005 [A])
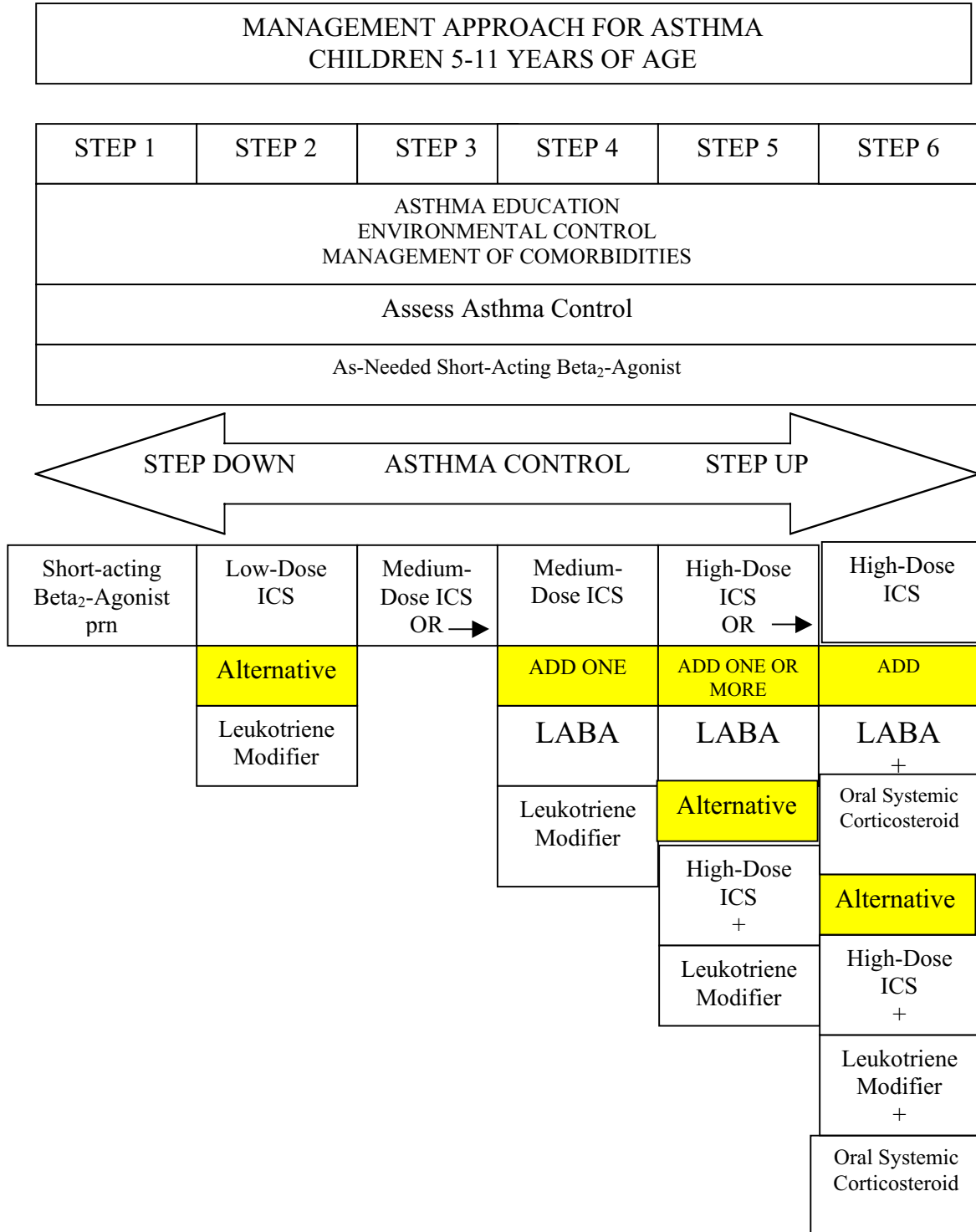
NOTE: Annual influenza vaccinations are recommended for patients with persistent asthma *(National Heart, Lung, Blood Institute, 1997 [R]).*

See Appendix B, "Usual Dosages for Quick-Relief Medications."

See Table 7, "Management Approach for Asthma in Children 5-11 Years of Age" and Table 8, "Management Approach for Asthma 12 Years of Age and Older."

Table 7.

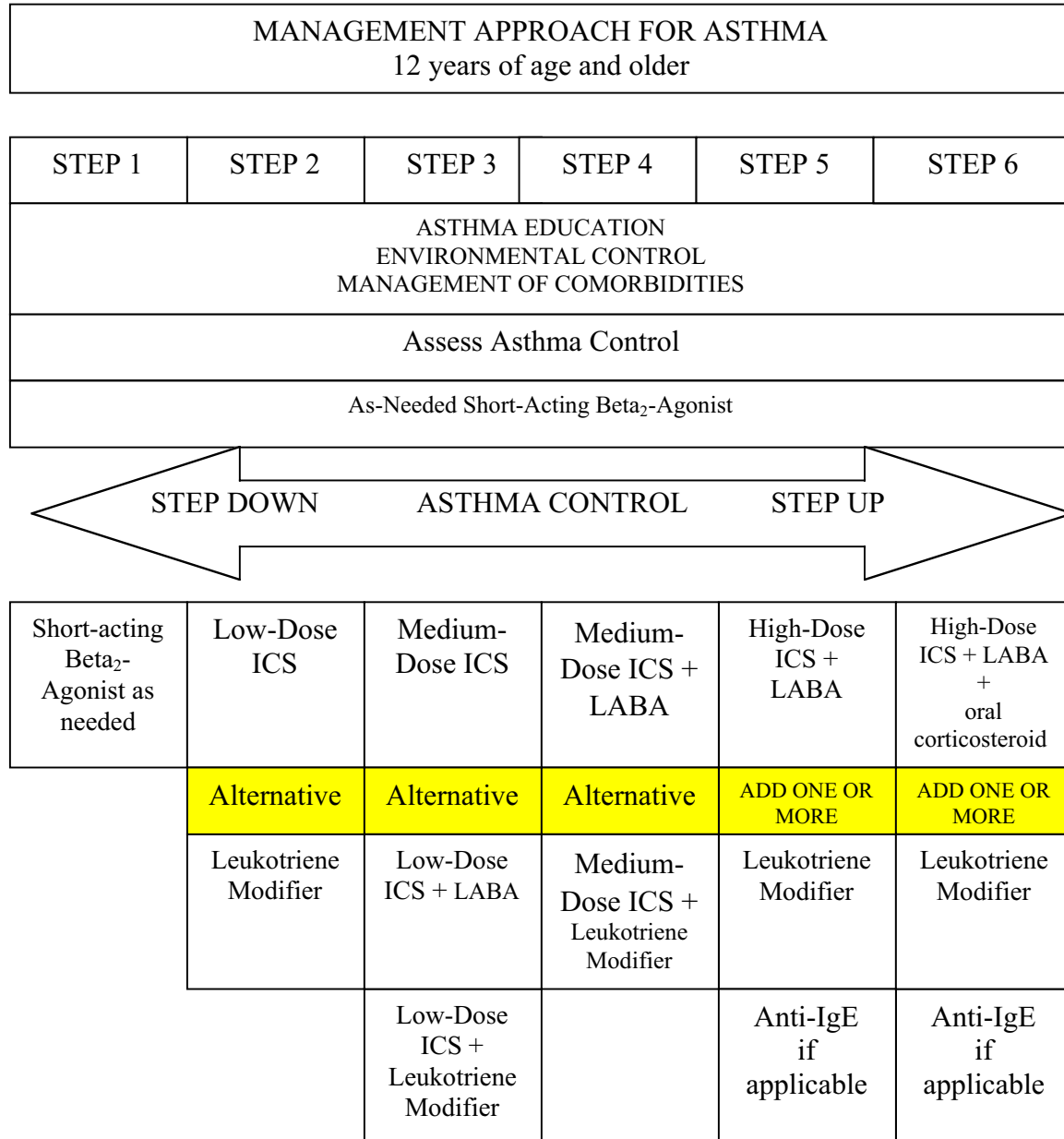| MANAGEMENT APPROACH FOR ASTHMA CHILDREN 5-11 YEARS OF AGE |
|:---:|

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
ASTHMA EDUCATION ENVIRONMENTAL CONTROL MANAGEMENT OF COMORBIDITIES					
Assess Asthma Control					
As-Needed Short-Acting Beta2-Agonist					

STEP DOWN ⟵ ASTHMA CONTROL ⟶ STEP UP

Short-acting Beta2-Agonist prn	Low-Dose ICS	Medium-Dose ICS OR ⟶	Medium-Dose ICS	High-Dose ICS OR ⟶	High-Dose ICS
	Alternative		**ADD ONE**	**ADD ONE OR MORE**	**ADD**
	Leukotriene Modifier		LABA	LABA	LABA +
			Leukotriene Modifier	**Alternative**	Oral Systemic Corticosteroid
				High-Dose ICS +	**Alternative**
				Leukotriene Modifier	High-Dose ICS +
					Leukotriene Modifier +
					Oral Systemic Corticosteroid

Adapted from: Global Initiative for Asthma, 2006; National Heart, Lung, Blood Institute EPR-3, 2007.

ICS = Inhaled corticosteroids

LABA = Long-acting beta2-agonist

Table 8.

MANAGEMENT APPROACH FOR ASTHMA 12 years of age and older					

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
ASTHMA EDUCATION ENVIRONMENTAL CONTROL MANAGEMENT OF COMORBIDITIES					
Assess Asthma Control					
As-Needed Short-Acting Beta$_2$-Agonist					

⟵ STEP DOWN   ASTHMA CONTROL   STEP UP ⟶

Short-acting Beta$_2$-Agonist as needed	Low-Dose ICS	Medium-Dose ICS	Medium-Dose ICS + LABA	High-Dose ICS + LABA	High-Dose ICS + LABA + oral corticosteroid
	Alternative	**Alternative**	**Alternative**	**ADD ONE OR MORE**	**ADD ONE OR MORE**
	Leukotriene Modifier	Low-Dose ICS + LABA	Medium-Dose ICS + Leukotriene Modifier	Leukotriene Modifier	Leukotriene Modifier
		Low-Dose ICS + Leukotriene Modifier		Anti-IgE if applicable	Anti-IgE if applicable

Adapted from: Global Initiative for Asthma, 2006; National Heart, Lung, Blood Institute EPR-3, 2007.

ICS = Inhaled corticosteroids

LABA = Long-acting beta$_2$-agonist

14. Asthma Education

Key Points:

- Asthma self-management education is essential to provide patients with the skills necessary to control asthma and improve outcomes.

- Asthma self-management education should be integrated into all aspects of asthma care, and it requires repetition and reinforcement.

Asthma self-management should include:

- Begin at the time of diagnosis and continue through follow-up care.

- Involve all members of the health care team.

- Introduce the key educational messages by the principal clinician, and negotiate agreements about the goals of treatment, specific medications, and the actions patients will take to reach the agreed-upon goals to control asthma.

- Reinforce and expand key messages (e.g., the patient's level of asthma control, inhaler techniques, self-monitoring, and use of a written asthma action plan) by all members of the health care team.

- Occur at all points of care where health professionals interact with patients who have asthma, including clinics, medical offices, emergency departments and hospitals, pharmacies, homes and community sites (e.g., schools, community centers).

Regular review, by an informed clinician, of the status of the patient's asthma control is an essential part of asthma self-management education. Teach and reinforce at **every** opportunity.

- Basic facts about asthma

    - The contrast between asthmatic and normal airways

    - What happens to the airways in an asthma attack

    - What defines well-controlled asthma and the patient's current level of control

- How medications work

    - Long-term control: medications that prevent symptoms, often by reducing inflammation

    - Quick relief: short-acting bronchodilator relaxes muscles around airways

    - Stress the importance of long-term control medications and not to expect quick relief from them

- Inhaler technique

    - Metered-dose inhaler (MDI) or nebulizer use (patient should repeat demonstration)

    - Spacer/valved holding chamber use with MDI

    - Dry powder inhaler

- Environmental control measures

    - Identifying and avoiding exposure to allergens or other environmental triggers

- Written asthma action plan

This guideline recommends the use of written action plans as part of an overall effort to educate patients in self-management and is especially beneficial for patients with moderate or severe persistent asthma and patients with a history of severe exacerbations.

All asthma patients should be given a written asthma action plan that includes two aspects: daily management and how to recognize and handle worsening asthma. Written action plans are particularly recommended

for patients who have moderate or severe persistent asthma, a history of severe exacerbations, or poorly controlled asthma. Review and refine the plan at follow-up visits.

- When and how to take actions

    - Symptom self-monitoring and recognizing early signs of deterioration

    - When and how to handle signs and symptoms of worsening asthma

    - When and where to seek care

    - Discuss plan for children at school, including management of exercise-induced broncho-spasm.

- Emphasize need for regular follow-up visits and asthma treatment adherence

Supervised self-management (using patient education and adjustments of anti-inflammatory medication based on PEFR or symptoms coupled with regular medical review, utilization and adherence to medication) reduces asthma morbidity. This reduction includes lost workdays, unscheduled office visits, and ED and hospital admissions *(Gibson, 2000 [M]; Ignatio-Garcia, 1995 [A]; Lahdensuo, 1996 [A])*.

Encourage adherence by:

- choosing a treatment regimen that achieves outcomes and addresses preferences that are important to the patient/caregiver, and

- reviewing the success of the treatment plan with the patient/caregiver at each visit and making adjustments as needed.

Tailor the asthma self-management teaching approach to the needs of each patient.

- Maintain sensitivity to cultural beliefs and ethnocultural practices.

Develop an active partnership with the patient and family by:

- establishing open communications,

- identifying and addressing patient and family concerns about asthma and asthma treatment,

- identifying patient/parent/child treatment preferences regarding treatment and barriers to its implementation,

- developing treatment goals together with patient and family, and

- encouraging active self-assessment and self-management of asthma.

Sample Asthma Action Plans are attached in Appendix F, "Example of Asthma Action Plan."

See Minnesota Department of Health Action Plan at http://www.mnasthma.org/AAP/

15. Schedule Regular Follow-Up Visits

Asthma is a chronic inflammatory lung disease, and all chronic diseases need regular follow-up visits. Practitioners need to assess whether or not control of asthma has been maintained and if a step down in therapy is appropriate. Further, practitioners need to monitor and review the daily self-management and action plans, the medications, and the patient's inhaler and peak flow monitoring techniques.

Regularly scheduled follow-up visits are essential to ensure that control is maintained and the appropriate step down in therapy is considered. The exact frequency of visits is a matter of clinical judgment. If asthma is uncontrolled or a change in medication or clinical status has occurred, the patient should be followed in

two to six weeks for an evaluation. A stable asthma patient should be followed at regular intervals of one to six months.

Emergency Department or Inpatient Management Algorithm Annotations

18. Assess Severity of Asthma Exacerbation

See Annotation #5.

21. Initial Treatment

Also see Annotation #8, "Management of Asthma Exacerbation."

Usual treatment is with short-acting beta$_2$-agonist by metered dose inhaler or nebulizer:

Albuterol or Albuterol HFA (90 micrograms per puff) 4-8 puffs

Albuterol solution 2.5 to 5 mg by nebulizer

Levalbuterol MDI solution 1.25-2.5 mg by nebulizer

25. Treatment (Incomplete Response)

Key Points:

- Systemic corticosteroids should be used for all patients who do not favorably respond to the initial beta$_2$-agonist therapy.

- Anticholinergic therapy may increase lung function and may decrease hospital admission rate.

Corticosteroids

Parenteral and enteral administration of corticosteroids requires about 6-24 hours to be effective. Intravenous (IV) and oral routes of corticosteroid administration appear to be equivalent *(Barnett, 1997 [A]; Becker, 1999 [A]; Cunnington, 2005 [A]; Engel, 1990 [A]; Harrison, 1986 [A]; Jonsson, 1988 [A]; Ratto, 1988 [A])*. Medium to high doses of corticosteroids appear to be better than low doses; however, there is still a large range, roughly 160 mg methylprednisolone per day or 2 mg/kg/day in children. There is no evidence to support very high doses of steroids *(Bowler, 1992 [A]; Rodrigo, 1999 [M])*. The National Asthma Education and Prevention Program guidelines recommend that patients admitted to the hospital should receive IV or oral steroids *(National Heart, Lung, Blood Institute EPR-3, 2007 [R])*.

There may be a role for inhaled high-dose corticosteroids in the emergency department in addition to the IV or oral route; however, the data do not support this as standard of care at this time *(Edmonds, 2002 [M]; Edmonds, 2003 [M]; Rodrigo, 2005 [A])*.

In adult asthmatic cases where intolerance or non-compliance with oral steroid therapy is a concern, consider the use of intramuscular (IM) methylpredisone *(Lahn, 2004 [A])*.

Anticholinergics

Ipratropium bromide or another anticholinergic may be used as an additional bronchodilator in conjunction with a beta$_2$-agonist in cases of acute moderate to severe asthma. *[Conclusion Grade II: See Conclusion Grading Worksheet B – Annotation #25 (Anticholinergic Therapy)]* It's most beneficial effects appear to be in multiple doses in more severe exacerbations *(Plotnick, 1998 [M])*. Literature has been inconsistent but indicates that anticholinergic therapy may increase FEV$_1$ or PEFR *(FitzGerald, 1997 [A]; Lanes, 1998 [M])*, may decrease hospital admission rates slightly *(Qureshi, 1998 [A])*, may decrease the amount of beta$_2$-agonist needed, and may prolong bronchodilator effect. These findings were not always statistically significant, and some studies found no benefits *(Diaz, 1997 [A]; Karpel, 1996 [A])*. There were no significant adverse reactions, however. In view of this, it is recommended to consider anticholinergic use in moderate to severe asthma exacerbations.

(Plotnick, 2000 [M]; Westby, 2004 [M])

27. Treatment (Poor Response)

See Appendix A, "Dosages of Drugs for Asthma Exacerbations in the Emergency Medical Care or Hospital."

Key Points:

- Early intervention with Bi-level positive airway pressure may prevent mechanical intubations.

- Heliox may be a secondary therapy in asthma patients who do not respond to first-line therapies.

- Ketamine should be considered for use only in severe asthma exacerbations.

- The decision when to discharge from the emergency department or admit to the hospital must be individualized and depends on response to treatment, pulmonary function and socioeconomic factors.

- Magnesium sulfate may be beneficial in the treatment of acute asthma.

- Reassess patients shortly after inpatient admission.

Intermittent Nebulization Versus Continuous Nebulization

Intermittent nebulization versus continuous nebulization in the treatment of acute asthma has been evaluated quite extensively. The data would suggest that these treatments are equally efficacious; however, there may be a trend toward improvement in patients with severe asthma using nebulization. In a subgroup analysis of patients whose initial FEV$_1$ was less than 50% predicted, there was a statistically significant improvement in FEV$_1$ in patients treated with continuous nebulization versus intermittent nebulization *(Lin, 1993 [A])*. Similarly, in another subgroup analysis of patients whose initial PEFR was less than 200, there was a statistically significant improvement in PEFR and a decrease in hospital admissions in patients treated with continuous versus intermittent nebulization *(Rudnitsky, 1993 [A])*. However, in another subgroup of patients whose FEV$_1$ was less than 50% predicted, there was no difference in improvement in FEV$_1$ or hospital admissions in patients treated with continuous versus intermittent nebulization *(Besbes-Quanes, 2000 [A])*.

A recent meta-analysis suggests equivalence of continuous versus intermittent albuterol in treating asthma. This is determined by spirometry measurement and rates of admission to the hospital *(Rodrigo, 2002 [M])*. There does not seem to be any advantage of higher doses of albuterol for continuous nebulization. There

was no difference in lung function in patients treated with 7.5 mg or 15 mg of albuterol *(Stein, 2003 [A])*. Utilizing albuterol and ipatroprium bromide continuously versus albuterol alone demonstrated a trend toward improvement in reducing the length of stay in the emergency department and in hospital admission rates *(Weber, 1999 [A])*.

Bi-level Positive Airway Pressure (Bi-Level PAP)

Bi-level PAP therapy should be considered for patients presenting with an acute asthma exacerbation. Accumulating studies have shown a benefit in using Bi-level PAP for patients presenting with non-cardiogenic respiratory failure. These studies included, but were not limited to, patients with asthma exacerbations.

A recent study *(Soroksky, 2003 [A])* compared Bi-level PAP ventilation plus conventional therapy versus conventional therapy in patients presenting with an acute asthma exacerbation. Patients in the Bi-level PAP group showed a statistically significant improvement in lung function (measured by FEV_1), improved faster, and were less likely to require admission to the hospital and mechanical intubations.

Heliox

Heliox, a blend of helium and oxygen, is a low-density gas that has been shown in some studies to improve deposition of albuterol into distal airways when compared with nebulized albuterol with oxygen alone. To date, only small-sized randomized controlled trials have been performed. At best, these studies showed mild improvement in spirometry measures and perceived dyspnea scores in patients receiving heliox-driven albuterol nebulization versus patients receiving albuterol nebulization with oxygen alone. These improved measures were more prominent in patients with moderate to severe asthma exacerbations.

There is not enough evidence from large, prospective, randomized controlled trials to recommend heliox as first-line therapy in patients with asthma exacerbations. However, it is recommended that heliox be considered *(Ho, 2003 [M]; Rodrigo, 2003 [M])* as a secondary therapy in patients with a severe asthma exacerbation who are not responding to first-line therapies.

Ketamine

Ketamine and propofol are anesthetic agents with neuro-regulatory properties resulting in bronchodilation. The use of ketamine has shown benefit in improving airway parameters *(Petrello, 2001 [D])*, but increased side effects have resulted in longer hospitalizations *(Lau, 2001 [M])*. Increased side effects of increased secretions, dysphorea and hallucinations are noted. Clinical data suggests that in the non-intubated patient that the side effects may cancel benefit. Some reported case reports suggest benefit in intubated patients *(Lau, 2001 [M])*. Well-controlled studies are required to make a clear strong recommendation for use. Use of ketamine has been pursued only in severe asthmatic exacerbations.

Magnesium Sulfate

In vitro, magnesium acts as a smooth muscle dilator and may have some anti-inflammatory effects by decreasing super-oxide production in neutrophils. Its efficacy has not been consistently demonstrated in randomized control trials. It has not been demonstrated to cause any harmful effects. In a recent multi-center trial, IV magnesium sulfate improved pulmonary function only in patients with severe asthma, (FEV_1 less than 25%). It did not shorten length of hospital stay *(Silverman, 2002 [A])*. In a systematic review, magnesium sulfate did not demonstrate improvement in PEFR, or in hospital length of stay. However, in a subset of patients with severe asthma exacerbations, PEFR, FEV_1 and length of stay were improved *(Rowe, 2000 [M])*. There is insufficient evidence to support the routine use of IV magnesium in the emergency room setting *(Cheuk, 2005 [M]; Kaye, 2002 [R])*. However since it is safe and inexpensive, it should be considered for use in patients with severe asthma exacerbations.

Leukotrienes

The evaluation of leukotrienes for acute asthma care is in its infancy. Pulmonary function has been shown to improve more rapidly when a leukotriene administered orally is added to the standard therapy of asthma care (beta$_2$-agonists/corticosteroids) in emergency room settings *(Emerman, 2001 [R]; Silverman, 1999 [A])*. More studies are needed to confirm these reports.

Montelukast in acute asthma management has been shown to improve pulmonary function in randomized controlled trials *(Camargo, 2003 [A]; Cylly, 2003 [A])*. However, statistical significance could not always be maintained.

The evidence is too preliminary to recommend leukotriene modifiers in acute asthma exacerbations.

29. Admit to Hospital?

Also see Annotation #10, "Does Patient Need ED or Inpatient Asthma Management?"

The decision when to discharge from the emergency department (ED) or admit to the hospital must be individualized and depends on response to treatment, pulmonary function and socioeconomic factors. It is important to consider risk factors for asthma-related death *(National Heart, Lung, Blood Institute EPR-3, 2007 [R])*. Actual length of stay in the ED will vary; some departments have the ability for more extended treatment and observation, provided there is sufficient monitoring and nursing care.

Response to initial treatment in the ED can be based on a repeat assessment approximately 60-90 minutes after initiating bronchodilator therapy, which is a better predictor of the need for hospitalization than is the severity of an exacerbation on presentation *(Rodrigo, 1993 [C])*. Evaluation includes the patient's subjective response, physical findings, O$_2$ saturation and measurement of airflow. Other aspects to consider include duration and severity of symptoms, course and severity of prior exacerbations, medications used at the time of the exacerbation, access to medical care and medications, adequacy of support and home conditions, and presence of psychiatric illness. Pretreatment O$_2$ saturation less than 90%, persisting respiratory acidosis, or severe obstruction that does not improve with the administration of sympathomimetics indicates the need for hospitalization *(Higgins, 2003 [R])*.

Discharge is appropriate if FEV$_1$ or PEFR has returned to greater than or equal to 80% personal best or predicted, and symptoms are minimal or absent. Patients with an incomplete response (FEV$_1$ or PEFR 50%-80%), and with mild symptoms should be assessed individually and may be appropriate for discharge with consideration of the above factors. It is recommended that patients with a rapid good response be observed for 30-60 minutes after the most recent dose of bronchodilator to ensure stability of response before being discharged home.

30. Continue Management in Hospital

Patients being admitted from the ED with an acute asthma exacerbation should be reassessed shortly after admission, with special emphasis on whether the patient is showing any clinical signs of improvement or deterioration (see Annotation #5, "Assess Severity of Asthma Exacerbation"). Objective data should include repeating of the patient's FEV$_1$ or PEFR. A complete physical exam should include emphasis on the patient's respiratory rate, air entry on lung exam, and the presence/absence of signs of increased work of breathing, such as supraclavicular or intercostal retractions.

Consider other illnesses and comorbidities. These may also cause dyspnea, chest tightness and wheezing.

- Viral pneumonitis
- Pneumothorax
- Pulmonary embolism

- Vocal cord dysfunction syndrome

- COPD

- Pulmonary edema

- Endobronchial obstruction (tumor or foreign body)

- Acute hypersensitivity pneumonitis

- Epiglottitis

(ten Brinke, 2005 [D])

32. Discharge Home

Key Points:

- At discharge, provide patients with necessary medications and education in how to use them, instruction in self-assessment, an action plan for managing recurrence of airflow obstruction, and a follow-up appointment.

It is recommended that follow-up with an asthma care provider occur within one week of discharge.

Medications

See Table 9, "Hospital Discharge Checklist for Patients with Asthma Exacerbations."

- Inhaled beta$_2$-agonist every two to six hours.

- Systemic corticosteroids are almost always the treatment of choice in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse.

- Initiate or increase anti-inflammatory medication:

  - Inhaled corticosteroids

    - The role of inhaled corticosteroids after an emergency room visit is controversial *(Edmonds, 2003 [M]; Rowe, 1999 [A])*. However, it is the consensus of this group that inhaled corticosteriods should be encouraged at the time of discharge.

  - Consider leukotriene modifiers as an additive therapy.

- Antibiotics are not routinely used but may be warranted if patient has signs of acute bacterial infection, fever and purulent sputum.

- Long-acting beta$_2$-agonists as monotherapy are NOT recommended.

See Annotation #14 for asthma education and action plan.

See Annotation #15 for follow-up care.

Table 9. Hospital Discharge Checklist for Patients with Asthma Exacerbations

Intervention	Dose/Timing	Education/Advice
Inhaled medications (MDI + spacer/holding chamber)	Select agent, dose, and frequency (e.g., albuterol)	Teach purpose. Teach technique.
Beta$_2$-agonist	2-6 puffs every 3-4 hours as needed	Emphasize need for spacer/holding chamber.
Corticosteroids	Medium dose	Check patient technique.
Oral medications	Select agent, dose and frequency (e.g., prednisone 20 mg twice daily for 3-10 days)	Teach purpose. Teach side effects.
Peak flow meter	Measure a.m. and p.m. PEF and record best of three tries each time	Teach purpose. Teach technique. Distribute peak flow diary.
Follow-up visit	Make appointment for follow-up care with primary clinician or asthma specialist	Advise patient (or caregiver) of date, time, and location of appointment within 7 days of hospital discharge.
Action plan	Before or at discharge	Instruct patient (or caregiver) on simple plan for actions to be taken when symptoms, signs and PEF values suggest recurrent airflow obstruction.

Source: National Heart, Lung, Blood Institute EPR-2, 1997

Special Populations

Asthma in pregnancy

The goals of asthma management in pregnancy include reducing medication toxicity, teratogenicity and preserving uteroplacenta circulation. Changes in the mother's asthma status are expected in almost half of patients, with half of these expecting a worsening of asthma status, particularly if previous pregnancies had similar outcomes. Typical changes of pregnancy – those of increased heart rate, respiratory rate and decreases in baseline CO_2 levels – can lead to underdiagnosing asthma severity if not recognized.

The treatment of acute asthma in pregnancy follows the guidelines for acute asthma care, keeping in mind the goals of the management and changes in physiology.

Albuterol is the preferred short-acting beta$_2$-agonist and has not been linked to adverse fetal outcomes in follow-up studies. Inhaled corticosteroids (ICS) are the preferred treatment for long-term control medication. Budesonide is the preferred ICS because more data are available on using budesonide in pregnant women than are available on other ICSs, and the data are reassuring *(NAEPP, 2005 [R]; National Heart, Lung, Blood Institute EPR-3,2007 [R]).* Systemic steroids, if used in the first trimester, may, though rarely, increase the frequency of cleft palate and possibly be associated with development of preeclampsia. However, the risk to both mother and fetus of an unmanaged severe asthmatic attack overshadows the medication observed risks *(Greenberger, 1990 [R]; Sakornbut, 2003 [R]).*

Appendix A – Dosages of Drugs for Asthma Exacerbations in Emergency Medical Care or Hospital

Medication	Adult Dose	Child Dose*	Comments
		Dosages	
Short-Acting Inhaled Beta$_2$-Agonists			
Albuterol			
Nebulizer solution (5.0 mg/mL, 2.5 mg/3 mL, 1.25 mg/3 mL, 0.63 mg/3 mL)	2.5-5 mg every 20 minutes for 3 doses, then 2.5-10 mg every 1-4 hours as needed, or 10-15 mg/hour continuously	0.15 mg/kg (minimum dose 2.5 mg) every 20 minutes for 3 doses, then 0.15-0.3 mg/kg up to 10 mg every 1-4 hours as needed, or 0.5 mg/kg/hour by continuous nebulization	Only selective beta$_2$-agonists are recommended. For optimal delivery, dilute aerosols to minimum of 3 mL at gas flow of 6-8 L/min. May mix with ipratropium nebulizer solution.
MDI (90 mcg/puff)	4-8 puffs every 20 minutes up to 4 hours, then every 1-4 hours as needed	4-8 puffs every 20 minutes for 3 doses, then every 1-4 hours inhalation maneuver. Use spacer/holding chamber	As effective as nebulized therapy if patient is able to coordinate.
Bitolterol			
Nebulizer solution (2 mg/mL)	See albuterol dose	See albuterol dose; thought to be half as potent as albuterol on a mg basis	Has not been studied in severe asthma exacerbations. Do not mix with other drugs.
MDI (370 mcg/puff)	See albuterol dose	See albuterol dose	Has not been studied in severe asthma exacerbations.
Levalbuterol (R-albuterol)			
Nebulizer solution (0.63 mg/3 mL, 1.25 mg/3 mL	1.25-2.5 mg every 20 minutes for 3 doses, then 1.25-5 mg every 1-4 hours as needed, or 5-7.5 mg/hour continuously	0.075 mg/kg (minimum dose 1.25 mg) every 20 minutes for 3 doses, then 0.075-0.15 mg/kg up to 5 mg every 1-4 hours as needed, or 0.25 mg/kg/hour by continuous nebulization	0.63 mg of levalbuterol is equivalent to 1.25 mg of racemic albuterol for both efficacy and side effects.
Pirbuterol			
MDI (200 mcg/puff)	See albuterol dose	See albuterol dose; thought to be half as potent as albuterol on a mg basis	Has not been studied in severe asthma exacerbations.
Systemic (Injected) Beta$_2$-Agonists			
Epinephrine 1:1,000 (1 mg/mL)	0.3-0.5 mg every 20 minutes for 3 doses subcutaneous	0.01 mg/kg up to 0.3-0.5 mg every 20 minutes for 3 doses subcutaneous	No proven advantage of systemic therapy over aerosol.
Terbutaline (1 mg/mL)	0.25 mg every 20 minutes for 3 doses subcutaneous	0.01 mg/kg every 20 minutes for 3 doses then every 2-6 hours as needed subcutaneous	No proven advantage of systemic therapy over aerosol.

* Children younger than 12 years of age.
Adapted from National Heart, Lung, Blood Institute EPR-3, 2007

Continued

Medication	Dosages		
	Adult Dose	Child Dose*	Comments
Anticholinergics			
Ipratropium bromide			
Nebulizer solution (0.25 mg/mL)	0.5 mg every 30 minutes for 3 doses then every 2-4 hours as needed	0.25 mg every 20 minutes for 3 doses, then every 2 to 4 hours	May mix in same nebulizer with albuterol. Should not be used as first-line therapy; should be added to beta$_2$-agonist therapy.
MDI (18 mcg/puff)	8 puffs every 20 minutes as needed up to 3 hours	4-8 puffs every 20 minutes as needed up to 3 hours	Dose delivered from MDI has been studied but its efficacy is inconclusive.
Ipratropium with albuterol			
Nebulizer solution (Each 3 mL vial contains 0.5 mg ipratropium bromide and 2.5 mg albuterol)	3 mL every 30 minutes for 3 doses, then every 2-4 hours as needed	1.5 mL every 20 minutes for 3 doses, then every 2-4 hours	May be used up to 3 hours in the initial management of severe exacerbation.
MDI (Each puff contains 18 mcg ipratropium bromide and 90 mcg of albuterol)	8 puffs every 20 minutes as needed up to 3 hours	4-8 puffs every 20 minutes as needed up to 3 hours	
Systemic Corticosteroids	Initiate dosing at:		
	(Dosages and comments apply to all three corticosteroids)		
Prednisone Methylprednisolone Prednisolone	120-180 mg/day in 3 or 4 divided doses for 48 hours, then 60-80 mg/day until PEF reaches 80% of predicted or personal best	1 mg/kg every 6 hours for 48 hours then 1-2 mg/kg/day (maximum = 60 mg/day) in 2 divided doses until PEF 80% of predicted or personal best	For outpatient "burst" use 40-60 mg in single or 2 divided doses for adults for a total of 5-10 days. Children: 1-2 mg/kg/day, maximum 60 mg/day for 3-10 days.

* Children younger than 12 years of age

Note

No advantage has been found for higher dose corticosteroids in severe asthma exacerbations, nor is there any advantage for intravenous administration over oral therapy, provided gastrointestinal transit time or absorption is not impaired. The usual regimen is to continue the frequent multiple daily dose until the patient achieves an FEV$_1$ or PEF of 50 percent of predicted or personal best and then lower the dose to twice daily. This usually occurs within 48 hours. Therapy following a hospitalization or emergency department visit may last from 3 to 10 days. If patients are then started on inhaled corticosteroids, studies indicate there is no need to taper the systemic corticosteroid dose. If the follow-up systemic corticosteroid therapy is to be given once daily, one study indicates that it may be more clinically effective to give the dose in the afternoon at 3 p.m., with no increase in adrenal suppression.

National Heart, Lung, Blood Institute EPR-3, 2007

Appendix B – Usual Dosages for Quick-Relief Medications

Medication	Dosage Form	Adult Dose	Child Dose	Comments
Inhaled Short-Acting Beta$_2$-Agonists (SABAs)				
Albuterol Albuterol HFA Pirbuterol Levalbuterol	*MDIs* 90 mcg/puff, 200 puffs/canister 90 mcg/puff, 200 puffs/canister 200 mcg/puff, 400 puffs/canister 45 mcg/puff, 200 puffs/canister	• 2 puffs 5 minutes prior to exercise • 2 puffs every 4-6 hours as needed	• 1-2 puffs 5 minutes prior to exercise • safety and efficacy not established • 2 puffs every 4-6 hours as needed	• An increasing use or lack of expected effect indicates diminished control of asthma. • Not recommended for long-term daily treatment. Regular use exceeding 2 days/week indicates the need for additional long-term controller therapy. • Differences in potency exist so that all products are essentially equal in efficacy on a per-puff basis. • May double usual dose for mild exacerbations. • Nonselective agents (e.g., epinephrine, isoproterenol, metaproterenol) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses. • Spacer/holding chambers are recommended with MDI.
Albuterol Levalbuterol nebulization	*DPI* *Nebulizer solution* 5 mg/mL (0.5%) *Premixed Vials* 2.5 mg/3 mL (0.088%) 1.25 mg/3mL (0.042%) 0.63 mg/3 mL and 1.25 mg/3 mL	1.25-5 mg (.25-1 cc) in 3 cc of saline every 4-8 hours as needed 12 yrs and older is 0.63 mg to 1.25 mg every 8 hours as needed	1.25-5 mg, in 3 cc of saline every 4-8 hours as needed 6-11 years is 0.31 mg to 0.63 mg every 8 hours as needed	• May mix with cromolyn or ipratropium nebulizer solutions, or budesonide inhalant suspension. May double dose for severe exacerbations. • Compatible with budesonide inhalant suspension 3 times daily
Anticholinergics				
Ipratropium HFA	*MDIs* 17 mcg/puff, 200 puffs/canister *Nebulizer/solution* .25 mg/mL (0.025%)	2-3 puffs every 6 hours 0.25 mg every 6 hours	Safety and efficacy not established	• Evidence is lacking for anticholinergics producing added benefit to beta$_2$-agonists in long-term control asthma therapy.
Systemic Corticosteroids		(Applies to all three systemic corticosteroids)		
Methylprednisolone Prednisolone Prednisone	2, 4, 8, 16, 32 mg tablets 5 mg tabs, 5 mg/5 cc, 15 mg/5 cc 1, 2.5, 5, 10, 20, 50 mg tabs; 5 mg/cc; 5 mg/5 cc	• short course "burst": 40-60 mg/day as single or 2 divided doses for 3-10 days	• short course "burst": 40-60 mg/day as single or 2 divided doses for 3-10 days	• Short courses or "bursts" are effective for establishing control when initiating therapy or during a period of gradual deterioration. • The burst should be continued until patient achieves 80% PEF personal best or symptoms resolve. This usually requires 3-10 days but may require longer. There is no evidence that tapering the dose following improvement prevents relapse if sufficient doses of inhaled corticosteroids are used simultaneously.

National Heart, Lung, Blood Institute EPR-3, 2007

Appendix C – Usual Dosages for Long-Term Medications

Medication	Dosage Form	Adult Dose	Child Dose*	Comments
Inhaled Corticosteroids (*See Estimated Comparative Daily Dosages for Inhaled Corticosteroids.*)				
Systemic Corticosteroids				
				(Applies to all three corticosteroids)
Methylprednisolone	2, 4, 8, 16, 32 mg tablets	7.5-60 mg daily in a single dose in a.m. or every other day as needed for control	0.25-2 mg/kg daily in single dose in a.m. or every other day as needed for control	• For long-term treatment of severe persistent asthma, administer single dose in a.m. either daily or on alternate days (alternate-day therapy may produce less adrenal suppression). If daily doses are required, one study suggests improved efficiency and no increase in adrenal suppression when administered at 3 p.m.
Prednisolone	5 mg tablets, 5 mg/5 cc, 15 mg/5 cc	Short-course "burst" to achieve control 40-60 mg per day as single or 2 divided doses for 3-10 days	Short course "burst": 1-2 mg/kg/day, maximum 60 mg/day for 3-10 days	
Prednisone	1, 2.5, 5, 10, 20, 50 mg tablets; 5 mg/cc, 5 mg/5 cc			• Short courses or "bursts" are effective for establishing control when initiating therapy or during a period of gradual deterioration. • The burst should be continued until patient achieves 80% PEF personal best or symptoms resolve. This usually requires 3-10 days but may require longer. There is no evidence that tapering the dose following improvement prevents relapse.
Inhaled Long-Acting Beta$_2$-Agonists (LABA)				• Should not be used for symptom relief or exacerbations. Use with corticosteroids.
Salmeterol	DPI 50 mcg/blister	1 blister every 12 hours	1 blister every 12 hours	
Formoterol	DPI 12 mcg/single-use capsule	1 capsule every 12 hours	1 capsule every 12 hours	• Each capsule is for single use only; additional doses should not be administered for at least 12 hours. • Capsules should be used only with the Aerolizor™ inhaler and should not be taken orally.

Continued

Medication	Dosage Form	Adult Dose	Child Dose*	Comments
Combined Medication				
Fluticasone/ Salmeterol	DPI 100 mcg/50 mcg, 250 mcg/50 mcg or 500 mcg/50 mcg	1 inhalation twice daily; dose depends on severity of asthma	1 inhalation twice daily; dose depends on severity of asthma	• 100/50 for patient not controlled on low- to medium-dose inhaled corticosteroids. 250/50 for patients not controlled on medium-to-high dose inhaled corticosteroids.
	HFA MDI 45 mcg/21 mcg 115 mcg/21 mcg 230 mcg/21 mcg	2 puffs twice daily; dose depends on severity of asthma	NA	
Budesonide/ Formoterol	HFA MDI 80 mcg/4.5 mcg 160 mcg/4.5 mcg	2 puffs twice daily	2 puffs twice daily; currently approved for use in youths ≥ 12 years of age	• 80/4.5 for patients who have asthma not controlled on low- to medium-dose ICS • 160/4.5 for patients who have asthma not controlled on medium- to high-dose ICS
Cromolyn	MDI 0.8 mg/puff Nebulizer 20/mg ampule	2 puffs 3 times a day 1 ampule 3 times a day	1-2 puffs 3-4 times a day 1 ampule 3 times a day	• One dose prior to exercise or allergen exposure provides effective prophylaxis for 1-2 hours.
Nedocromil	MDI 1.75 mg/puff	2 puffs 3 times a day	1 puff 3 times a day	• Once control is achieved, the frequency of dosing may be reduced.
Leukotriene Receptor Antagonists (LTRAs)				
Montelukast	4 mg or 5 mg chewable tablet 10 mg tablet	10 mg every hour	• 5 mg every hour (6-14 years of age) 10 mg every hour (more than 14 years of age)	• Montelukast exhibits a flat dose-response curve.
Zafirlukast	10 or 20 mg tablet	40 mg daily (20 mg tablet twice daily)	• 20 mg daily (7-11 years of age)	• Monitor for signs and symptoms of hepatic dysfunction. • For zafirlukast, administration with meals decreases bioavailability; take at least 1 hour before or 2 hours after meals.
Zileuton	600 mg tablet	2,400 mg daily (give tablets 4 times a day)	NA	
Methylxanthines				
Theophylline	Liquids, sustained-release tablets, and capsules	Starting dose 10 mg/kg/day up to 300 mg max; usual max 800 mg/day	Starting dose 10 mg/kg/day; usual max: 16 mg/kg/day	• Adjust dosage to achieve serum concentration of 5-15 mcg/mL at steady-state (at least 48 hours on same dosage). • Due to wide interpatient variability in theophylline metabolic clearance, routine serum theophylline level monitoring is important.
Immunomodulators Omalizumab	Subcutaneous injection, 150 mg/1.2 mL following reconstitution with 1.4 mL sterile water for injection	150-375 mg 2-4 weeks, depending on body weight and pretreatment serum IgE level		• Do not administer more than 150 mg per injection site. • Monitor for anaphylaxis for 2 hours following at least the first 3 injections.

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Appendix D – Estimated Comparative Daily Dosages for Inhaled Corticosteroids

Drug	Low Daily Dose		Medium Daily Dose		High Daily Dose	
	Adult	**Child***	**Adult**	**Child***	**Adult**	**Child***
Beclomethasone HFA 40 or 80 mcg/puff	80-240 mcg (1-6 puffs)	80-160 mcg (1-4 puffs)	240-480 mcg (3-12 puffs)	160-320 mcg (2-8 puffs)	> 480 mcg (> 6-12 puffs)	> 320 mcg (> 4-8 puffs)
Budesodine DPI 90, 180, 200 mcg/ inhalation	180-600 mcg (1-3 inhalations)	200-400 mcg (1-2 inhalations)	600-1,200 mcg (3-6 inhalations)	400-800 mcg (2-4 inhalations)	> 1,200 mcg (> 6 inhalations)	> 800 mcg (> 4 puffs)
Inhalation suspension for nebulization (child dose)	NA	0.5 mg	NA	1.0 mg	NA	2.0 mg
Flunisolide 250 mcg/puff	500-1,000 mcg (2-4 puffs)	500-750 mcg (2-3 puffs)	1,000-2,000 mcg (4-8 puffs)	1,000-1,250 mcg (4-5 puffs)	> 2,000 mcg (> 8 puffs)	> 1,250 mcg (> 5 puffs)
Flunisolide 80 HFA	320 mcg	160 mcg	> 320-640 mcg	320 mcg	> 640 mcg	$\geq$ 640 mcg
Fluticasone HFA MDI: 44, 110 or 220 mcg/puff DPI: 50, 100 or 250 mcg/inhalation	88-264 mcg (2-6 puffs) 100-300 mcg	88-176 mcg (2-4 puffs) 100-200 mcg	264-440 mcg (2-6 puffs) 300-500 mcg	176-352 mcg (2-10 puffs) 200-400 mcg	> 440 mcg (> 3-6 puffs) > 500 mcg	> 352 mcg (2-4 puffs) > 400 mcg
Triamcinolone acetonide 75 mcg/puff	300-750 mcg (4-10 puffs)	300-600 mcg (4-8 puffs)	750-1,500 mcg (10-20 puffs)	600-900 mcg (8-12 puffs)	> 1,500 mcg (> 20 puffs)	> 900 mcg (> 12 puffs)
Mometasone** 200 mcg/inhalation	200-800 mcg (1-4 inhalations)	(Doses greater than 400 mcg may be split to twice dosing daily. 800 mcg/day is recommended only for patients on oral steroid therapy.				

* Children 12 years of age or younger

** Patients 12 years of age or older

NOTES:

- The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy. The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.

- Some dosages may be outside package labeling.

- MDI dosages are expressed as the actuater dose (the amount of drug leaving the actuater and delivered to the patient), which is the labeling required in the United States. This is different from the dosage expressed as the valve dose (the amount of drug leaving the valve, all of which is not available to the patient), which is used in many European countries and in some of the scientific literature. DPI doses are expressed as the amount of drug in the inhaler following activation.

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Appendix E – Example of Asthma Action Plan

Asthma Action Plan

Patient Name _____

Date of Birth _____

Chart Number _____

Provider(s) _____

Clinic Phone Number _____

To best manage your asthma, you will need to follow the instructions in this asthma action plan especially designed for you.

For information, call:
American Lung Association of Minnesota at (612) 227-8014 or 1-800-642-LUNG

American Lung Association of Hennepin County at (612)871-7332

Additional Information
Write or call:
Allergy and Asthma Network/
Mothers of Asthmatics, Inc.
3554 Chain Bridge Road, Suite 200
Fairfax, VA 22030-2709
(703) 385-4403

Additional Reading
Children with Asthma by Thomas F. Plaut, MD
The Asthma Handbook and *The Best of Super Stuff* by the American Lung Association
What Everyone Needs to Know About Asthma by the Allergy and Asthma Network
Winning Over Asthma by Eileen Dolan Savage

How to use the peak flow meter

1. Place indicator at base of the scale.
2. Stand up.
3. Take a deep breath.
4. Place the meter in mouth and close lips around the mouthpiece.
5. Blow out as hard and fast as possible.
6. Repeat the process two more times.
7. Record the highest of the three numbers.

How to use the inhaler

1. Shake the inhaler and attach spacer if needed.
2. Stand up.
3. Breathe in medication slowly through spacer.
4. Hold breath for 10 seconds.
5. Breathe out slowly.
6. Repeat puffs as directed and wait two to five minutes between puffs.
7. Rinse mouth with water after inhaling steroids to prevent thrush.

Community Asthma Education

Super Asthma Saturday
Asthma Camps
Open Airway for Schools
Asthma Support Groups
Asthma Update Newsletter

Green Zone: All Clear

Personal best peak flow _____
Peak flow _____
(80-100% of personal best)

Symptoms:
- No symptoms of asthma
- Able to participate in usual activities
- No sleep disturbance by asthma such as coughing, wheezing, shortness of breath or chest tightness

Medications:
Name   Dose   Time
_____
_____
_____

Medication side effects:
_____

☐ Inhaler, spacer, nebulizer or rotocaps
☐ Participation in running, playing and sports; take _____ before exercise
☐ Diary can be used with peak flow meter and / or symptoms
☐ Environmental control of asthma triggers, e.g., cigarette smoke, exercise, illness, cold air, animals.

Yellow Zone: Caution

Peak flow _____
(50-80% of personal best)

Early warning signs of acute asthma episode:
- Coughing
- Runny, stuffy or congested nose
- Sneezing
- Not sleeping or eating well
- Tired, weak or low energy
- Itchy or watery eyes
- Drop in peak flow meter reading

Symptoms of acute asthma episode:
- Rapid breathing
- Wheezing
- Frequent, tight cough
- Difficulty breathing out
- Sucking in the chest skin between the ribs

Begin or increase medications if warning signs or symptoms become worse or last more than 12 hours. If unsure, call your clinic.

Medications:
Name   Dose   Time
_____
_____
_____

Medication side effects:
_____

If no symptom relief within 30 minutes of giving medication and peak flow is _____%, add oral steroid

Red Zone: Medical Alert

Peak flow: _____
(less than 50% of personal best)

Severe symptoms requiring immediate medical care:
- Flared nostrils
- Hunched body
- Prolonged shortness of breath not relieved by medication or only brief relief

Medication instructions:
_____

Give oral steroid: _____
Call clinic # _____

Call 911 if you observe these symptoms:
- Gasping for air with sweating
- Extreme anxiety due to difficulty breathing
- Condition rapidly getting worse

☐ Asthma in school or day care
☐ Next asthma appointment and how much time will be needed

Patient Name _____
Date of Birth _____
Provider Signature _____
Date _____

HENNEPIN COUNTY MEDICAL CENTER
LEVEL 1 TRAUMA CENTER
Minneapolis, MN 55415

ASTHMA ACTION PLAN

N17150

Name _____

MR# _____

Birthdate _____
(Addressograph / Label)

Primary Care Provider Name _____ Phone _____

Primary Care Clinic Name _____ Phone _____

☐ No Primary Care Provider ☐ Primary Care Provider Unknown

ASTHMA SEVERITY (Check one):
☐ Mild Intermittent ☐ Moderate Persistent
☐ Mild Persistent ☐ Severe Persistent

GREEN ZONE "GO! All clear!"

Peak Flow Range: ___ to ___
(80-100% of personal best)

- Breathing is easy
- Can play, work, and sleep without asthma symptoms

When you are in the GREEN ZONE, take the following controller medicine(s) every day.

Controller medicines	How much to take	When to take it

Spacer used: ☐ Optichamber: ☐ with mask ☐ without mask OR ☐ Inspirease

Medicine	How much to take	When to take it

Take this medicine as needed 10-20 minutes before sports or any other strenuous activity.

☐ Student may carry and use this medicine at school after approval by the School Nurse

YELLOW ZONE "Caution..."

Peak Flow Range: ___ to ___
(50-79% of personal best)

- Wake up at night
- Cough & wheeze
- Chest is tight

When you are in the YELLOW ZONE, keep taking your GREEN ZONE controller medicine(s) every day and add the following reliever medicine(s) to help keep the asthma episode from getting worse.

Reliever medicine	How much to take	When to take it

If you are in the YELLOW ZONE for more than 12-24 hours, call your doctor. If your breathing symptoms get worse, call your doctor.

☐ Student may carry and use this medicine at school after approval by the School Nurse

RED ZONE "STOP! Medical Alert!"

Peak Flow Range: ___ to ___
(Below 50% of personal best)

- Medicine is not helping
- Breathing is hard and fast
- Can't walk
- Can't talk well
- Ribs show
- Nose opens wide to breathe

When you are in the RED ZONE, start taking your RED ZONE medicine(s) and *Call Your Doctor NOW!*
- Take these medicines until you talk with your doctor.
- If your symptoms do not get better and you can't reach your doctor, go to the emergency room or call 911 immediately.

Reliever medicines	How much to take	When to take it

_____ (Date) _____
MD/NP/PA signature

This asthma action plan is good for one year beginning: _____

I give my permission for this asthma action plan to be used by the following, and for them to share information with each other about my child's asthma for one year beginning today, so that they can work together to help my child manage her/his asthma. This plan, when signed and dated, may replace the school's *consent to administer medication* form, and allows my child's medicine to be given at school.

☐ My child's school / School health office   ☐ My child's clinic / Hospital
☐ My child's day care provider   ☐ Visiting nurse / Home care agency
☐ Insurance case management / Education program

If verbal / telephone consent, signatures of persons taking consent / witnessing:

Parent / guardian signature _____ Date _____

1) _____   2) _____

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HENNEPIN COUNTY MEDICAL CENTER
LEVEL 1 TRAUMA CENTER
Minneapolis, MN 55415

PLAN DE ACCIÓN PARA EL ASMA

N17150

Nombre_____

MR#_____

Fecha de nacimiento _____
(Addressograph / Label)

SEVERIDAD DEL ASMA:
☐ Leve, intermitente ☐ Moderada, persistente
☐ Leve, persistente ☐ Severa, persistente

Nombre del proveedor principal de servicios médicos _____ Teléfono: _____
Nombre de la clínica principal de servicios médicos _____ Teléfono: _____
☐ No existe proveedor principal de servicios médicos ☐ Se desconoce el nombre del proveedor principal de servicios médicos

ZONA VERDE
"¡Avance! ¡Todo está bien!"

Rango de flujo máximo:
_____ a _____
(80-100% del valor mayor)

- Es fácil respirar
- Puede jugar, trabajar y dormir sin síntomas de asma

La **ZONA VERDE** significa que debe tomar diariamente las siguientes medicinas:

Medicinas *controladores*

Cantidad a tomar	Cuándo tomarlas

Con espaciador: ☐ Optichamber: ☐ con máscara ☐ sin máscara **ó** ☐ *Inspírease*

Medicina | Cantidad a tomar | *Tome esta medicina como sea necesario 10-20 minutos antes de hacer deporte u otra actividad extenuante.*

☐ El alumno puede llevar esta medicina a la escuela y usarla allí después de se lo apruebe la enfermera.

ZONA AMARILLA
"Precaución…"

Rango de flujo máximo:
_____ a _____
(50-79% del valor mayor)

- Se despierta durante la noche
- Tos y sibilancia
- Presión en el pecho

La **ZONA AMARILLA** significa que debe continuar tomando diariamente las medicinas controladores indicadas para la Zona Verde. Incluya las siguientes medicinas dilatadores para evitar el empeoramiento de los episodios asmáticos:

Medicinas *dilatadores*

Cantidad a tomar	Cuándo tomarlas

Si permanece en la ZONA AMARILLA por más de 12-24 horas, llame al médico. Si empeoran los síntomas respiratorios, llame al medico.

☐ El alumno puede llevar esta medicina a la escuela y usarla allí después de se lo apruebe la enfermera.

ZONA ROJA
"¡ALTO! ¡Alerta médica!"

Rango de flujo máximo:
_____ a _____
(Por debajo de 50% del valor mayor)

- La medicina no está ayudando
- La respiración es difícil y rápida
- No puede caminar
- No puede hablar bien
- Se ven las costillas
- Se abre bien la nariz para respirar

La **ZONA ROJA** significa que debe tomar las medicinas para la Zona Roja y *llamar a su médico ¡¡¡INMEDIATAMENTE!!!*
- Tome estas medicinas mientras logra comunicarse con el médico.
- Si no mejoran los síntomas y no puede comunicarse con el médico, vaya a la Sala de Emergencias o llame inmediatamente al 911.

Medicinas *dilatadores*

Cantidad a tomar	Cuándo tomarlas

_____ _____
Firma de MD/NP/PA (Fecha)

Este plan de acción para el asma es efectivo por un año a partir de: _____

Yo autorizo el uso de este plan de acción para el asma a las siguientes personas/instituciones con el fin de compartir información sobre el asma de mi niño/a durante un año, a partir de hoy, para que puedan trabajar juntos y ayudar a mi niño/a con el control de su asma. Este plan de acción, una vez firmado y fechado, puede reemplazar el formulario escolar que da *consentimiento para suminstrar medicina,* y permite que se le da a mi niño/a su medicina en la escuela.

☐ La escuela de mi niño/a / La enfermería de la escuela ☐ Clínica / Hospital de mi niño/a
☐ Proveedor de cuidado infantil ☐ Enfermera visitante / Agencia de
☐ Manejo del caso de aseguranza / Programa educativo cuidado en el hogar

Si se autoriza verbal/telefónicamente, firma de la persona que recibe la autorización y testigo: _____
Firma del padre/madre/responsable

1) _____ 2) _____

SPANISH

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Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in the Foreword and are assigned a designator of +, -, or ø to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols **+**, **–**, **ø**, and **N/A** found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

– indicates that these issues have not been adequately addressed;

ø indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

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Conclusion Grading Worksheet A – Annotation #13 (Leukotriene Receptor Antagonists [LTRAs])

Work Group's Conclusion:　Based on data comparing LTRAs to inhaled corticosteroids, inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and by extrapolation until published data become available, for children. LTRAs are an alternative – although not preferred – treatment.

Conclusion Grade: I

Author/Year	Design Type	Class	Quality +, –, ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Malmstrom et al., 1999	RCT	A	ø	-Ages 15 yrs and older; males and females; healthy, nonsmoking; asthma for ≥1 yr; FEV₁ 50-85% of predicted; increase of ≥15% in absolute FEV₁ after use of inhaled β-agonist (at least 2 of 3 visits); daytime asthma symptom score ≥64 (of 336 possible); average daily use of ≥1 puff of short-acting β-agonist -Excluded: use of inhaled and oral corticosteroids, cromolyn, or nedocromil within 4 wks before initial eval; use of long-acting β-agonists, antimuscarinics, or theophylline within 2 wks before initial eval; had used long-acting antihistamines -2 wk placebo run-in, 12 wk treatment period, 3 wk washout -Randomized to montelukast (10 mg 1X/day [evening]), inhaled beclomethasone (200μg 2X/day), or placebo (3:2:2 ratio) -Clinic: FEV₁ -Home: daily diary card for symptoms, PEFR, and need for salbutamol	-895 patients randomized (387 montelukast, 251 beclomethasone, 257 placebo); treatment completed by 91.5%, 92.8%, and 83.7%, respectively; total study completed by 89.4%, 90.4%, and 81.7% -Groups similar at baseline; mean compliance with inhaled medication (treatment phase) 88%-90% for all groups; mean compliance with oral medication >99% for all groups -Outcomes: 					Placebo	Montelukast	Beclomethasone	 FEV₁*	0.7%	7.4%ᵃ	13.1%ᵃ Symptom Score#	-0.17	-0.41ᵃ	-0.62ᵃ PEFR-am	0.8 l/min	23.8 l/minᵃ	39.2 l/minᵃ PEFR-pm	0.3 l/min	20.8 l/minᵃ	32.1 l/minᵃ Attacks^	27.3%	15.6%ᵃ	10.1%ᵃ ᵃ$p<0.001$ compared with placebo; *morning value, % change from baseline; #daytime score, change from baseline; ^percentage of patients -During 3 wk washout, patients switched to placebo returned to baseline levels -Initial response greater for montelukast group; effect of beclomethasone surpassed montelukast 7-10 days after start of therapy -No interactions based on baseline FEV₁, symptom score, need for β-agonist, or PEFR -Improvements in quality of life greater with montelukast and beclomethasone ($p<0.001$) -Most common clinical adverse effects: worsening asthma ($p<0.05$ for active treatment vs. placebo), headache, upper respiratory infection (both NS)	-Oral montelukast therapy has been shown to be effective in chronic asthma, producing significant improvements in FEV₁ and significant alleviation of daytime asthma symptoms. Although inhaled beclomethasone had a larger average effect than montelukast, montelukast had a more rapid initial response. The two agents each protected against worsening episodes of asthma. *NOTES: use of immunotherapy was permitted if it had been started ≥6 mos before initial evaluation; run-in was single-blind, treatment and washout was double-blind; during washout some patients continued active treatment and others switched to placebo; study done at 36 centers in 19 countries; patients could use short-acting inhaled β-agonist (salbutamol) as needed; if additional therapy was needed oral corticosteroids were given (if ≥2 such episode patient was dropped from study); compliance monitored by weighing inhalers and counting tablets; analysis included all patients with baseline and at least one measurement after randomization; did sample size estimation for 95% power to detect difference of 6% in change from baseline and 10% in daytime symptom scores (montelukast vs. placebo)*

Author	Design	Quality	Class	Population/Methods	Results	Conclusions
Bleeker et al., 2000	RCT	A	❽	-Ages 12+; persistent asthma (≥6 mos); predose FEV_1 of 50-80% of predicted normal and increase FEV_1 ≥12% from baseline after 180μg inhaled albuterol; had used albuterol on schedule or as-needed bases during 4 wks before screening; no montelukast, zafirlukast, or zileuton within 2 wks of screening -Excluded: history of life-threatening asthma; >3 bursts of oral or parenteral corticosteroids within 1 yr; use of tobacco products in past yr or smoking history of >10 pack-yrs; respiratory infection within 2 wks of screening, current evidence of significant disorders -8-14 day run-in with rescue albuterol (baseline data, compliance assessment) -Eligible patients randomized to inhaled fluticasone propionate (FP) aerosol (88μg) or oral zafirlukast (20 mg); both 2X/day for 12 wks with albuterol as needed -Home: symptoms, PEFR, albuterol use -Clinic: FEV_1	-220 randomized to zafirlukast, 231 to FP; groups similar at baseline; 77% of zafirlukast and 87% of placebo groups finished protocol -Outcomes (change after 12 wks of treatment): FP Zafirlukast FEV_1-am (L) +0.42 +0.20* PEFR-am (L/min) +49.94 +11.68* PEFR-pm (L/min) +38.91 +10.50* Symptom score -0.46 -0.19* Symptom-free days (%) +28.5 +15.6* Albuterol (puffs/day) -2.39 -1.45* Rescue-free days +40.4 +24.2* # Night awakenings -0.28 -0.15* *p<0.001 -56% of physicians rated treatment with FP as "effective" or "very effective" compared with 41% for zafirlukast (p<0.001) -4% of FP group and 6% of zafirlukast group had an exacerbation (NS) -10% in each group had ≥1 adverse event considered potentially related to treatment; headache, dry mouth, & hoarseness were most common	-The clinical effectiveness of a low dose of FP as first-line therapy in patients with persistent asthma who are symptomatic on β_2-agonists alone is superior to that of zafirlukast. NOTES: concurrent use of medications that might affect the course of asthma or interact with zafirlukast were prohibited; antihistamines, decongestants, and intranasal medications for allergic rhinitis were allowed; double-blind treatment phase; patients with asthma exacerbation (requiring corticosteroids) during study phase were withdrawn; study designed with ≥80% power to detect difference of 0.178 L/min in FEV_1 between groups

Author/Study	Design	Class	Quality	Population/Methods	Results	Conclusions
Busse et al. for the Fluticasone Propionate Clinical Research Study, 2001	RCT	A	∞	-Ages 15+; asthma diagnosed for ≥6 mos; predose FEV_1 50-80% of predicted normal and increase in FEV_1 of ≥15% after 180 μg albuterol; used inhaled or oral short-acting β_2-agonist on a regular or as-needed basis for 3 mos before screening -Excluded: use of ICSs in past 2 mos; use of tobacco products in past year; smoking history of ≥10 pack-yrs; hospitalized for asthma in past 3 mos; respiratory tract infection in past 4 wks; hypersensitivity to asthma drugs -8-14 day run-in period (confirm eligibility, baseline data); use of albuterol as needed -Randomized (see NOTES) to 88μg 2X/day FP + placebo capsule in evening or 10 mg oral montelukast in evening + 2 puffs placebo 2X/day for 24 wks; inhaled albuterol as needed -Clinic visits: FEV_1, adverse events; physician rating of effectiveness, quality of life, patient satisfaction with medication -Home (am/pm): symptoms, PEFR, puffs of albuterol, nighttime awakenings, compliance	-271 in FP group, 262 in montelukast group; groups comparable at baseline; study completed by 72% of FP group and 71% of montelukast group; reported compliance (inhaler and capsules) ≥91% -Outcomes (change from baseline): FP Montelukast FEV_1 (L) 0.51 0.33* PEFR-am (L/min) 68.5 34.1* PEFR-pm (L/min) 53.9 28.7* Symptom score -0.85 -0.60* Albuterol (puffs/day) -3.10 -2.31* *p<0.001 -Physicians global assessment favored FP over montelukast (71% rated FP effective or very effective vs. 53% for montelukast, p<0.001) -Patient satisfaction favored FP over montelukast (85% of patients satisfied with FP vs. 65% for montelukast, p<0.001); quality-of-life scores significantly greater in FP patients (p<0.001) especially asthma symptoms and emotional function domains -Adverse events: 71% of FP patients, 68% of montelukast patients; few were considered drug related; most common (possibly drug related) were headache, sore throat, hoarseness, oral pharyngeal candidiasis -Asthma exacerbations: 4% of FP group, 8% of montelukast group	-Low-dose FP is more effective than montelukast as first-line maintenance therapy for patients with persistent asthma who are underrated and remain symptomatic while taking short-acting β_2-agonists alone. NOTES: at randomization patients had to demonstrate that additional therapy was warranted (unmedicated FEV_1 of 50-80% of predicted normal and within 15% of screening FEV_1, use of albuterol on ≥6 of 7 days before randomization, and asthma symptom score ≥2 [0-5 scale] on ≥4 of 7 days before randomization); use of mediations for rhinitis was allowed; did sample size estimation for ≥80% power to detect difference of 6 percentage points in FEV_1 change between 2 treatment groups; study conducted at 52 sites

Author	Design type	M	+	Methods	Results	Conclusions
Ducharme & Hicks, 2002	Systematic Review	M	+	-Search of clinical trials databases; contact with pharmaceutical companies -Quality of studies assessed by 2 masked reviewers -14 trials met inclusion criteria (including Bleeker, 2000, Busse 2001, and Malmstrom, 1999, [above]); all RCTs except one; 12 focused on adults; intervention duration of 4 to 37 wks; included montelukast, pranlukast, zafirlukast, beclomethasone, and fluticasone -10 trials had high quality (≥4 of 5 points); 11 with appropriate randomization methods; 11 double-blind; withdrawal rates of 0%-29%	-**Primary outcome (results from 11 trials):** rate of exacerbations requiring systemic corticosteroids; patients treated with anti-leukotrienes had 61% increased risk of exacerbation compared to patients treated with ICSs (RR=1.61; 95%CI 1.15-2.25); no apparent difference due to montelukast vs. zafirlukast, beclomethasone vs. fluticasone, quality of studies, published vs. unpublished data, source of funding; greater effect in trials of 12-16 wks vs 4-6 wks, patients with moderate vs. mild asthma -**Other outcomes:** improvements in FEV, PEFRam, change in symptom score, nighttime awakenings, symptom-free days, and quality of life all favored ICSs; anti-leukotriene therapy associated with greater risk of overall withdrawals (RR=1.3; 95%CI 1.1-1.6) apparently due to poor asthma control; no difference in patients experiencing "any adverse effects"	-For most asthma outcomes, ICSs at 400 mcg/day of beclomethasone-equivalent are more effective than anti-leukotriene agents given in the usual licensed doses. The exact dose-equivalence of anti-leukotriene agents in mcg of ICSs remains to be determined.

Conclusion Grading Worksheet B – Annotation #25 (Anticholinergic Therapy)

Work Group's Conclusion: Ipratropium bromide or another anticholinergic may be used as an additional bronchodilator in conjunction with a beta₂-agonist in cases of acute moderate to severe asthma.

Conclusion Grade: II

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Karpel et al., 1996	RCT	A	ø	-Patients presenting to ED with acute asthma; ages 18 to 55 years; able to perform forced expiratory maneuver, FEV₁ ≤60% of normal; smoking history <10 pack-years -Excluded: known or suspected to be pregnant or nursing; significant concomitant medical problems; previous chest surgery; any known intolerance to anticholinergic or β-agonist medications; history of glaucoma, urinary retention, or prostate hypertrophy; COPD; other respiratory diseases; clinical manifestations of severe airway obstruction; prior participation in study -Randomized to either 0.5 mL of 2.5 normal saline OR 0.5 mL of 0.5% albuterol mixed with 2.5 mL of 0.02% ipratropium bromide -Treatment at 0 and 45 min; oxygen at 3L/min throughout 90 min study period	-384 randomized; 380 completed study; groups did not differ at baseline (demographics, ED visits in past year, medication usage in 24 hrs prior to study ED visit, FEV₁, precipitating factors) -No difference between groups in median change in FEV₁ at 45 min after 1st treatment and 45 min after 2nd treatment; subgroup analyses indicated no differences between treatment groups for patients with FEV₁ of >1.0 L or ≤1.0 L -Proportion of responders (≥15% improvement in FEV₁ from baseline) was higher in combined therapy group at 45 min (85% vs. 78%; p<0.05) but not at 90 min (89% vs. 88%) -No differences in vital signs, oxygen saturation, or decrease in potassium levels -Adverse events comparable between groups; all mild and of no clinical significance -54% of combined group and 60% of albuterol only group required further ED treatment before discharge (no difference between groups) -12% of combined group admitted to general hospital ward and 1% admitted to ICU; 13% of albuterol only group admitted to general ward and 1% to ICU (no differences between groups)	-In this population of inner-city asthmatics, there was no significant advantage of treating patients with acute asthma exacerbations with the combination of inhaled ipratropium bromide and a β-agonist compared with a β-agonist alone. NOTES: patients recruited from 3 university-affiliated medical centers; study was multi-site, double-blind *Work Group's Comments: study was supported by a grant from Boehringer Ingelheim Pharmaceuticals, Inc.*
Diaz et al., 1997	RCT	A	ø	-Patients (18–70 yrs old) presenting to ED with acute exacerbations of asthma -Excluded: in extremis; received out-of-hospital therapy for bronchospasm; history of urinary retention, bladder neck obstruction, prostatic hypertrophy, glaucoma, or coronary artery disease; pregnant -All patients received 3 nebulized treatments with 2.5 mg albuterol at 0, 30, and 60 min plus (by randomization) either 1) saline placebo in all 3 nebulizers, 2) 2.0 mg atropine sulfate in 1st nebulizer and saline in 2nd and 3rd, or 3) 2.0 mg atropine sulfate in 1st and 3rd nebulizer with saline in 2nd -Evaluated for admission or release at 90 minutes	-148 randomized; 141 in intention-to-treat analysis; 126 completed protocol; groups were comparable at baseline -No differences between 3 treatment groups on vital signs, peak expiratory flow rate (PEFR), degree of wheezing, level of distress -No difference in admission rate (22% of group 3 [2 doses of atropine sulfate], 26% of group 2 [1 dose of atropine sulfate], 26% of group 1 [control]) -No difference in incidence of side effects - overall 18% reported single or multiple side effects (range from 14% of control group to 21% of 1 dose group)	-In this study population, combination therapy with atropine sulfate and albuterol offered no significant benefit over the use of albuterol alone in the treatment for acute exacerbation of asthma. NOTES: setting was large, inner-city, university-affiliated teaching hospital; no other medications during 90-minute study period; predetermined criteria for admission/release; study was double-blind *Work Group's Comments: no funding information was provided*

Author/Year	Design Type	Class	Quality +,-,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ Work Group's Comments (italicized)
FitzGerald et al., 1997	RCT	A	ø	-Patients presenting to ED with acute asthma; diagnosis of asthma consistent with ATS criteria; 18-55 years old; able to perform reproducible spirometry; initial FEV$_1$ ≤70 of predicted normal -Excluded: in extremis; smoked >10 pack-years; history consistent with COPD; other significant medical illnesses; required drugs other than nebulized study drugs, methylprednisolone, or oxygen; pregnant or lactating -Randomized to combination of 0.5 mg ipratropium bromide and 3.0 mg salbutamol sulfate or 3.0 mg salbutamol sulfate only; all patients received IV bolus of 125 mg methylprednisolone within 15 min of nebulization; supplemental oxygen as needed during 90 min monitoring period	-342 randomized; 309 completed protocol; groups did not differ at baseline (demographics, medication taken in 24 hrs prior to ED, baseline FEV$_1$) -FEV$_1$ improved significantly for both groups (change of 0.52 L at 45 min and 0.52 L at 90 min for salbutamol group; change of 0.58 L at 45 min and 0.61 L at 90 min for combination group); no difference between groups -No difference in adverse reactions -No differences in hospitalizations and asthma exacerbations (after study visit)	-There was no observed benefit to the routine use of a combination of ipratropium bromide and salbutamol compared with salbutamol alone. NOTES: setting was 13 academic and non-academic centers in Canada; 2 received no study drugs and 33 withdrew or were withdrawn by study physician; analysis was by intention-to-treat; approximately 89% of patients in both groups had taken inhaled β-agonist prior to ED arrival *Work Group's Comments: study was supported, in part, by a research grant from Boehringer Ingelheim (Canada) Ltd.*
Garrett et al., 1997	RCT	A	ø	-Patients presenting to ED with acute severe asthma; 18-55 years old; able to perform adequate forced expiratory maneuver; FEV$_1$ <70 of predicted normal -Excluded: smoking history of >10 pack-years; complicating medical illness (including COPD, pneumonia, MI, CHF, renal or hepatic impairment; glaucoma); pregnant or lactating; required drugs other than study drug to treat acute attack -Randomized to one dose of either 2.5 mg salbutamol sulfate or 0.5 mg ipratropium plus 2.5 mg salbutamol; all patients received 200 mg hydrocortisone within 15 min of start of treatment	-Total of 338 randomized; 59 withdrawn before primary outcome (FEV$_1$ at 90 min) assessed; groups did not differ at baseline (age, duration of asthma, number of ED visits in past yr, saw doctor earlier in attack, FEV$_1$, current smoking) -Mean absolute difference in change in FEV$_1$ was 93 ml (p=0.03) at 45 min and 113 ml (p=0.02) at 90 min in favor of combined treatment group -Poor response to either treatment predicted by: frequent use of inhaled β-agonist in 6 hrs prior to presentation (p<0.001), severity of attack (p<0.01), longer duration of attack (p<0.05), and older age (p<0.05) -22% of salbutamol group and 15% of combined treatment group required hospitalization (non-significant) -No difference in mean heart rate, blood pressure, oxygen saturation, or respiratory rate during 90 min study period -No difference in frequency of adverse events	-A single-dose of nebulized combined therapy (Combivent and salbutamol) confers additional bronchodilation over salbutamol alone. Patients who exhibited most benefit from the addition of ipratropium were those who had consumed the least β-agonist before presentation, not those with the most severe asthma. NOTES: setting was 2 New Zealand emergency departments; patients were permitted to have received nebulized bronchodilator in the 6 hrs prior to presentation; study was double-blind; if additional treatment was needed, FEV$_1$ assessed and participation in study ended *Work Group's Comments: study was supported by Boehringer Ingelheim Ltd.*

Author/Year	Design Type	Class	Quality +,-,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ Work Group's Comments (italicized)
Lanes et al., 1998	Meta-Analysis	M	N/A	-Pooled analysis of 3 studies (including Karpel et al., 1996, Fitz-Gerald et al., 1997, and Garrett et al., 1997) -Patients received either 3.0 mg salbutamol sulfate solution (equivalent to 2.5 mg salbutamol base plus 0.5 mg saline) or 2.5 mg salbutamol base plus 0.5 mg ipratropium bromide	-Total of 1,064 randomized; 1,055 received treatment -Groups similar at baseline (demographics and recent medication use) -Difference between treatment groups in *mean change* in FEV_1: 43 mL at 45 min, 47 mL at 90 min (non-significant but favoring combination treatment) -Difference between treatment groups in *median change* in FEV_1: 40 mL at 45 min, 70 mL at 90 min (both p=0.03 favoring combination treatment) -Excluded outliers (change in FEV_1 of >1.7 L at 45 min [n=38 of 1,015] and change in FEV_1 of >2 L at 90 min [n=35 of 961]); differences in *mean* changes in FEV_1 were 55 mL at 45 min and 85 mL at 90 min -Clinical outcomes: relative risks for requiring additional treatment (0.92, 95%CI 0.84-1.0), asthma exacerbation (0.84, 95%CI 0.67-1.04), and hospitalization (0.80, 95%CI 0.61-1.06) favored combination treatment	-The results from the 3 studies are individually imprecise but they are generally consistent and indicate a small benefit in favor of combination therapy. NOTES: inclusion and exclusion criteria for all 3 studies were consistent; protocols were similar but not identical; analysis included completers only (1,015 [95%] at 45 min, 961 [90%] at 90 min) *Work Group's Comments: study was supported by Boehringer Ingelheim*
Qureshi et al., 1998	RCT	A	ø	-Children (ages 2 to 18 years), known history of asthma; presenting to pediatric ED with acute exacerbation (moderate or severe based on % of predicted PEFR or asthma score [signs & symptoms]) -Excluded: treatment with ipratropium within 6 hrs before ED visit; disease with chronic effect on respiratory function; concurrent stridor; possible intrathoracic foreign body; contraindications to study drugs; need for immediate intervention -All received 2.5 mg or 5 mg (based on weight) of nebulized 0.5% albuterol solution every 20 min for 3 doses and an oral corticosteroid with 2nd dose; treatment group received 500 µg ipratropium bromide with 2nd and 3rd doses, control group received saline (randomized)	-480 children randomized; 434 completed the study; groups similar at baseline except more girls in ipratropium group (p=0.04) -Overall rate of hospitalization lower in ipratropium group (27.4% vs. 36.5%; p=0.05); for 171 with severe asthma 52.6% of ipratropium group and 37.5% of control group were hospitalized (p=0.02); no difference for 163 children with moderate asthma -Among children with severe asthma, number needed to treat with ipratropium to prevent one hospitalization was 6.6 -No differences between groups in change in PEFR, heart rate, respiratory rate, or adverse effects -Asthma score improved in ipratropium group (p=0.05 for overall improvement, p=0.01 for children with severe asthma) -Oxygen saturation improved significantly for children with severe asthma in ipratropium group (p=0.02)	-Among children with a severe exacerbation of asthma, the addition of ipratropium bromide to albuterol and corticosteroid therapy significantly decreased the hospitalization rate. NOTES: setting was urban tertiary care medical center; study was double-blind; analysis included only children who received both doses of ipratropium (46 children improved before second dose); after 60 min albuterol given at physician's discretion until decision made to admit or discharge the patient; oxygen given if saturation was ≤94% *Work Group's Comments: study was supported by a grant from the Department of Pediatrics at the study site*

Author/Year	Design Type	Class	Quality +,–,ø	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/Work Group's Comments (italicized)
Plotnick & Ducharme, 1998	Systematic Review	M	ø	-Searched literature databases, reviewed reference lists, contacted manufacturer, & contacted trialists to identify trials -Included: randomized controlled trials in ED setting; unprovoked asthma exacerbation in children 18 months to 17 years; single or multiple doses of anticholinergics combined with β-agonists compared with β-agonists alone; hospital admission as primary outcome; clinical measures as secondary outcomes	-37 studies reviewed; 10 selected for inclusion -Grouped trials according to intensity of protocol -*Single dose protocols (single dose of anticholinergic added to β-agonist):* 5 studies with 453 patients; no reduction in hospital admission (2 trials, relative risk=0.93 [95%CI 0.65-1.32]); change in lung function favored anticholinergic use at 60 min and 120 min (3 trials); single dose not associated with increased vomiting or tremor but with reduction in nausea -*Multiple dose fixed protocols (multiple doses in a predetermined fixed regimen):* 5 studies with 366 patients; reduction in hospital admission favoring combination treatment (4 trials, relative risk=0.72 [95%CI 0.53-0.99]); significant change in lung function favoring anticholinergic use (5 trials); no difference in occurrence of side effects -*Multiple dose flexible protocol (number of doses determined by patient's needs):* 1 study with 31 patients; no significant differences in outcomes	-Adding multiple doses of anticholinergics to β-agonists seems safe, improves lung function, and may avoid hospital admission in 1 of 11 such treated patients. Although multiple doses should be preferred to single doses, the available evidence only supports their use in school aged children and adolescents with severe asthma exacerbations. NOTES: tests for heterogeneity were non-significant; 2 trials with no differences were unpublished (potential publication bias) *Work Group's Comments: study was not funded*
Westby, Benson, and Gibson, 2004	Systematic review and meta-analysis	M	+	Randomized or quasi-randomized trials in adult asthma patients that evaluated inhaled anticholinergic agents as compared to placebo (13 studies, 205 patients) or inhaled anticholinergics + short-acting beta-agonists to short-acting beta-agonists alone (9 studies, 440 patients); short term trials (< 2 days in length) were excluded from this review	For anticholinergic agents compared to placebo, anticholinergics resulted in improved symptom scores, especially for daytime dyspnea (weighted mean difference [WMD] -0.09, 95% CI: -0.14, -0.04; 3 studies with 59 total pts, equating to about a 15% decrease in symptom score compared to placebo) and morning peak flow (WMD 14.38 liters/min, 95% CI: 7.69, 21.08, 3 studies with 59 pts, equating to about a 7% improvement over placebo) and evening peak flow (WMD 23.48 liters/min, 95% CI: 12.32, 34.65, 3 studies with 60 pts, also equating to about a 7% improvement over placebo); no significant differences were reported for frequency of use of rescue medications and adverse effects. For combination anticholinergics + beta-agonists compared to beta-agonists alone no significant differences between groups in terms of symptom scores or peak flow measurements were noted; no significant differences in adverse effects were noted between groups	Significant reservations exist concerning overall study quality (number of studies small, small sample sizes, significant heterogeneity existed for studies on combination beta-agonist + anticholinergics compared to beta-agonists alone, making pooling problematic); in studies of anticholinergics compared to placebo, the clinical significance of the differences between groups were small. No rationale exists at this time for routinely including anticholinergics as add-on treatment to short-acting beta-agonists in patients responding inadequately to standard treatments, although still cannot rule out benefits for certain subgroups (e.g., high vs. low asthma severity) as the studies were not powered to detect any subgroup differences in treatment response.

Author/Year	Design Type	Class	Quality (+,−,Ø)	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ *Work Group's Comments (italicized)*
Plotnick and Ducharme, 2000	Systematic review and meta-analysis	M	+	Randomized trials that compared combination inhaled anticholinergics and short-acting beta₂-agonists with beta₂-agonists alone in children (18 months to 17 years of age) with acute asthma resulting in an ER visit; 13 trials were found that meet inclusion criteria with 8 of these labeled as high quality	Single-dose anticholinergic + beta2- agonists (5 studies, 453 patients) resulted in no significant decrease in hospital admits compared to beta₂-agonists alone; significant differences in lung function measurements favoring combination treatment were found at 60 minutes (standardized mean difference [SMD] 0.57, 95% CI: 0.21, 0.93) and at 120 minutes (SMD 0.53, 95% CI: 0.17, 0.90) after anticholinergic dose; when analysis restricted to mild/moderate exacerbations, no significant differences were found at 60 and 120 minutes. In cases where multiple doses of anticholinergics were used in combination according to a fixed protocol (multiple dose fixed protocol, 7 trials, 1045 children), the risk of hospital admission was reduced by 25% (relative risk [RR] 0.75, 95% CI: 0.62, 0.89), but only the severe exacerbation subgroup showed a significant reduction (RR: 0.71, 95% CI: 0.58, 0.89), driving the improvement. Number needed to treat (NNT) for children with severe exacerbations was seven children to prevent one admit; weighted mean group difference (WMD) for percent predicted FEV1 was 9.68 (95% CI: 5.70, 13.68) 60 minutes after last anticholinergic dose, favoring combination anticholinergic and beta-agonist treatment 2 small trials using multiple dose, flexible protocol (adding anticholinergics to each beta-agonist dose until clinical response) showed no group differences in outcomes. No increase in nausea, vomiting, or tremor was observed in the group treated with anticholinergics	A single dose of an anticholinergic agent is not sufficient for treatment

Multiple doses of anticholinergic agents added to beta₂-agonists improves lung function and helps avoid hospital admissions resulting from asthma exacerbations presenting in the ER

Evidence thus far only favors the addition of anticholinergics to beta-agonists in school age children with severe exacerbations; no clear evidence exists in favor of multiple anticholinergic doses in mild to moderate asthma exacerbations |

This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Promote the accurate assessment of asthma severity and control through the use of objective measures of lung function and symptoms.

    Possible measures of accomplishing this aim:

    a. Percentage of patients with asthma with spirometry or peak flow documented at the last visit.

    b. Percentage of patients with asthma, for whom a peak flow meter is appropriate, who report using a home peak flow meter.

    c. Percentage of patients with asthma with assessment of asthma severity using a validated questionnaire.

2. Promote long-term control of asthma through the use of inhaled corticosteroid drug therapy.

    Possible measure of accomplishing this aim:

    a. Percentage of patients with uncontrolled asthma who are on inhaled corticosteroid medication.

3. Promote the partnership of patients with asthma and/or their parents with health care professionals through education and the use of written action plans.

    Possible measures of accomplishing this aim:

    a. Percentage of patients with asthma with an asthma action plan in the medical record.

    b. Percentage of patients with asthma with education about asthma documented in the medical record.

4. Improve the timely and accurate assessment of patients presenting with an asthma exacerbation.

    Possible measures of accomplishing this aim:

    a. Percentage of patients with diagnosed asthma who have documentation of peak flow measurement during the initial assessment.

    b. Percentage of patients with asthma with any assessment of asthma severity documented during the initial assessment.

    c. Percentage of patients with diagnosed asthma who receive appropriate treatment as rapidly as possible based on response.

5. Improve the treatment and management of inpatient asthma.

    Possible measures of accomplishing this aim:

    a. Percentage of inpatients with diagnosed asthma who are discharged on an inhaled anti-inflammatory medication.

    b. Percentage of inpatients with diagnosed asthma who are readmitted to hospital (hospital admission rate) within 30 days.

    c. Percentage of patients with diagnosed asthma who return to the ED for treatment of asthma within 30 days of last visit.

6. Schedule follow-up visits to ensure asthma control is maintained and appropriate therapy is administered.

   Possible measures of accomplishing this aim:

   a. Percentage of asthma patients who are uncontrolled or have a change in medication or clinical status, who are seen by a health care provider within two to six weeks.

   b. Percentage of stable asthma patients who are seen by a health care provider every one to six months.

   c. Percentage asthma patients who are seen by a health care provider within one week of hospital discharge.

Measurement Specifications

Possible Success Measurement #1a

Percentage of patients with asthma with spirometry or peak flow meter reading documented in the medical record at the last visit.

Population Definition

Patients age five and older diagnosed with asthma, continuously enrolled for six months.

Data of Interest

$$\frac{\text{\# of patients with asthma with spirometry or peak flow meter reading documented at the last visit}}{\text{total \# of patients age five and older with asthma}}$$

Numerator/Denominator Definitions

Numerator: Documented is defined as any evidence in the medical record that spirometry or peak flow reading was done at the last visit as recommended in the guideline.

Denominator: Patients with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for six months.

Method/Source of Data Collection

Data may be collected electronically using the claims/encounter database or the enrollment database. Medical groups should identify patients with asthma seen at the clinic. Each medical group can then generate a list of all eligible patients with asthma seen during the target month/quarter. A random sample of 20 charts can be chosen from this list. The eligible patients are those who are age five and older who have been diagnosed with asthma. The patient medical records are reviewed for any evidence that spirometry or peak flow meter reading was done at the last visit as recommended in the guideline.

Time Frame Pertaining to Data Collection

A minimum of 20 charts per month can be reviewed.

Notes

It is important to periodically assess pulmonary function. The main methods are spirometry or PEFR. Spirometry is more precise and yields more information than PEFR. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of PEFR (e.g., very young or elderly, neuromuscular or orthopedic problems). PEFR provides a simple, quantitative and reproductive measure of severity of airflow obstruction. The results are more reliable if the same type of meter, and preferably the patient's own, is used.

Possible Success Measurement #2a (children)

Percentage of children with uncontrolled asthma who are on inhaled corticosteroids medication.

Population Definition

Children with uncontrolled asthma, continuously enrolled for six months.

Data of Interest

$$\frac{\text{\# children in denominator who have one or more prescriptions for inhaled corticosteroids medications}}{\text{\# of children with uncontrolled asthma}}$$

Numerator/Denominator Definitions

Numerator: Among the children in the denominator, the number who have one or more prescriptions for inhaled corticosteroids medications.

Denominator: Children with uncontrolled asthma with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for six months.

Method/Source of Data Collection

This measure may be collected electronically using the pharmacy data base, the claims/encounter data base, or the enrollment data base.

Time Frame Pertaining to Data Collection

It is suggested that data are collected quarterly.

Notes

Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for uncontrolled asthma emphasizes efforts to suppress inflammation over the long term and prevent exacerbations.

Possible Success Measurement #2a (adults)

Percentage of adults with uncontrolled asthma who are on inhaled corticosteroids medication.

Population Definition

Adults with uncontrolled asthma, continuously enrolled for six months.

Data of Interest

$$\frac{\text{\# of adults in the denominator who have one or more prescriptions for inhaled corticosteroids medications}}{\text{\# of adults with uncontrolled asthma}}$$

Numerator/Denominator Definitions

Numerator: Persons in the denominator who have 1 or more prescriptions filled for inhaled anti-inflammatory medications.

Denominator: Adults with uncontrolled asthma with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for six months.

Method/Source of Data Collection

Data may be collected electronically using the pharmacy database, the claims/encounter database or the enrollment database.

Time Frame Pertaining to Data Collection

It is suggested that data are collected quarterly.

Possible Success Measurement #3b

Percentage of patients with asthma with education about asthma documented in the medical record.

Population Definition

Patients age five and older with asthma continuously enrolled for six months.

Data of Interest

of patients in the denominator with documentation in the record of education about asthma

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total # of patients with asthma whose medical records are reviewed

Numerator/Denominator Definitions

Numerator: Documented is defined as any evidence in the medical record that a clinician provided patient (or parent) education related to:

- Basic facts about asthma

- Role of medications

- Inhaler technique

- Environmental control measures

- Written action plan

- When and how to take actions

- Need for follow-up visits

Denominator: Patients with a diagnosis code of 493.00, 493.01, 493.10, 493.11, 493.90, 493.91, continuously enrolled for six months.

Method/Source of Data Collection

Data may be collected electronically using the claims/encounter database or the enrollment database. Medical groups should identify patients with asthma seen at the clinic. Each medical group can then generate a list of all eligible patients with asthma seen during the target month/quarter. The eligible patients are those age five and older who have been diagnosed with asthma. A random sample of 20 charts can be chosen from this list. The patients' medical records will be reviewed for any evidence that a clinician provided patient education.

Time Frame Pertaining to Data Collection

A minimum of 20 charts per month can be reviewed.

Notes

Patient education is essential for successful management of asthma. It should begin at the time of diagnosis and be ongoing.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Facilitate timely and accurate diagnosis of asthma and asthma severity and control.

2. Educate providers in the use of spirometry as a diagnostic tool.

3. Educate providers and patients in the importance of developing and maintaining an asthma action plan and assessing adherence.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Diagnosis and Management of Asthma guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.

- The content is supported by evidence-based research.

- The content includes the source/author and contact information.

- The content clearly states revision dates or the date the information was published.

- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/knowledge. To access these materials on the Web site you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	Allergy and Asthma Network/Mothers of Asthmatics	A national non-profit network of families whose desire is to overcome allergies and asthma through knowledge. This Web site produces accurate, timely, practical and livable alternatives to suffering.	Patients and Families; Health Care Providers	http://www.aanma.org 1-800-878-4403
	American College of Allergy, Asthma and Immunology (AACAAI)	Provides both patient- and professional-oriented information on asthma diagnosis and management.	Patients and Families; Health Care Providers	http://www.acaai.org
	American Lung Association (ALA)	Offers comprehensive information for patients and practitioners on asthma care and reduction of exacerbations and asthma triggers.	Patients and Families; Health Care Providers	http://www.lungusa.org/ 1-800-548-8252
	Association of Asthma Educators (AAE)	Promotes asthma education as an integral comprehensive asthma program, to raise the competence of health care professionals who educate individuals and families affected by asthma, and to raise the standard of care and quality of asthma education delivered.	Health Care Providers	http://www.asthmaeducators.org/
	Asthma and Allergy Foundation of America (AAFA)	Focus is on improving the quality of life for people with asthma and allergies and their caregivers, through education, advocacy and research. Provides practical information, community-based services, support and referrals through a national network of chapters and educational groups.	Patients and Families; Health Care Providers	http://www.aafa.org
*	Institute for Clinical Systems Improvement	Action Plans; Assessment Surveys; Education (ideas for elementary classrooms); Flow Sheets, Information/Patient Education Modules, Manual for Families of Children with Special Needs; NAEPP Expert Panel Report, Shingle; other tools.	Health Care Providers	http://www.icsi.org/
*	Institute for Clinical Systems Improvement	Emergency and Inpatient Management of Asthma Focus Group Video	Health Care Providers	http://www.icsi.org/

* Available to ICSI members only.

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
*	Institute for Clinical Systems Improvement	HealthEast Improvement Report on Asthma, Process Improvement Report #4	Health Care Providers	http://www.icsi.org/
*	Institute for Clinical Systems Improvement	Improvement Case Report on Asthma: Family Health Services Minnesota PA, Process Improvement Report #19	Health Care Providers	http://www.icsi.org/
	Minnesota Department of Health	Offers information for health care professionals, schools and patients about asthma. An asthma action plan is also included in English and Spanish.	Patients and Families; Health Care Providers	http://www.health.state.mn.us
	National Heart, Lung, and Blood Institute (NHLBI)	Provides asthma health education resources for patients, school/day care providers and health professionals. Materials written in Spanish are available.	Patients and Families; Health Care Providers	http://www.nhlbi.nih.gov
	U.S. Environmental Protection Agency (EPA)	Offers asthma education that incorporates an awareness of indoor environmental asthma triggers (e.g., secondhand smoke, dust mites, mold, pet dander and cockroaches) and actions that can be taken to reduce children's exposure to them in homes, schools and child care settings.	Patients and Families; Health Care Providers	http://www.epa.gov/iaq

* Available to ICSI members only.