Asthma Pharmacotherapy 2017: Stepwise Approach to Managing Asthma

Webinar for
Michigan Center for Clinical Systems Improvement
(Mi-CCSI)

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Priority Health

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Global INitiative for Asthma

Asthma Pharmacotherapy

Quick-relief

- Short-acting beta-agonists
- Inhaled anticholinergics
- Systemic corticosteroids

Long-term control

- Corticosteroids
- Cromolyn sodium
  - Mast cell stabilizer
  - Only available in nebulized form
- Long-acting inhaled beta-agonists
- Theophylline
- Leukotriene Receptor Antagonists (LTRA)

Quick-Relief Medications

- Short-acting beta$_2$-agonists (SABA): albuterol (Pro-Air®, Ventolin®, Proventil®); levalbuterol (Xopenex®)
- Relax bronchial smooth muscles
- Short-acting
  - Work within 10 - 15 minutes
  - Last 4 - 6 hours
- Bind to and activate beta$_2$ receptors in cardiac and smooth muscle tissues
  - Cause bronchodilation in lungs
  - Side effects can include shakiness (tremors), tachycardia
- (Older) beta-blockers are contraindicated in asthma as they can cause the opposite effect - bronchoconstriction
- Danger of over-use

Short-acting β_2-agonists (SABA)

- Most effective medication for relief of acute symptoms

RED FLAG

  - more than 2 canisters per year

- Regularly scheduled use not generally recommended
  - May “lower” effectiveness
  - May increase airway hyperresponsiveness

Anticholinergics

- Ipratropium bromide (Atrovent) or ipratropium bromide & albuterol (Combivent)
- Not specifically indicated for “usual” quick-relief medication in asthma
  - contrast with COPD
- Now well-studied as adjunct to beta-agonists in emergency departments
  - i.e., acute exacerbations

Long-term Control Medications

- Inhaled corticosteroids (ICS): fluticasone propionate (Flovent®, ArmonAir® RespiClick®); beclomethasone (QVAR®); budesonide (Pulmicort®); mometasone (Asmanex®); ciclesonide (Alvesco®); triamcinolone (Aerospan®), fluticasone furoate (Arnuity®)
- Combination products (inhaled corticosteroids and long-acting beta$_2$-agonists or ICS/LABA):
  - fluticasone & serevent (Advair®, AirDuo® RespiClick®) – BID, 3 strengths
  - budesonide & formoterol (Symbicort®) – BID, 2 strengths
  - mometasone & formoterol (Dulera®) – BID, 2 strengths
  - fluticasone furoate & vilanterol (Breo®) – once daily, 2 strengths
- Leukotriene receptor antagonist (LTRA): montelukast (Singulair®), zafirlukast (Accolate®), zileuton (Zyflo®)
- Methylxanthines: theophylline (Theo-Dur®, Slo-bid®)
- Anti-IgE blocker: omalizumab (Xolair®)

Long-term Control Medications

- Should be taken daily and chronically to maintain control of persistent asthma and to prevent exacerbations:
  - Soothes airway swelling
  - Helps prevent asthma flares - very effective for long-term control but must be taken daily
  - Often under-used

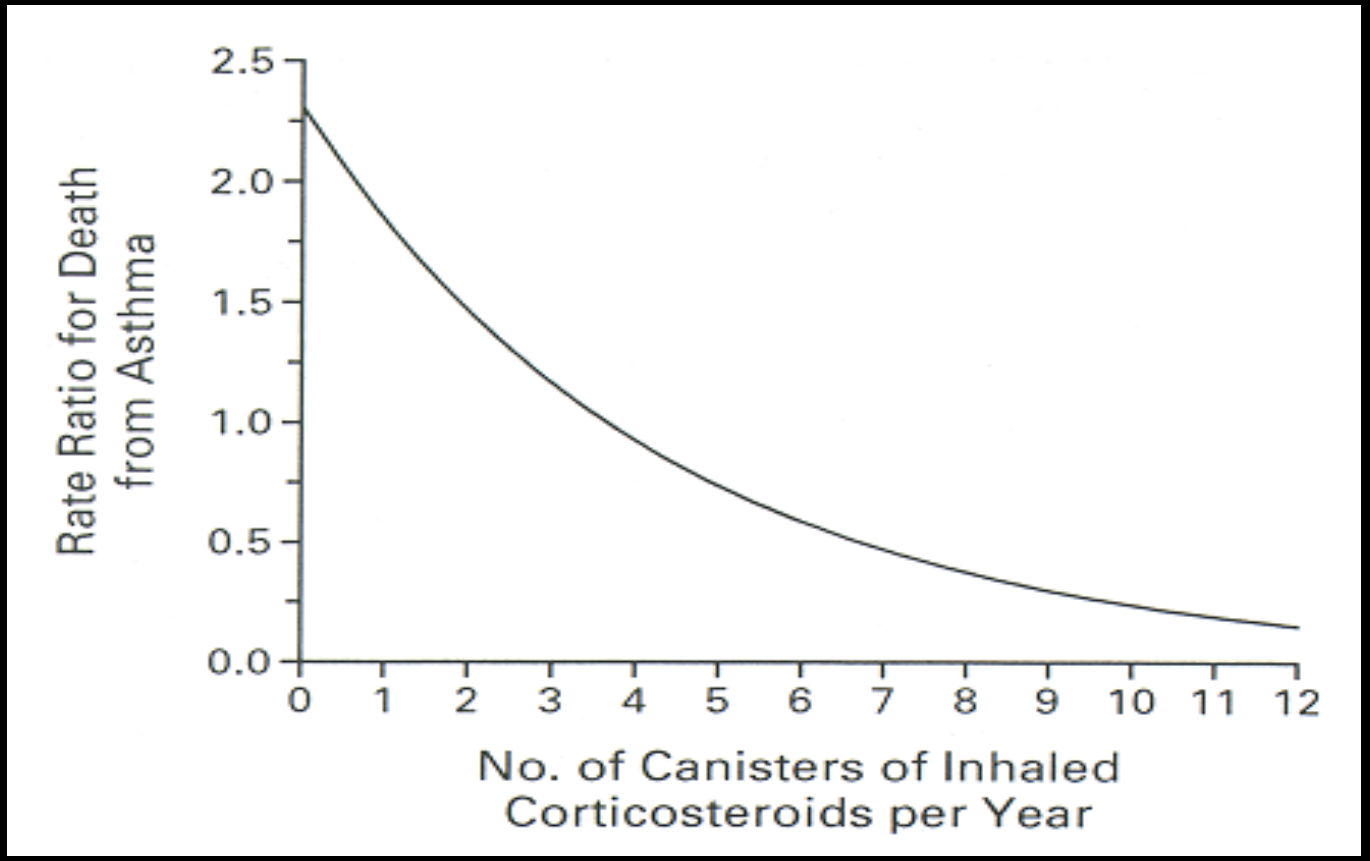
Inhaled Corticosteroids (ICS)

- Actions:
  - potentiate b-receptor responsiveness
  - reduce mucus production and hypersecretion
  - inhibit inflammatory response at all levels
- Best effects if started early after diagnosis
- Symptomatic and spirometric improvement within 2 weeks
  - maximum effects within 4-8 weeks

Inhaled Corticosteroids (ICS) (continued)

- THE most effective long-term control medication for persistent asthma
- Small risk for adverse events at usual doses
  - Risk can be reduced even further by:
    - Using spacer and rinsing mouth
    - Using lowest effective dose
    - Using with long-acting β_2-agonist when appropriate
    - Monitoring growth in children

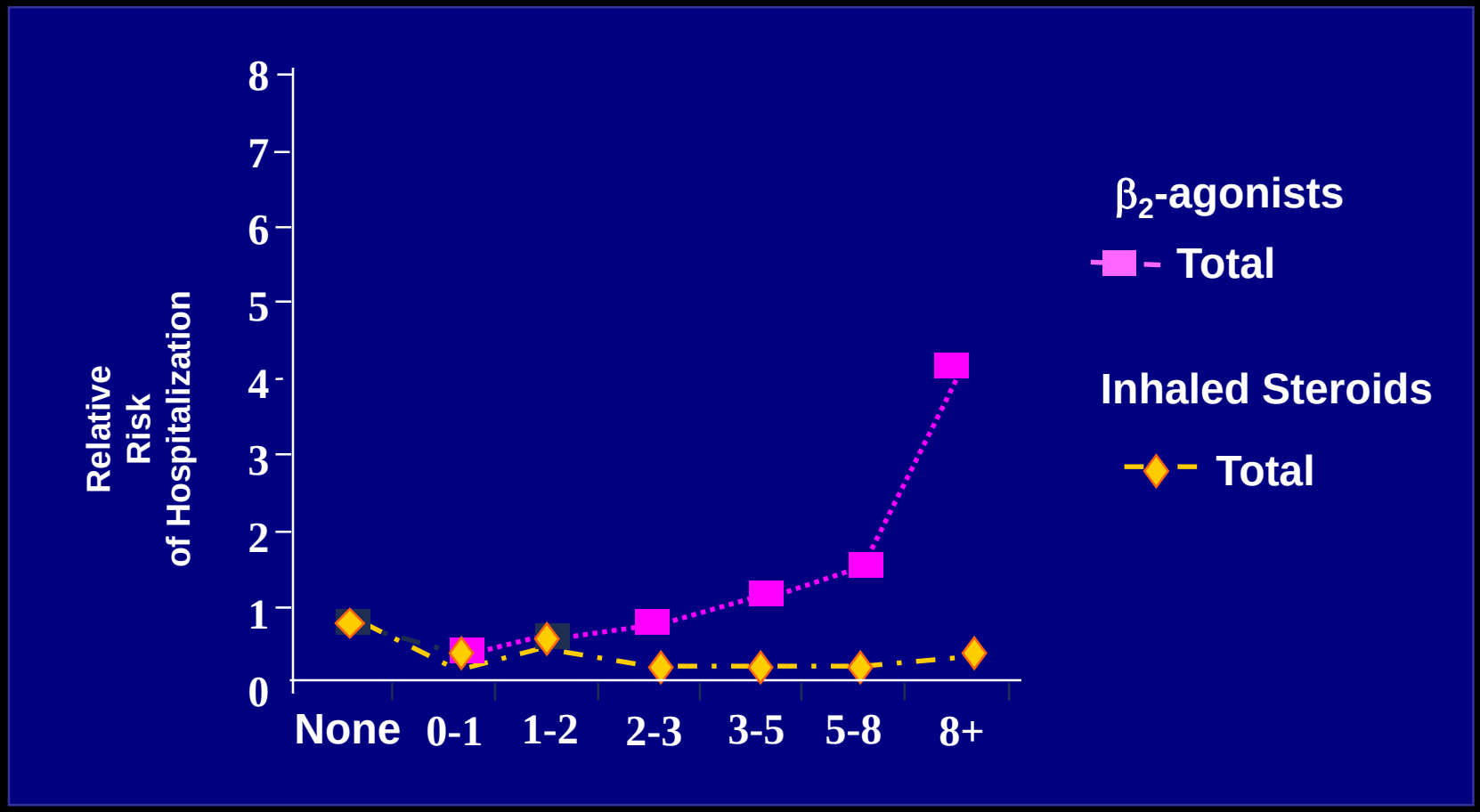
Low dose ICS and the Prevention of Asthma Deaths



- ICS protects patients from asthma-related deaths
- Users of > 6 canisters/yr. had a death rate ~ 50% lower than non-users of ICS
- Death rate decreased by 21% for each additional ICS canister used during the previous year.

Suissa et al. *N Eng J Med* 2000;343:332-336.

ICS May Help Prevent the Risk of Asthma Related Hospitalizations



Adapted from Donahue et. al. JAMA 1997;277(11):887-891.

Inhaled Corticosteroids (ICS) (continued)

- Hypothalamic-pituitary-adrenal (HPA) suppression
  - Not seen in usual doses
- Cataracts
  - Not seen in usual doses
- Long bone growth
  - Growing understanding of this risk
  - Childhood Asthma Management Program (CAMP) study (2000)* showed small, transient reduction in growth velocity from ICS
  - Update (2012)** showed growth reduction persisted as lowered adult height (1.2 cm) – need to weigh risks & benefits
- Osteoporosis/Bone Fractures
  - Some attention at high doses, high-risk patients
- Candidiasis (thrush)
- Dysphonia (hoarseness)

*N Engl J Med. 2000 Oct 12;343(15):1054-63
**N Engl J Med 2012 367(10):904-912.

Checking height in children with asthma

NEW 2017

- Check height at least yearly, because:
  - Poorly-controlled asthma can affect growth *[Pedersen 2001]*
  - Growth velocity may be lower in the first 1-2 years of ICS treatment but this is not progressive or cumulative *[Kelly 2012, Loke 2015]*.
  - The one study that examined long-term outcomes showed a difference of only 0.7% in adult height *[Kelly 2012, Loke 2015]*
- If decreased growth velocity is seen, also consider:
  - Poorly-controlled asthma
  - Frequent use of OCS
  - Poor nutrition

Inhaled corticosteroids and growth in children

NEW SLIDE 2017

- Discuss decisions about controller treatment with parents/carers
  - Discuss the relative benefits and risks of treatment/no treatment
  - Emphasize the importance of maintaining normal activity levels for normal physical and social development
- ICS can have a small but usually temporary effect on growth
  - An effect of ICS on growth velocity is seen in pre-pubertal children in the first 1-2 years of treatment
  - This is not progressive or cumulative *[Kelly 2012, Loke 2015]*.
  - The one study that examined long-term outcomes showed a difference of only 0.7% in adult height *[Kelly 2012, Loke 2015]*
- Poorly-controlled asthma itself adversely affects adult height *[Pedersen 2001]*
- For more detail see GINA 2017 Appendix Chapter 5B

Leukotriene Receptor Antagonists (LTRA)

- Two mechanisms
  - 5-lipoxygenase inhibitors
    - zileuton (Zyflo®)
  - Cysteinyl leukotriene receptor antagonists
    - zafirlukast (Accolate®), montelukast (Singulair®)
- Indications
  - Generally, alternative therapy in mild persistent asthma or as add-on in higher stages
    - Improve lung function
    - Decrease short-acting β_2-agonist use
    - Prevent exacerbations

Methylxanthines (Theophylline) (continued)

- Places in therapy:
  - When inhaled corticosteroids not possible
  - Patients who can't/won't use inhalers
  - Additive therapy at later stages
- Adverse Drug Reactions/Serum Levels
  - Therapeutic Range 5-15 mcg/mL, or 10-20 mcg/mL
  - Levels > 20 mcg/mL: nausea, vomiting, diarrhea, headache, irritability, insomnia, tachycardia
  - Levels > 30 mcg/mL: seizures, toxic encephalopathy, hyperthermia, brain damage
- Drug Interactions: PLENTY!!

Long-Acting β_2-Agonists

- Not a substitute for anti-inflammatory therapy
- Not appropriate for monotherapy

RED FLAG

- Literature supporting role in addition to inhaled corticosteroids
- Not for acute symptoms or exacerbations
- Salmeterol (Serevent®) first of class in US (in Advair®)
- Newer LABAs: formoterol (Foradil®) & vilanterol (in Breo®)
  - Newer long-acting beta-agonists
  - Have rapid onset and long duration
  - Formoterol is available in combination with inhaled steroid in Symbicort® & Dulera® (BID dosing), vilanterol is in Breo® (qd dosing)

Long-Acting β_2-Agonists

- Salmeterol Multicenter Asthma Research Trial (SMART)
- A comparison of usual pharmacotherapy for asthma or usual pharmacotherapy plus salmeterol.
- Nelson HS, Weiss ST, Bleecker ER, et al.

  Chest 2006; 129:15-26.

CHEST

Original Research

ASTHMA

The Salmeterol Multicenter Asthma Research Trial*

A Comparison of Usual Pharmacotherapy for Asthma or Usual Pharmacotherapy Plus Salmeterol

Harold S. Nelson, MD; Scott T. Weiss, MD, MS; Eugene R. Bleecker, MD; Steven W. Yancey, MS; and Paul M. Dorinsky, MD; and the SMART Study Group

Long-Acting β_2-Agonists (LABAs)

- Patients > 12 years old with asthma
- Sought to evaluate the effects of salmeterol or placebo added to usual asthma care on
  - respiratory and asthma related deaths
  - life-threatening episodes
- Initial aim to enroll 30,000 patients; later changed with aim to enroll 60,000

Long-Acting β_2-Agonists (LABAs)

- Increase in adverse events in salmeterol group during SMART trial:
  - Particularly in those recruited in Phase 1
  - Particularly among African-Americans who were noted to have markers of more severe asthma and less likely to be using ICS
- Increase in adverse events in salmeterol group:
  - Due to adverse effect of salmeterol?
  - Due to inappropriate bronchodilator use? (affected patients were more severe at baseline and less likely to be using ICS)

FDA Safety Requirements for Long-Acting β_2-Agonists (LABAs) in Asthma

- The use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid. Single-ingredient LABAs should only be used in combination with an asthma controller medication; they should not be used alone.
- LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications.
- LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication.
- Pediatric and adolescent patients who require the addition of a LABA to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA, to ensure compliance with both medications.

~ February 2010

Long-Acting β_2-Agonists (LABAs)

- Conclusions:
  - Black Box warning
  - Do not use long-acting bronchodilators alone
  - Always use with inhaled corticosteroids
  - Newer Data:
    - LABAs when used with inhaled corticosteroids are helpful. Multiple reviews/meta-analyses suggest that long-acting beta-agonists + inhaled corticosteroids reduce asthma hospitalizations compared to inhaled corticosteroids alone.
    - Emphasize the weakness of the primary data in terms of statistical strength, simply because asthma-related deaths and intubations are so rare.

Rodrigo GJ, Castro-Rodriguez JA. Safety of long-acting β agonists for the treatment of asthma: clearing the air. Thorax 2012;67:342-349.

Patients Are Candidates for Maintenance Therapy if The "RULES OF TWO"™* Apply…

- They are using a quick-relief inhaler more than *2 times per week*
- They awaken at night due to asthma more than *2 times per month*
- They refill a quick-relief inhaler Rx more than *2 times per year*

*"RULES OF TWO"™ is a trademark of the Baylor Health Care System.

Out of Control!

Rules of Two ™

- If your patient can answer “YES” to ANY of these questions, his/her asthma is probably not under good control.
- These rules define persistent asthma.

Asthma Severity

- *Intermittent*
- *Mild Persistent*
- *Moderate Persistent*
- *Severe Persistent*

CLASSIFYING ASTHMA SEVERITY AND INITIATING TREATMENT IN YOUTHS ≥ 12 YEARS AND ADULTS

EPR-3, p74, 344

Components of Severity		Classification of Asthma Severity			
		Intermittent	Persistent		
			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 not daily	Daily	Continuous
	Nighttime Awakenings	≤2x/month	3-4x/month	>1x/week not nightly	Often nightly
	SABA use for sx control	≤2 days/week	>2 days/week not daily	Daily	Several times daily
	Interference with normal activity	none	Minor limitation	Some limitation	Extremely limited
	Lung Function	•Normal FEV_1 between exacerbations • FEV_1 > 80% • FEV_1/FVC normal	• FEV_1 >80% •FEV_1/FVC normal	• FEV_1 >60% but< 80% •FEV_1/FVC reduced 5%	•FEV_1 <60% •FEV_1/FVC reduced> 5%
Risk	Exacerbations (consider frequency and severity)	0-2/year	> 2 /year →		
		Frequency and severity may vary over time for patients in any category			
		Relative annual risk of exacerbations may be related to FEV			
Recommended Step for Initiating Treatment		**Step 1**	**Step 2**	**Step 3**	**Step 4 or 5**
				Consider short course of oral steroids	
		In 2 -6 weeks, evaluate asthma control that is achieved and adjust therapy accordingly			

Asthma Control

The purpose of periodic assessment and ongoing monitoring is to determine whether the goals of asthma therapy are being achieved and asthma is controlled.

- ***Well Controlled***
- ***Not Well Controlled***
- ***Very Poorly Controlled***

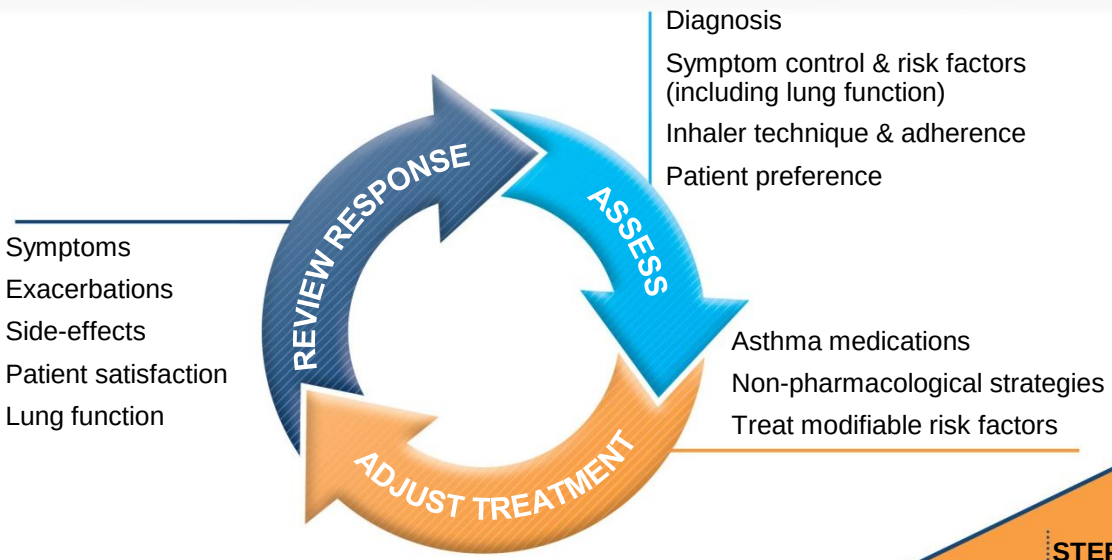
ASSESSING ASTHMA CONTROL AND ADJUSTING THERAPY IN YOUTHS ≥ 12 YEARS OF AGE AND ADULTS

EPR-3, p77, 345

Components of Control		Classification of Asthma Control		
		Well Controlled	**Not Well Controlled**	**Very Poorly Controlled**
IMPAIRMENT	Symptoms	≤ 2 days/week	> 2 days/week	Throughout the day
	Nighttime awakenings	≤ 2/month	1-3/week	≥ 4/week
	Interference with normal activity	none	Some limitation	Extremely limited
	SABA use	≤ 2 days/week	> 2 days/week	Several times/day
	FEV_1 or peak flow	> 80% predicted/ personal best	60-80% predicted/ personal best	<60% predicted/ personal best
	Validated questionnaires ATAQ/ACT	0/≥ 20	1-2/16-19	3-4/≤ 15
RISK	Exacerbations	0- 1 per year	2 - 3 per year	> 3 per year
	Progressive loss of lung function	Evaluation requires long-term follow up care		
	Rx-related adverse effects	Consider in overall assessment of risk		
Recommended Action For Treatment		**•Maintain current step** **•Consider step down if well controlled at least 3 months**	**•Step up 1 step** **•Reevaluate in 2 - 6 weeks**	**•Consider oral steroids** **•Step up (1-2 steps) and reevaluate in 2 weeks**

Stepwise management - pharmacotherapy

UPDATED 2017



	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
PREFERRED CONTROLLER CHOICE		Low dose ICS	Low dose ICS/LABA**	Med/high ICS/LABA	Refer for add-on treatment e.g. tiotropium,*† anti-IgE, anti-IL5*
Other controller options	*Consider low dose ICS*	*Leukotriene receptor antagonists (LTRA) Low dose theophylline**	*Med/high dose ICS Low dose ICS+LTRA (or + theoph*)*	*Add tiotropium*† High dose ICS + LTRA (or + theoph*)*	*Add low dose OCS*
RELIEVER	As-needed short-acting beta2-agonist (SABA)		As-needed SABA or low dose ICS/formoterol#		

*Not for children <12 years

**For children 6-11 years, the preferred Step 3 treatment is medium dose ICS

#For patients prescribed BDP/formoterol or BUD/formoterol maintenance and reliever therapy

† Tiotropium by mist inhaler is an add-on treatment for patients ≥12 years with a history of exacerbations

Stepwise management – additional components

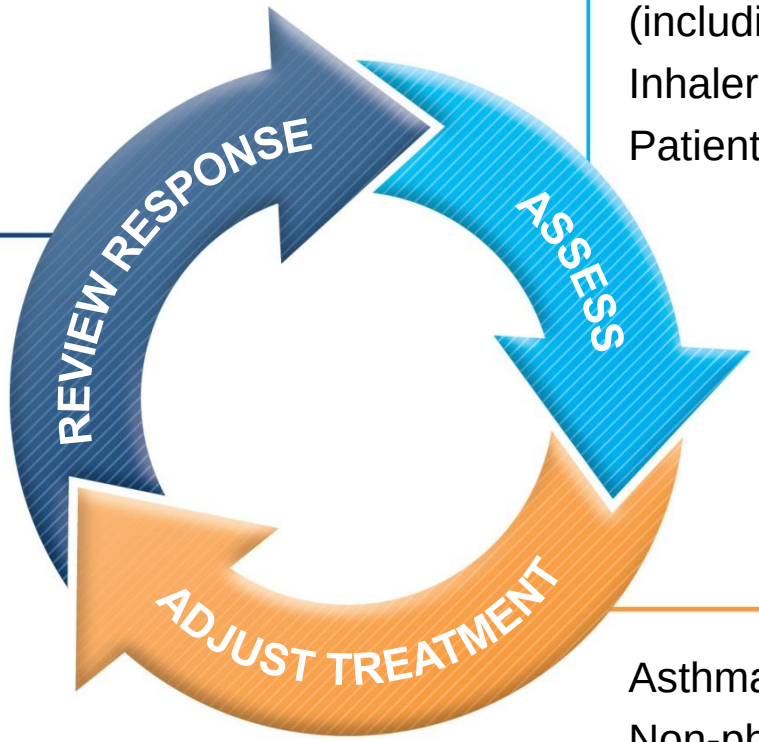
UPDATED 2017

REMEMBER TO...

- Provide guided self-management education
- Treat modifiable risk factors and comorbidities
- Advise about non-pharmacological therapies and strategies
- Consider stepping up if … uncontrolled symptoms, exacerbations or risks, but check diagnosis, inhaler technique and adherence first
- Consider adding SLIT in adult HDM-sensitive patients with allergic rhinitis who have exacerbations despite ICS treatment, provided FEV_1 is 70% predicted
- Consider stepping down if … symptoms controlled for 3 months + low risk for exacerbations. Ceasing ICS is not advised.

SLIT: sublingual immunotherapy

The control-based asthma management cycle



Diagnosis

Symptom control & risk factors (including lung function)

Inhaler technique & adherence

Patient preference

Symptoms

Exacerbations

Side-effects

Patient satisfaction

Lung function

Asthma medications

Non-pharmacological strategies

Treat modifiable risk factors

General principles for stepping down controller treatment

- Aim
  - To find the lowest dose that controls symptoms and exacerbations, and minimizes the risk of side-effects
- When to consider stepping down
  - When symptoms have been well controlled and lung function stable for ≥3 months
  - No respiratory infection, patient not travelling, not pregnant
- Prepare for step-down
  - Record the level of symptom control and consider risk factors
  - Make sure the patient has a written asthma action plan
  - Book a follow-up visit in 1-3 months
- Step down through available formulations
  - Stepping down ICS doses by 25–50% at 3 month intervals is feasible and safe for most patients *(Hagan et al, Allergy 2014)*
  - See GINA 2017 report Box 3-7 for specific step-down options
- Stopping ICS is not recommended in adults with asthma because of risk of exacerbations *(Rank et al, JACI 2013)*

Current Therapy

- Use Asthma Guidelines as a guide
- Poor adherence with inhaled therapy
- No curative therapy
- Many patients remain poorly controlled
- Recognition of different phenotypes of asthma

New/Upcoming Asthma Therapies

- Recognition that there are different phenotypes or endotypes of asthma
  - Phenotype – observable characteristics or clinical presentation (e.g., transient vs. persistent wheezing)
  - Endotype – a subtype of a condition defined by a distinct pathophysiological mechanism
- As treatments become more specific, targeting specific inflammatory cells (such as blockade of specific cytokines or kinases) may be effective in the treatment of asthma
- Because new therapies are likely to be very expensive (especially antibodies) it will become increasingly important to recognize responder patients

New Long-Acting Bronchodilators

- Prevention and relief of bronchoconstriction
- LABAs offered 12 hour action
  - Salmeterol (Serevent®), formoterol (Foradil®)
- Now Ultra-LABAs in development with 24-hour action
  - indacaterol, carmoterol, vilanterol and olodaterol.

Risks of LABAs

- Increased risk of overall death if monotherapy
- Evidence supports LABA + ICS in a single inhaler device for patient with mod/severe asthma

Thorax 2012; 67: 67 342-349

ProAir RespiClick®
albuterol sulfate dry powder inhaler

- Breath actuated

Side Effects

- Back pain
- Body aches and pains
- Upset stomach
- Heart racing
- Urinary tract infection
- Shakiness

Arnuity Ellipta®
fluticasone furoate

- Approved August 2014
- Once daily maintenance therapy of asthma in those 12 and older
- Normal dose is one inhalation daily
- Starting dose is 100mcg
- May increase to 200mcg after 2 weeks

Side Effects

- Upper infections
- Nasopharyngitis
- Headache
- Bronchitis
- Oral candidiasis

LABA/Corticosteroid

- New products aimed for ease of use and adherence to therapy
- One inhalation/once daily

Breo Ellipta®
fluticasone furoate/vilanterol

- FDA approval 4/30/2015 for ages 18 and older
- LABA warning continues
- Once daily inhalation therapy for individuals with asthma
- Side Effects - Headache, nasopharyngitis, pneumonia, fractures

Respimat®
New Inhalation Device
SMI (Soft Mist Inhaler)


Image courtesy of Boehringer Ingelheim International GmbH, Germany.

Respimat Medications:

- Combivent®
  - albuterol and ipratropium (quick-relief)
- Spiriva®
  - Tiotropium (LAMA)
- Stiolto®
  - Tiotropium/olodaterol (LAMA/LABA)

Spiriva Respimat®
(tiotropium)

- New indication for asthma
- Dose 1.25mcg/actuation = 2 actuations once daily
- Add-on maintenance bronchodilator treatment
- Once-daily maintenance treatment for patients with asthma > 6 years (new age indication)
- Not for the relief of acute bronchospasm
- Can be used in patients who remain symptomatic on ICS/LABA
- Adverse reactions: pharyngitis, cough, headache, palpitations, dizziness, dysphonia

Choosing an inhaler device for children ≤5 years

Age	Preferred device	Alternate device
0–3 years	Pressurized metered dose inhaler plus dedicated spacer with face mask	Nebulizer with face mask
4–5 years	Pressurized metered dose inhaler plus dedicated spacer with mouthpiece	Pressurized metered dose inhaler plus dedicated spacer with face mask, or nebulizer with mouthpiece or face mask

Device Selection in Children (2017)

- Inhaled therapy is cornerstone of asthma treatment
- Tidal breathing in young children with spacer/face mask
- Takes 5-10 breaths to empty spacer depending on child's tidal volume and spacer volume (passive)
- Place face mask tightly around mouth and nose
- Nebulizers are reserved for minority of children who cannot be taught effective use of a spacer device (use with mouthpiece to avoid medication reaching the eyes) – never use blow-by technique!


AeroChamber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Biologics: Xolair® (omalizumab)
Anti-IgE Therapy

- Biologic antibody therapy binds IgE in the circulation and prevents it from activating mast cells and basophils.
- In moderate to severe asthma, anti-IgE therapy reduced exacerbation rate and reduced steroid dose needed.
- Anti IgE therapy is recommended as an add-on to optimized standard therapy in individuals 12 years and older who need continuous or frequent treatment with oral corticosteroids.
- Elevated serum IgE 30-700 IU/ml
- Positive allergy test

Xolair® Indication

- Omalizumab (Xolair) is indicated for adults and adolescents 12 years of age and above
  - With moderate to severe, persistent asthma
  - Who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen
  - Whose symptoms are inadequately controlled with inhaled corticosteroids
  - Elevated serum immunoglobulin E (IgE) level (≥ 30-700 IU/mL)
- Xolair has been shown to decrease the incidence of asthma exacerbations in these patients
- Safety and efficacy have not been established in other allergic conditions

Biologics: Nucala® (mepolizumab)

- Indicated for the maintenance treatment of asthma in people over 12 years whose asthma is not otherwise controlled on current asthma medicines
- For patients with an eosinophilic phenotype – eosinophils are responsible for airway inflammation in asthma
- Helps prevent exacerbations
- Reduces blood eosinophils in patients with severe eosinophilic asthma (>150 cells/microliters at start or >300 anytime in past 12 months).
- Dose: 100 mg subcutaneously q 4 weeks

Nucala® (mepolizumab)

- Anti-interleukin 5 (IL-5) targeted therapy for individuals with severe asthma with an eosinophilic phenotype
- Patients 12 years and older with severe asthma who have:
  - Current therapy (high dose ICS and additional controller(s)
  - Exacerbation history ≥2 in prior 12 months*
  - Blood eosinophil levels ≥150 cells/μL
  - Obtain CBC with differential
- Once-monthly fixed dose SC injection
- Adverse reactions: anaphylaxis, headache, dizziness, back pain, local reaction at injection site

*Oral steroids, hospitalization(s) or ED visit(s)

Biologics: Cinqair® (reslizumab)

- Anti-interleukin-5 monoclonal antibody
- Intravenous infusion
- Indicated for maintenance treatment of patients with severe asthma 18 years and older
- Binds to human IL-5 and prevents it from binding to IL-5 receptor, thereby reducing eosinophilic inflammation
- Dose is 3 mg/kg every 4 weeks
- Adverse reactions: anaphylaxis, cancer and muscle pain

Bronchial Thermoplasty

- Indicated for treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and LABAs
- Performed with a bronchoscope – involves the delivery of controlled, therapeutic radiofrequency energy to the airway wall
- This results in heating of the tissue and reduces the amount of smooth muscle present in the airway way
- Requires 3 separate bronchoscopic procedures
- Reduces asthma exacerbations, ER visits and hospitalizations

Timothy Grass Extract
Grastek®

- Used for grass pollen-induced allergic rhinitis confirmed by positive allergy testing
- Dose one tablet sublingual daily
- First dose in allergy office (observed for 30 minutes), then taken once daily at home
- Leave under tongue for at least 1 minute
- Start 12 weeks before grass season
- Ages 5 - 65
- Do not use in severe or uncontrolled asthma

Timothy Grass Extract
Grastek®

- Side effects
  - Throat irritation
  - Itchy ears
  - Oral itching
  - Mouth edema
  - Headache
- Stop taking if trouble breathing, throat tightness or swelling, trouble swallowing, dizziness, rapid heartrate, severe stomach symptoms
- Possibility of systemic (anaphylactic) reaction (lower risk than immunotherapy injections)
- Offer an EpiPen for home use

Grass Pollen Extract
Oralair®

- Used for treatment of grass pollen-induced allergic rhinitis confirmed by positive allergy testing
- 5 grass species included
- Dose: one sublingual tab daily
- Ages 10 - 65
- Do not use in uncontrolled asthma

Grass Pollen Extract
Oralair®

- Side Effects
  - Oral itching
  - Throat irritation
  - Ear itching
  - Edema mouth
- Stop taking if trouble breathing, throat tightness or swelling, trouble swallowing, dizziness, rapid heart rate, severe stomach symptoms
- Possibility of systemic (anaphylactic) reaction (lower risk than immunotherapy injections)
- Offer an EpiPen for home use

Short Ragweed Pollen Extract
Ragwitek®

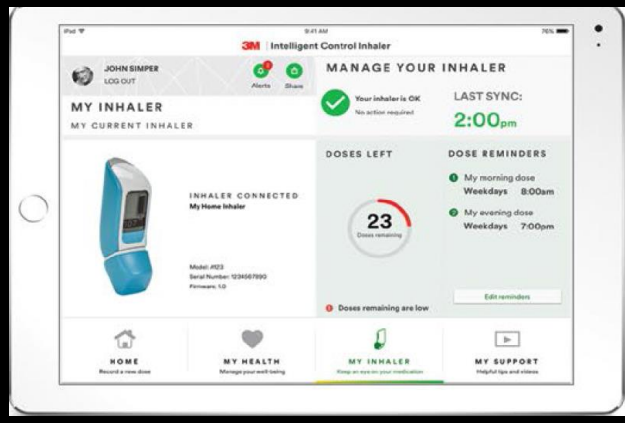
- Indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis confirmed by positive allergy testing
- Dose one tablet sublingual daily
- Start 12 weeks prior to season
- Ages 18 - 65
- Do not use in severe or uncontrolled asthma

Short Ragweed Pollen Extract Ragwitek®

- Side Effects
  - Throat irritation
  - Ear itching
  - Oral itching
  - Mouth tingling
  - Mouth edema
- Stop taking if throat tightness or swelling, trouble breathing, trouble swallowing, dizziness, rapid heart rate, severe stomach problems
- Possibility of systemic (anaphylactic) reaction (lower risk than immunotherapy injections)
- Offer an EpiPen for home use

Asthma & Allergy Pipeline

- SLIT – Dust mite or cat allergy
- Generic version of Advair – may be up to 8 generic versions in the pipeline, all using different devices
- 3M's Intelligent Control Inhaler (2016) – provides data on inspiratory flow, integrated patient instructions, profiles to help monitor disease progression



- Novartis' Breezhaler digital inhaler device integrated with smart phone
- Generic albuterol – expected by end of 2017
- New biologics: Anti-IgE antibodies, Anti-IL-13 antibodies and Anti-IL-13/Anti-IL-4 receptor antibodies – show real promise
- Triple therapy – ICS/LABA/LAMA

What is Success: How do we measure it and how do we get there?

- Begin therapy based on *Severity*
- Monitor and adjust therapy based on *Control* and *Risk* and *Responsiveness to Therapy*
- Use routine standardized multifaceted measures
- The goal of therapy is to achieve control
- Individualize therapy based on likelihood of response and patient needs, desires and goals

Questions?

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- **Download the NIH Guidelines at:**
  - http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf

- **Download the GINA Guidelines at:**
  - http://ginasthma.org/