EPR-4 vs GINA-Asthma Care Differences, Overlap & Challenges in 2021
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February 10, 2021

OUR SPEAKER

Dr. Bradley Chipps
• Medical Director of Allergy & Respiratory Disease Center
LEARNING OBJECTIVES

- Understand 2020 Focused Updates to the NHLBI Asthma Management Guidelines

- Compare & Contrast NHLBI Update to GINA 2020

- Ensure patients, providers and policymakers understand and reflect the latest scientific evidence in treatment decisions

EPR-4: Focused Updates - Not Complete Revision of 2007 Guidelines

Intended to improve asthma management and support informed, shared decision making between patients and their providers.

Offer new guidance in six key areas of asthma diagnosis, management and treatment, selected through a comprehensive literature review, consultation with experts and soliciting comments from the public.

Updates offers 19 recommendations and include new features to help clinicians engage with patients.

Used GRADE Methodology

Evidence to Decision Tables determined direction (for or against intervention) and strength (strong or conditional)
Intermittent Inhaled Corticosteroids
Long-Acting Muscarinic Antagonists
Indoor Allergen Mitigation
Immunotherapy in the Treatment of Allergic Asthma
Fractional Exhaled Nitric Oxide Testing
Bronchial Thermoplasty

Intermittent Use of ICS
For children ages 0-4 with recurrent wheeze triggered by respiratory infections only and no wheezing between infections, the Expert Panel conditionally recommends

A short course of daily ICS at the onset of a respiratory tract infection

With an inhaled short-acting beta2-agonist (SABA) as needed for quick-relief therapy

(Conditional recommendation, high certainty)
Interruption ICS in Individuals 12 years & older

For individuals with mild persistent asthma, either of the following two treatments are recommended as part of Step 2 therapy:

- A daily low-dose ICS and as needed SABA for quick-relief therapy, or
- Intermittent as-needed ICS and SABA used one after the other for worsening asthma.
- (Conditional, moderate certainty)

Individuals with Persistent Asthma

Ages 4 & older
- 4 years or older with moderate to severe persistent asthma, preferred treatment is a single inhaler with ICS-formoterol (referred to as single maintenance and reliever therapy, “SMART”) used both daily and as-needed.
- (Strong, high certainty for ages >12 years, moderate certainty for ages 4-11 years)

Ages 12 & older
- 12 years or older with moderate to severe persistent asthma, preferred treatment with a single inhaler with ICS-formoterol (SMART therapy) used both daily and as-needed to daily higher dose ICS-LABA combination with as-needed SABA.
- (Conditional, high certainty)
Expert Panel: No Short-Term Increase in ICS

**Ages 4 & older**
- For children ages 4 years or older and adults with mild to moderate persistent asthma who are likely to be adherent to daily ICS treatment, the Expert Panel conditionally recommends against a short-term increase in the ICS dose for increased symptoms or decreased peak flow.
- (Conditional, low certainty)

LAMA Recommendations

**Ages 12 & older**
- In individuals >12 years of age with asthma not controlled by ICS therapy alone, *adding a LABA rather than a LAMA* to an ICS is recommended. (Conditional, moderate certainty)
- If a LABA cannot be used, *adding a LAMA to an ICS is acceptable alternative*. (Conditional, moderate certainty)
- If asthma is not controlled with ICS-LABA, *adding a LAMA* is recommended for many people because it offers a small potential benefit.
- (Conditional, moderate certainty)
**Allergen Mitigation Recommendations**

- For individuals with asthma with no history of exposure and **no allergies (IgE or sensitization) or symptoms after exposure** to indoor allergens, environmental interventions in the home are not recommended. (Conditional, low certainty)
- For individuals with asthma who are exposed and allergic to a specific indoor substance using **multiple strategies to reduce the allergen is recommended**—using only one strategy often does not improve asthma outcomes. (Conditional, low certainty)
- For individuals with asthma who are sensitive to dust mites, **impermeable pillow/mattress covers are recommended only as a part of a multicomponent intervention.** (Conditional, moderate certainty)
- **Integrated pest management** in the home is recommended for individuals with asthma who are allergic and exposed to cockroaches, mice or rats. (Conditional, low certainty)

**Immunotherapy Recommendations**

**Immunotherapy** (aka allergy shots) are **recommended as an adjunct treatment to standard pharmacotherapy for individuals with mild-moderate allergic asthma** who have demonstrated allergic sensitization and evidence of worsening asthma symptoms after exposure to relevant antigen(s). (Conditional, moderate certainty)

Evidence reviewed **did not support** using sublingual immunotherapy to specifically treat allergic asthma. (Conditional, moderate certainty)
**FeNO Recommendations: Ages 5 Years & Older**

**FeNO Measurement** may support a diagnosis of asthma in individuals for whom the diagnosis is uncertain even after a complete history, physical examination and spirometry testing including bronchodilator responsiveness. (Conditional, moderate certainty)

**May be used as part of ongoing asthma monitoring and management** when there is uncertainty in adjusting therapy using clinical and laboratory assessment. (Conditional, low certainty)

**FeNO Recommendations: Ages 5 Years & Older**

**Should not be used in isolation** to assess asthma control, predict a future asthma exacerbation or assess the severity of an exacerbation. (Strong, low certainty)

In children ages 4 years and younger who have recurrent episodes of wheezing, FeNO measurement does not predict the future development of asthma. (Strong, low certainty)
Bronchial Thermoplasty Recommendations

Most individuals 18 years and older with uncontrolled asthma

- Should not undergo bronchial thermoplasty because benefits are small, risks are moderate, and long-term outcomes are uncertain. (Conditional, low certainty)

Some individuals with persistent asthma

- May be willing to accept the risks of bronchial thermoplasty and, therefore, might choose intervention after shared decision making with their healthcare provider. (Strong, low certainty)
Patient/Caregiver Resources

Downloadable fact sheets

nhlbi.nih.gov/BreatheBetter

Patient/Caregiver Resources

Educational videos

Social media
For More Information

NHLBI Asthma Guidelines Info:
https://www.nhlbi.nih.gov/asthmaguidelines

JACI December 3 Issue:
https://www.jacionline.org/article/S0091-6749(20)31404-4/fulltext

Global Initiative for Asthma (GINA)
What’s new in GINA 2020?

GINA Global Strategy for Asthma Management and Prevention

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A reminder – the key change in GINA 2019

GINA 2019: a fundamental change in asthma management

Treatment of asthma with short-acting bronchodilators alone is no longer recommended for adults and adolescents


Background to changes in 2019 - the risks of ‘mild’ asthma

- Patients with apparently mild asthma are at risk of serious adverse events
  - 30–37% of adults with acute asthma
  - 16% of patients with near-fatal asthma
  - 15–20% of adults dying of asthma

- Exacerbation triggers are variable (viruses, pollens, pollution, poor adherence)

- Inhaled SABA has been first-line treatment for asthma for 50 years
  - This dates from an era when asthma was thought to be a disease of bronchoconstriction
  - Patient satisfaction with, and reliance on, SABA treatment is reinforced by its rapid relief of symptoms, its prominence in ED and hospital management of exacerbations, and low cost
  - Patients commonly believe that “My reliever gives me control over my asthma”, so they often don’t see the need for additional treatment

had symptoms less than weekly in previous 3 months (Dusser, Allergy 2007)
Assessment of symptom control

- Frequency of SABA use is included in symptom control assessment
  - Higher SABA use is associated with worse outcomes, even in patients taking ICS

<table>
<thead>
<tr>
<th>In the past 4 weeks, has the patient had:</th>
<th>Well controlled</th>
<th>Partly controlled</th>
<th>Uncontrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Daytime asthma symptoms more than twice/week?</td>
<td>Yes □ No □</td>
<td>None of these</td>
<td>3–4</td>
</tr>
<tr>
<td>• Any night waking due to asthma?</td>
<td>Yes □ No □</td>
<td>1–2 of these</td>
<td></td>
</tr>
<tr>
<td>• Releveve SABA for symptoms more than twice/week?</td>
<td>Yes □ No □</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Any activity limitation due to asthma?</td>
<td>Yes □ No □</td>
<td></td>
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</tbody>
</table>

- Our current view is that frequency of ICS-formoterol use should not be included in symptom control assessment, particularly in patients not taking maintenance ICS
  - The as-needed ICS-formoterol is providing the patient’s controller therapy
  - Further data awaited: this issue will be reviewed again next year

Adverse effects with montelukast

- FDA boxed warning in March 2020 about risk of serious neuropsychiatric events, including suicidality, with montelukast
  - Includes suicidality in adults and adolescents
  - Nightmares and behavioral problems in children
- Before prescribing montelukast, health professionals should consider its benefits and risks, and patients should be counselled about the risk of neuropsychiatric events

FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis

Risks may include suicidal thoughts or actions
Difficult-to-treat and severe asthma

- Pocket guide v2.0 published April 2019
  - A practical guide for primary and specialist care
  - Includes a decision tree about assessment and management of adults and adolescents with uncontrolled asthma or exacerbations despite Step 4-5 treatment
  - Includes strategies for clinical settings in which biologic therapy is not available or affordable
- Content also included in full GINA 2020 report
- Aim is to produce a similar pocket guide for children in 2020
Patients with features of asthma and COPD

**Initial Pharmacological Treatment** (as well as treating comorbidities and risk factors. See Box 3-5A)

- **ICS-CONTAINING TREATMENT IS ESSENTIAL**
  - to reduce risk of severe exacerbations and death. (See Box 3-5A)
  - As-needed low dose ICS/long-acting beta-agonist (LABA) in asthmatics may be used as reliever. See Box 3-5A
  - DO NOT GIVE LABA and/or LAMA without ICS
  - Avoid maintenance LABA or LAMA

**TREAT AS COPD (see GOLD report)**
- Initially LABA and/or LAMA
- Add ICS as per GOLD for patients with frequent exacerbations requiring OCS, or blood eosinophils >300/μL
- Avoid high dose ICS, avoid maintenance OCS
- Reliever containing ICS is not recommended

**Box 3-5A**

**Adults & adolescents 12+ years**

Personalized asthma management:
- Assess, Adjust, Review response

**Asthma medication options:**
- Adjust treatment up and down for individual patient needs

**Preferred Controller**
- to prevent exacerbations and control symptoms

**Other controller options**

**Preferred Reliever**
- As-needed low dose ICS-formoterol *
- As-needed low dose ICS-formoterol for patients prescribed maintenance and reliever therapy

**Step 2**
- Daily low dose inhaled corticosteroid (ICS), or as-needed low dose ICS-formoterol *

**Step 3**
- Low dose ICS-LABA
- Medium dose ICS, or low dose ICS-LABA
- High dose ICS, add-on LABA, or add-on LTRA *

**Confirmation of diagnosis if necessary**
- Symptom control & modifiable risk factors (including lung function)
- Comorbidities
- Inhaler technique & adherence
- Patient preferences and goals

**ICS-formoterol** is the preferred reliever for patients prescribed maintenance and reliever therapy. For other ICS-LABAs, the reliever is SABA

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GINA 2020, Box 3-5A
Box 3-5B
Children 6-11 years

Personalized asthma management:
Assess, Adjust, Review response

Symptoms
Exacerbations
Side-effects
Lung function
Child and parent satisfaction

Confirmation of diagnosis if necessary
Symptom control & modifiable risk factors (including long function)
Comorbidities
Inhaler technique & adherence
Child and parent preferences and goals

Treatment of modifiable risk factors & comorbidities
Non-pharmacological strategies
Asthma medications (adjust down or up)
Education & skills training

Asthma medication options:
Adjust treatment up and down for individual child’s needs

**PREFERRED CONTROLLER**
to prevent exacerbations and control symptoms

Other controller options

**RELIEVER**
As-needed short-acting β₂-agonist (SABA)

GINA 2020, Box 3-5B © Global Initiative for Asthma, www.ginasthma.org

SUGGESTED INITIAL CONTROLLER TREATMENT IN ADULTS AND ADOLESCENTS WITH A DIAGNOSIS OF ASTHMA

**ASSESS:**
Confirmation of diagnosis
Symptom control & modifiable risk factors (including long function)
Comorbidities
Inhaler technique & adherence
Patient preferences and goals

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

**PREFERRED CONTROLLER**
to prevent exacerbations and control symptoms

Other controller options

**PREFERRED RELIEVER**
As-needed low dose ICS-formoterol *
As-needed low dose ICS-formoterol for patients prescribed maintenance and reliever therapy2

As-needed short-acting β₂-agonist (SABA)

GINA 2020, Box 3-4A © Global Initiative for Asthma, www.ginasthma.org
COVID-19 and asthma *(as at April 3, 2020)*

Advise patients with asthma to continue taking their prescribed asthma medications, particularly *inhaled corticosteroids* (ICS), and oral corticosteroids (OCS) if prescribed

- Asthma medications should be continued as usual. Stopping ICS often leads to potentially dangerous worsening of asthma
- For patients with severe asthma: continue biologic therapy, and do not suddenly stop OCS if prescribed

Make sure that all patients have a *written asthma action plan* with instructions about:

- Increasing controller and reliever medication when asthma worsens
- Taking a short course of OCS for severe asthma exacerbations
- When to seek medical help
- See the GINA 2020 report for more information about treatment options for asthma action plans.

**Avoid nebulizers where possible**

- Nebulizers increase the risk of disseminating virus to other patients AND to health care professionals
- Pressurized metered dose inhaler via a spacer is the preferred treatment during severe exacerbations, with a mouthpiece or tightly fitting face mask if required
COVID-19 and asthma *(as at March 30, 2020)*

**Avoid spirometry** in patients with confirmed/suspected COVID-19

- Spirometry can disseminate viral particles and expose staff and patients to risk of infection
- While community transmission of the virus is occurring in your region, postpone spirometry and peak flow measurement within health care facilities unless there is an urgent need
- Follow contact and droplet precautions

**Follow strict infection control procedures** if aerosol-generating procedures are needed

- For example: nebulization, oxygen therapy (including with nasal prongs), sputum induction, manual ventilation, non-invasive ventilation and intubation

**Follow local health advice** about hygiene strategies and use of personal protective equipment, as new information becomes available in your country or region

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**Other resources for COVID-19** *(as at March 30, 2020)*

**Information for health professionals**

- World Health Organization (WHO) recommendations for infection control
- Centers for Disease Control and Prevention (CDC)

**Information for patients**


**Information for health systems**


Follow local health advice about hygiene strategies and use of personal protective equipment as new information becomes available in your country or region.
Other changes in GINA 2020

<table>
<thead>
<tr>
<th>Acute asthma</th>
<th>Role of trained lay health workers in asthma education has been emphasized</th>
<th>Factors contributing to development of asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td>References to ‘high flow oxygen’ have been corrected to ‘high concentration oxygen’</td>
<td>Improved outcomes compared with usual care including increased symptom-free days, reduced healthcare utilization, improved adherence, inhaler technique, symptom control and quality of life</td>
<td>Obesity may be a risk factor for developing asthma (Deng et al, Pediatr Obes 2019), but not vice versa (Xu et al, Int J Epidemiol 2019)</td>
</tr>
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<td>13% of global asthma incidence in children may be attributable to traffic-related air pollution (Achakulwisut et al, Lancet Plan Health 2019)</td>
</tr>
</tbody>
</table>

Key Takeaways

NHLBI EPR-4 Update only covers 6 key topic areas and is based on data prior to 2016

GINA 2020 Update is comprehensive and reflects data prior to 2020
Key Takeaways

1. **Step 1 Change**—No SABA only---SMART approach
2. **Step 5 Change**—OCS is last resort
3. Asthma COPD Overlap addressed

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COVID 19 addressed

Shared Decision Making is key in both guidelines
TIME FOR QUESTIONS

Record your questions in the question box
We’ll get to as many as we can!

JOIN US FOR OUR NEXT WEBINAR

• COVID-19: New Approaches to Prevention & Treatment for Allergy & Asthma Patients
  • February 17th
  • 4:00 PM ET
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