Global Initiative for Asthma (GINA)

What’s new in GINA 2016?

GINA Global Strategy for Asthma Management and Prevention

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GINA: A Brief History

- Established in 1993
- Collaboration between NHLBI and WHO
- Multiple updates since 1993
- Meetings to discuss changes twice yearly
- Latest revision 2016
GINA: Objectives

- Increase awareness of asthma and its public health consequences
- Promote identification of reasons for increased prevalence of asthma
- Promote study of asthma
- Reduce asthma morbidity and mortality
- Improve management of asthma
- Improve availability and accessibility of effective asthma therapy
Not a guideline, but a practical approach to managing asthma in clinical practice

A global strategy, relevant to both low and high resource countries

Evidence-based and clinically-oriented

Provides clinical tools and measurable outcomes
Assessing asthma severity

How?
- Asthma severity is assessed retrospectively from the level of treatment required to control symptoms and exacerbations

When?
- Assess asthma severity after patient has been on controller treatment for several months
- Severity is not static – it may change over months or years, or as different treatments become available

Categories of asthma severity
- **Mild asthma**: well-controlled with Steps 1 or 2 (as-needed SABA or low dose ICS)
- **Moderate asthma**: well-controlled with Step 3 (low-dose ICS/LABA)
- **Severe asthma**: requires Step 4/5 (moderate or high dose ICS/LABA ± add-on), or remains uncontrolled despite this treatment
The long-term goals of asthma management are:

1. **Symptom control**: to achieve good control of symptoms and maintain normal activity levels.
2. **Risk reduction**: to minimize future risk of exacerbations, fixed airflow limitation and medication side-effects.
3. *Note: no mention of lung function here; use for diagnosis.*

Achieving these goals requires a partnership between patient and their health care providers:
- Ask the patient about their own goals regarding their asthma.
- Good communication strategies are essential.
- Consider the health care system, medication availability, cultural and personal preferences and health literacy.
Establish a patient-doctor partnership

Manage asthma in a continuous cycle:

- **Assess**
- **Adjust** treatment (pharmacological and non-pharmacological)
- **Review** the response

Teach and reinforce essential skills

- Inhaler skills
- Adherence
- Guided self-management education
  - Written asthma action plan
  - Self-monitoring
  - Regular medical review
The control-based asthma management cycle

- Symptoms
- Exacerbations
- Side-effects
- Patient satisfaction
- Lung function

**ASSESS**
- Diagnosis
- Symptom control & risk factors (including lung function)
- Inhaler technique & adherence
- Patient preference

**REVIEW RESPONSE**

**ADJUST TREATMENT**
- Asthma medications
- Non-pharmacological strategies
- Treat modifiable risk factors
Stepwise management - pharmacotherapy

Diagnosis
- Symptom control & risk factors (including lung function)
- Inhaler technique & adherence
- Patient preference

Asthma medications
- Non-pharmacological strategies
- Treat modifiable risk factors

Symptoms
- Exacerbations
- Side-effects
- Patient satisfaction
- Lung function

REVIEW RESPONSE

ADJUST TREATMENT

GSTA 2016, Box 3-5 (2/8) (upper part)

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**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 treatment for adults and adolescents

- **Step 3**
  - Low-dose **fluticasone furoate/vilanterol** an option for Step 3

- **Step 4**
  - **Tiotropium** now an add-on option for adolescents (age ≥12 years) as well as adults, with a history of exacerbations

- **Step 5**: refer for expert investigation and add-on treatment, such as:
  - *Add-on tiotropium* by mist inhaler for patients age ≥12 years with a history of exacerbations
  - *Add-on omalizumab* (anti-IgE) for severe allergic asthma
  - *Add-on mepolizumab* (anti-IL5) for severe eosinophilic asthma (≥12 years)
  - *Sputum-guided treatment*, if available

- **Low, medium and high ICS doses**
  - **Fluticasone furoate**: 100mcg (low dose); 200mcg (high dose)

- **Stepping down ICS** when asthma well-controlled now Evidence A
  - *(Hagan et al, Allergy 2014)*
Step 1 – as-needed inhaled short-acting beta$_2$-agonist (SABA)

**PREFERRED CONTROLLER CHOICE**

**STEP 1**
- As-needed short-acting beta$_2$-agonist (SABA)
- Consider low dose ICS

**STEP 2**
- Low dose ICS
- Leukotriene receptor antagonists (LTRA)
- Low dose theophylline*

**STEP 3**
- Low dose ICS/LABA**
- Med/high dose ICS/LABA
- Add tiotropium*†
- Add low dose OCS

**STEP 4**
- Refer for add-on treatment e.g., tiotropium,*† omalizumab, mepolizumab*
- High dose ICS + LTRA (or + theoph*)
- Add low dose OCS

**STEP 5**
- Add tiotropium*
- Refer for add-on treatment e.g., tiotropium,† omalizumab, mepolizumab*
- High dose ICS + LTRA (or + theoph*)

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*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

GINA 2016, Box 3-5, Step 1 (4/8) © Global Initiative for Asthma
Step 1 – as-needed reliever inhaler

- Preferred option: as-needed inhaled short-acting beta$_2$-agonist (SABA)
  - SABAs are highly effective for relief of asthma symptoms
  - However … there is insufficient evidence about the safety of treating asthma with SABA alone
  - This option should be reserved for patients with infrequent symptoms (less than twice a month) of short duration, and with no risk factors for exacerbations

- Other options
  - Consider adding regular low dose inhaled corticosteroid (ICS) for patients at risk of exacerbations
Step 2 – low-dose controller + as-needed inhaled SABA

**PREFERRED CONTROLLER CHOICE**

**STEP 1**
- Consider low dose ICS

**STEP 2**
- Low dose ICS
- Leukotriene receptor antagonists (LTRA)
- Low dose theophylline*

**STEP 3**
- Med/high dose ICS/LABA**
- Med/high dose ICS
- Low dose ICS+LTRA (or + theoph*)

**STEP 4**
- Add tiotropium**†
- High dose ICS + LTRA (or + theoph*)
- Add low dose OCS

**STEP 5**
- Refer for add-on treatment e.g. tiotropium,† omalizumab, mepolizumab*

**RELEIVER**

- As-needed short-acting beta₂-agonist (SABA)
- As-needed SABA or low dose ICS/formoterol#

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#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
Step 2 – Low dose controller + as-needed SABA

- Preferred option: regular low dose ICS with as-needed inhaled SABA
  - Low dose ICS reduces symptoms and reduces risk of exacerbations and asthma-related hospitalization and death

- Other options
  - Leukotriene receptor antagonists (LTRA) with as-needed SABA
    • Less effective than low dose ICS
    • May be used for some patients with both asthma and allergic rhinitis, or if patient will not use ICS
  - Combination low dose ICS/long-acting beta\(_2\)-agonist (LABA) with as-needed SABA
    • Reduces symptoms and increases lung function compared with ICS
    • More expensive, and does not further reduce exacerbations
  - Intermittent ICS with as-needed SABA for purely seasonal allergic asthma with no interval symptoms
    • Start ICS immediately symptoms commence, and continue for 4 weeks after pollen season ends
Step 3 – one or two controllers + as-needed inhaled reliever

**PREFERRED CONTROLLER CHOICE**

**STEP 1**
- Low dose ICS
  - Consider low dose ICS

**STEP 2**
- Low dose ICS
  - Leukotriene receptor antagonists (LTRA)
  - Low dose theophylline*

**STEP 3**
- Med/high dose ICS/LABA
  - Med/high dose ICS
  - Low dose ICS/LABA**
  - As-needed SABA or low dose ICS/formoterol#

**STEP 4**
- Add tiotropium**†
  - High dose ICS + LTRA (or + theoph*)
  - Add low dose OCS

**STEP 5**
- Refer for add-on treatment e.g. tiotropium,*
- omalizumab,*
- mepolizumab*

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**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

GINA 2016, Box 3-5, Step 3 (6/8) © Global Initiative for Asthma
Step 3 – one or two controllers + as-needed inhaled reliever

- Before considering step-up
  - Check inhaler technique and adherence, confirm diagnosis

- Adults/adolescents: preferred options are either combination low dose ICS/LABA maintenance with as-needed SABA, OR combination low dose ICS/formoterol maintenance and reliever regimen*
  - Adding LABA reduces symptoms and exacerbations and increases FEV$_1$, while allowing lower dose of ICS
  - In at-risk patients, maintenance and reliever regimen significantly reduces exacerbations with similar level of symptom control and lower ICS doses compared with other regimens

- Children 6-11 years: preferred option is medium dose ICS with as-needed SABA

- Other options
  - Adults/adolescents: Increase ICS dose or add LTRA or theophylline (less effective than ICS/LABA)
  - Children 6-11 years – add LABA (similar effect as increasing ICS)

*Approved only for low dose beclometasone/formoterol and low dose budesonide/formoterol
Step 4 – two or more controllers + as-needed inhaled reliever

- **STEP 1**
  - Low dose ICS
  - Consider low dose ICS

- **STEP 2**
  - Leukotriene receptor antagonists (LTRA)
  - Low dose theophylline*

- **STEP 3**
  - Low dose ICS/LABA**
  - Med/high dose ICS/LABA
  - Med/high dose ICS
  - Add levalbuterol (or theoph*)
  - Add tiotropium**†

- **STEP 4**
  - As-needed SABA or low dose ICS/formoterol#
  - High dose ICS + LTRA (or + theoph*)
  - Add low dose OCS

- **STEP 5**
  - Refer for add-on treatment e.g. tiotropium,† omalizumab, mepolizumab*

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**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

GINA 2016, Box 3-5, Step 4 (7/8) © Global Initiative for Asthma
Before considering step-up
  ▪ Check inhaler technique and adherence

Adults or adolescents: preferred option is combination low dose ICS/formoterol as maintenance and reliever regimen*, OR combination medium dose ICS/LABA with as-needed SABA

Children 6–11 years: preferred option is to refer for expert advice

Other options (adults or adolescents)
  ▪ Tiotropium by mist inhaler may be used as add-on therapy for patients aged ≥12 years with a history of exacerbations
  ▪ Trial of high dose combination ICS/LABA, but little extra benefit and increased risk of side-effects
  ▪ Increase dosing frequency (for budesonide-containing inhalers)
  ▪ Add-on LTRA or low dose theophylline

*Approved only for low dose beclometasone/formoterol and low dose budesonide/formoterol
Step 5 – higher level care and/or add-on treatment

**PREFERRED CONTROLLER CHOICE**

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- Consider low dose ICS

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- Med/high dose ICS + LTRA (or + theoph*)
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**STEP 5**
- Refer for add-on treatment e.g. tiotropium,*omalizumab, mepolizumab*

**RELIEVER**

- As-needed short-acting beta\(_2\)-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
Step 5 – higher level care and/or add-on treatment

Preferred option is referral for specialist investigation and consideration of add-on treatment

- If symptoms uncontrolled or exacerbations persist despite Step 4 treatment, check inhaler technique and adherence before referring
- Add-on tiotropium for patients ≥12 years with history of exacerbations
- Add-on omalizumab (anti-IgE) for patients with severe allergic asthma
- Add-on mepolizumab (anti-IL5) for severe eosinophilic asthma (≥12 yrs)

Other add-on treatment options at Step 5 include:

- Sputum-guided treatment: available in specialized centers; reduces exacerbations and/or corticosteroid dose
- Add-on low dose oral corticosteroids (≤7.5mg/day prednisone equivalent): this may benefit some patients, but has significant systemic side-effects. Assess and monitor for osteoporosis
- See ERS/ATS Severe Asthma Guidelines (Chung et al, ERJ 2014) for more detail
Low, medium and high dose inhaled corticosteroids

Adults and adolescents (≥12 years)

- This is not a table of equivalence, but of estimated clinical comparability
- Most of the clinical benefit from ICS is seen at low doses
- High doses are arbitrary, but for most ICS are those that, with prolonged use, are associated with increased risk of systemic side-effects

<table>
<thead>
<tr>
<th>Inhaled corticosteroid</th>
<th>Total daily dose (mcg)</th>
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<td>Low</td>
</tr>
<tr>
<td>Beclometasone dipropionate (CFC)</td>
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<tr>
<td>Beclometasone dipropionate (HFA)</td>
<td>100–200</td>
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<tr>
<td>Budesonide (DPI)</td>
<td>200–400</td>
</tr>
<tr>
<td>Ciclesonide (HFA)</td>
<td>80–160</td>
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<tr>
<td>Fluticasone furoate (DPI)</td>
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<tr>
<td>Fluticasone propionate (DPI or HFA)</td>
<td>100–250</td>
</tr>
<tr>
<td>Mometasone furoate</td>
<td>110–220</td>
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<tr>
<td>Triamcinolone acetonide</td>
<td>400–1000</td>
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## Low, medium and high dose inhaled corticosteroids

**Children 6–11 years**

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Reviewing response and adjusting treatment

How often should asthma be reviewed?

- 1-3 months after treatment started, then every 3-12 months
- During pregnancy, every 4-6 weeks
- After an exacerbation, within 1 week

Stepping up asthma treatment

- **Sustained step-up**, for at least 2-3 months if asthma poorly controlled
  - Important: first check for common causes (symptoms not due to asthma, incorrect inhaler technique, poor adherence)
- **Short-term step-up**, for 1-2 weeks, e.g. with viral infection or allergen
  - May be initiated by patient with written asthma action plan
- **Day-to-day adjustment**
  - For patients prescribed low-dose ICS/formoterol maintenance and reliever regimen*

Stepping down asthma treatment

- Consider step-down after good control maintained for 3 months
- Find each patient’s minimum effective dose, that controls both symptoms and exacerbations

*Approved only for low dose beclometasone/formoterol and low dose budesonide/formoterol
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 2016 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)*
Treating modifiable risk factors

■ Provide skills and support for guided asthma self-management
  ▪ This comprises self-monitoring of symptoms and/or PEF, a written asthma action plan and regular medical review

■ Prescribe medications or regimen that minimize exacerbations
  ▪ ICS-containing controller medications reduce risk of exacerbations
  ▪ For patients with ≥1 exacerbations in previous year, consider low-dose ICS/formoterol maintenance and reliever regimen*

■ Encourage avoidance of tobacco smoke (active or ETS)
  ▪ Provide smoking cessation advice and resources at every visit

■ For patients with severe asthma
  ▪ Refer to a specialist center, if available, for consideration of add-on medications and/or sputum-guided treatment

■ For patients with confirmed food allergy:
  ▪ Appropriate food avoidance
  ▪ Ensure availability of injectable epinephrine for anaphylaxis

*Approved only for low dose beclometasone/formoterol and low dose budesonide/formoterol
Non-pharmacological interventions

- Avoidance of tobacco smoke exposure
  - Provide advice and resources at every visit; advise against exposure of children to environmental tobacco smoke (house, car)

- Physical activity
  - Encouraged because of its general health benefits. Provide advice about exercise-induced bronchoconstriction

- Occupational asthma
  - Ask patients with adult-onset asthma about work history. Remove sensitizers as soon as possible. Refer for expert advice, if available

- Avoid medications that may worsen asthma
  - Always ask about asthma before prescribing NSAIDs or beta-blockers

- Remediation of dampness or mold in homes
  - Reduces asthma symptoms and medication use in adults

- (Allergen avoidance)
  - (Not recommended as a general strategy for asthma)

This slide shows examples of interventions with high quality evidence.
Indications for considering referral, where available

- **Difficulty confirming the diagnosis of asthma**
  - Symptoms suggesting chronic infection, cardiac disease, etc
  - Diagnosis unclear even after a trial of treatment
  - Features of both asthma and COPD, if in doubt about treatment

- **Suspected occupational asthma**
  - Refer for confirmatory testing, identification of sensitizing agent, advice about eliminating exposure, pharmacological treatment

- **Persistent uncontrolled asthma or frequent exacerbations**
  - Uncontrolled symptoms or ongoing exacerbations or low FEV$_1$ despite correct inhaler technique and good adherence with Step 4
  - Frequent asthma-related health care visits

- **Risk factors for asthma-related death**
  - Near-fatal exacerbation in past
  - Anaphylaxis or confirmed food allergy with asthma
Indications for considering referral, where available

- Significant side-effects (or risk of side-effects)
  - Significant systemic side-effects
  - Need for oral corticosteroids long-term or as frequent courses

- Symptoms suggesting complications or sub-types of asthma
  - Nasal polyposis and reactions to NSAIDS (may be aspirin exacerbated respiratory disease)
  - Chronic sputum production, fleeting shadows on CXR (may be allergic bronchopulmonary aspergillosis)

- Additional reasons for referral in children 6-11 years
  - Doubts about diagnosis, e.g. symptoms since birth
  - Symptoms or exacerbations remain uncontrolled
  - Suspected side-effects of treatment, e.g. growth delay
  - Asthma with confirmed food allergy
Management of asthma in low-resource settings

- **Where?**
  - Low-resource settings may be found not only in low and middle income countries (LMIC), but also in affluent nations

- **Diagnosis in low-resource settings**
  - Up to 50% asthma undiagnosed, up to 34% over-diagnosed (*José 2014*)
  - Ask about symptoms suggestive of chronic respiratory infections e.g. TB
  - Peak flow meters recommended by WHO as essential tools for Package of Essential Non-communicable Diseases Interventions (WHO-PEN)

- **Management of asthma in low-resource settings**
  - GINA strategy for stepwise treatment includes options for low-resource settings
  - Prioritize the most cost-effective approach; include ICS and SABA
  - Build capacity of primary health care teams, including nurses and pharmacist
  - WHO-PEN recommends inclusion of peak flow meters as essential tools, and oximeters if resources permit

*What’s new in GINA 2016*
Maternal diet in pregnancy
- No firm evidence that ingestion of any specific foods in pregnancy increases risk for asthma
- Instead, maternal intake of foods commonly considered allergenic (peanut, milk) is associated with a decrease in allergy and asthma in offspring *(Bunyavanich et al, JACI 2014; Maslova et al, JACI 2012, 2013)*
- Therefore, no dietary changes are recommended during pregnancy for prevention of allergies or asthma

Maternal obesity in pregnancy
- Maternal obesity and maternal weight gain in pregnancy are associated with an increased risk for asthma in children *(Forno et al, Pediatrics 2014)*
- However, no recommendations can be made at present, as unguided weight loss in pregnancy should not be encouraged

Dampness and mold
- For children at risk of asthma, dampness, visible mold and mold odor in the home are associated with increased risk of developing asthma *(Quansah et al, PLoS ONE 2012)*
Non-pharmacological strategies for people with asthma

- Remediation of dampness or mold in homes reduces asthma symptoms and medication use in adults (Evidence A) *(Sauni et al, Cochrane 2015)*

Other therapies

- In randomized controlled trials, Vitamin D supplementation has not been associated with improvement in asthma symptom control or reduction in exacerbations
  - This statement was included in the GINA report because there had been wide expectation from cross-sectional studies that Vitamin D supplementation would be beneficial for asthma control
  - Sections on allergen immunotherapy, vaccinations and bronchial thermoplasty have been included in the main report (previously only in Appendix)

Methodology

- More details provided about GINA methodology, including the number of articles identified at each step
Management of severe asthma

- Optimize dose of ICS/LABA
  - Complete resistance to ICS is rare
  - Consider therapeutic trial of higher dose
- Consider low dose maintenance oral corticosteroids
  - Monitor for and manage side-effects, including osteoporosis
- Add-on treatments without phenotyping
  - Tiotropium - reduces exacerbations (history of exacerbations, age ≥12 years)
  - Theophylline, LTRA – limited benefit
- Phenotype-guided treatment
  - Severe allergic asthma: add-on omalizumab (anti-IgE)
  - Severe eosinophilic asthma: add-on mepolizumab (anti-IL5)
  - Sputum-guided treatment to reduce exacerbations and/or steroid dose
  - Aspirin-exacerbated respiratory disease: consider add-on LTRA
- Non-pharmacological interventions
  - Consider bronchial thermoplasty for selected patients
  - Comprehensive adherence-promoting program
- For detailed guidelines, see Chung et al, ERJ 2014

- Longer and more detailed
- Extensive discussion of underlying pathophysiology and disease mechanisms
- Severity assessed before starting therapy
- Greater emphasis on lung function testing (spirometry) and attaining normal or near normal lung function
- Separates assessment of asthma severity from asthma control
- Severity based on 6 steps (5 for GINA); control is well controlled, not well controlled, very poorly controlled
- Medications not updated – tiotropium, biologics, new longer acting beta agonists, etc.
Questions??