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Summary of the 2020 focused updates to U.S. Asthma Management Guidelines: What has changed and what hasn't?

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Asthma is one of the most common, treatable, chronic respiratory conditions in the United States (US) and globally. Despite availability of effective treatment, the majority of pediatric and adult patients with persistent asthma have chronically uncontrolled symptoms (Center for Disease Control, 2016). This is often attributed to patient-level factors such as lack of adherence to prescribed treatment and poor self-management. However, increasing evidence indicates clinicians play a major role in national patterns of sub-optimal asthma management. In particular, it has been shown that clinicians often do not assess and manage asthma appropriately, and that lack of effective medication management (i.e., adherence to prescribing guidelines) subsequently decreases patient adherence to controller medications (Akinbami et al., 2019). Thus, improving patient outcomes requires improving asthma management by healthcare providers, including increasing familiarity with best-practice guidelines. Therefore, the purpose of this brief report is to (1) summarize key points of current guidelines for asthma management and (2) delineate important changes enacted by the recent 2020 Expert Panel Report-4 (EPR-4) updates.

The National Asthma Education and Prevention Program (NAEPP) developed the first set of U.S. asthma management guidelines in 1991. In 2007, the NAEPP Expert Panel Report-3 (EPR-3) released a comprehensive set of guidelines that summarized research-to-date and provided detailed "best practice" guidelines for clinical asthma management (National Asthma Education and Prevention Program, 2007). This included defining criteria for classification of asthma severity and control based on patterns of symptoms, medication use, exacerbation history, and spirometry, along with recommendations for selecting appropriate stepwise therapy.
Abstract

Despite availability of effective medications, the majority of pediatric and adult patients with persistent asthma have uncontrolled symptoms. This has been attributed to patient non-adherence and poor self-management, but clinicians also contribute through inaccurate assessment of asthma and lack of familiarity with best practice guidelines for medication management. Thus, improving patient outcomes will require improving clinical management by healthcare providers, including utilization of evidence-based practice guidelines. In this report, we briefly summarize key points of the national guidelines for asthma management and delineate important changes enacted by 2020 Expert Panel Report-4 updates. These include revised recommendations on the use of fractional exhaled nitric oxide testing (FeNO), indoor allergen mitigation, bronchial thermoplasty, adjunctive immunotherapy, and important modifications to medication management that are likely to have wide-spread impact on prescribing throughout the United States. In particular, for all patients ages 5 and older taking Stepwise therapy levels 3-4, it is now recommend to use single maintenance and reliever therapy (SMART), whereas use of intermittent inhaled corticosteroids (ICS) administered at the same time as short-acting beta agonist (SABA) is recommended for Step 2 to reduce symptom burden, improve control, and minimize total ICS dose.
(i.e., systematic, incremental increases in controller medication doses) corresponding with the level of severity and control (National Heart Lung and Blood Institues, 2011).

From 2007 to 2020, no further updates were published. While the Global Initiative for Asthma (GINA) released annual updates reflecting a rapidly-evolving global science of asthma management, U.S. guidelines remained static (Global Initiative for Asthma, 2020). In December 2020, the long-awaited EPR-4 released a number of selected updates to EPR-3 (National Heart Lung and Blood Institute, 2020). These are summarized below, along with core recommendations that remain unchanged from EPR-3.

Unchanged core recommendations for all ages include:

1. **Classification of asthma severity** quantitatively by frequency of daytime symptoms, nocturnal wakening, activity limitations, short-acting beta-agonist (SABA) use, exacerbations requiring oral corticosteroid (OCS) use, and FEV1%predicted;

2. **Classification of asthma control** by preceding criteria but utilizing different thresholds;

3. **Use of stepwise therapy that corresponds with level of severity and control**, with recommendation to seek expert help for all patients at Step 4 and above;

4. **Treatment of non-life-threatening asthma exacerbations** with one SABA treatment (range 2 to 6 puffs) every 20 minutes as needed based on severity, up to three times in one-hour prior to seeking emergency care, and consider short course of OCS;

5. **Emphasis on self-management training** to be provided at each asthma-related visit;

and

6. **Reevaluation of uncontrolled asthma** every 2-6 weeks until controlled and every 3-6 months thereafter.
EPR-4 changes to previous guidelines for management and treatment of asthma include modifications to several therapeutic areas (Cloutier et al., 2020).

(1) *Fractional exhaled nitric oxide testing (FeNO)* should not be used to assess severity of asthma exacerbations or to determine treatment. FeNO testing may be considered for the diagnosis of allergic asthma in conjunction with history and exam, particularly if spirometry results are unclear. FeNO may also be used as part of an ongoing management plan that includes regular FeNO testing.

(2) *Indoor allergen mitigation* (e.g., dust mite covers) is not routinely recommended, unless the patient has a history of atopic (allergic type) asthma. For those with atopic asthma, a multimodal approach to allergen mitigation should be used to increase efficacy.

(3) *Bronchial thermoplasty* (i.e., high heat directed at the bronchial walls to reduce hyperresponsiveness and bronchospasm), is no longer recommended based on procedural risk and limited evidence of efficacy.

(4) *Adjunctive subcutaneous immunotherapy (SCIT)* may be used in patients with moderate persistent atopic asthma, but should be avoided in patients with severe asthma. SCIT should not be administered during exacerbations due to increased risk of adverse events. Use of sublingual immunotherapy is not recommended, based on limited evidence of efficacy.

(5) *Changes to first-line medication management* of adults and children, will likely result in major shifts in prescribing practices across the United States.
These important changes to medication management can be briefly summarized as follows:

1. For children ages 0-4 years with recurrent wheezing, consider initiating a 7-10 day course of inhaled corticosteroids at onset of upper respiratory infection;

2. For Step 2 (mild persistent asthma), consider use of *intermittent* low-dose inhaled corticosteroids (ICS) for adults and children ages 5+ years;

3. For Steps 3 and 4 (moderate persistent asthma), use of low- to medium-dose Single Maintenance and Reliever Therapy (SMART) is strongly recommended as first-line treatment for patients ages 5 years and older;

4. For Step 5 (severe persistent asthma), in adults and children over 12 years, consider adding long-acting muscarinic agonist (LAMA) to daily ICS and LABA;

5. For patients with Type 2 allergic asthma, consider adjunct use of immunotherapy in patients with worsening symptoms following exposure to allergens.

The introduction of SMART therapy and intermittent use of inhaled corticosteroids for mild asthma are the most significant prescribing changes that have occurred with EPR-4. SMART is the use of ICS together with formoterol (LABA) for both daily (controller) and as needed (rescue), instead of SABA alone. Use of SMART has been shown to reduce exacerbation risk and improve asthma control and quality of life. For this reason, SMART has been the preferred treatment globally for several years, however is only recently being integrated into US standards of care. Similarly, *intermittent* use of ICS with LABA or SABA as needed for symptom relief in mild asthma has been shown to reduce total ICS exposure and improve symptom control, with equivalent or superior reduction in risk of acute exacerbation. Based on these changes, for patients with mild to moderate persistent asthma, it is no longer recommended
to increase the daily dose of ICS during respiratory infection; those using SMART or as needed ICS will automatically receive additional ICS with increased rescue puffs.

Currently, Formoterol is the only LABA that is recommended for use in this manner, as the evidence for these changes was derived from formoterol-based studies. For children ages 5-11 years, up to 8 total puffs of ICS with formoterol can be administered (36 mcg); for adults and children older than 12 years, up to 12 total daily puffs may be administered (54 mcg). While SMART is now the recommended first-line treatment for Steps 3 and 4, it is actually off-label use, as these combination inhalers have not yet been FDA approved for use in this manner in the United States. The lack of policy concordance poses problems for clinicians who might attempt to utilize SMART, as many insurers currently cover only a single-month supply of these expensive medications. Thus, changes to insurance coverage will likely be needed to enable wide-spread access and adherence to this new evidence-based recommendation. Additionally, individuals with inaccurate symptom perception may be poor candidates for as needed ICS.

The changes implemented by EPR-4 correspond closely with current GINA guidelines, with the exception that GINA also advocates the intermittent use of ICS with LABA for all individuals older than 12 years at both Step 1 and 2 (mild asthma) and generally discourages use of any SABA monotherapy in this population (Global Initiative for Asthma, 2020). Thus, when managing teen and adult patients with asthma, nurse practitioners should consider prescribing low dose ICS, either intermittent or daily, based on level of symptoms.

A few helpful rules can help to simplify understanding of stepwise therapy. In general, for EPR3, EPR4, and GINA guidelines, use of low dose inhaled corticosteroids are recommended for Steps 1-3, medium dose for Steps 3-4, and high dose for Step 5-6, in both adults and children. Furthermore, the addition of any LABA, LAMA, or LTRA to ICS therapy
generally increases the Stepwise therapy by one level. For example, an adult patient taking Budesonide 180 mcg, one puff twice daily, with albuterol as needed (SABA) would be classified as Step 2 (low dose ICS), whereas use of the same low dose Budesonide plus formoterol (LABA) twice daily would be classified as Step 3 therapy.

Prescribers should also be aware that ICS dosing is non-equivalent across different formulations (National Heart Lung and Blood Institues, 2011). This point cannot be over-emphasized, and mistakes in this area contribute substantially to prescribing errors. For instance, an adult daily dose of fluticasone propionate 200 mcg (100 mcg given twice daily) is low-dose (Step 2), whereas fluticasone furoate 200 mcg (given once daily) is high-dose (Step 5). For this reason, prescribers should utilize comparative dosing tables (see online e-supplement A) to ensure that appropriate doses of ICS are prescribed, consistent with best-practices. Caution should be used when making insurance driven formulary changes, as evidence indicates that these changes might precede deterioration in lung function (Bickel, Nemer Eid, & Sayat, 2019).

Lastly, minimum standards for asthma-related visits should include assessment and documentation of severity, control, stepwise therapy, and comparative ICS dosing (Box 1). Printable, clinician-friendly pocket-guides are included in the reference list for ages 5-11 years (Mammen, 2021b) and ages 12 years to adult (Mammen, 2021a) to facilitate accurate assessment and classification of asthma, and appropriate step-wise medication management.

Conclusion. Clinical management of asthma requires increasing precision in assessment and medication management. Greater familiarity with asthma management guidelines will promote delivery of high-quality evidence-based care, and will help to improve patient outcomes and quality of life.
References


### Box 1. Checklist to promote clinician compliance with U.S. National guidelines for asthma care

For all asthma related visits, assess and document:

- Asthma severity
- Asthma control (document all core criteria)*
- Stepwise therapy level
- Daily dose of ICS (intermittent, low, medium, high)
- Self-management training provided
- Follow up plan for uncontrolled asthma (2-6 weeks)

Core criteria: *frequency of day time symptoms, nocturnal wakening due to asthma, activity limitations, SABA use, systemic corticosteroid use, and FEV1/spredicted or Peak expiratory flow % of personal best if available.*