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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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2 3 Asthma is one of the most common, treatable, chronic respiratory conditions in the 4 United States (US) and globally. Despite availability of effective treatment, the majority of 5 pediatric and adult patients with persistent asthma have chronically uncontrolled symptoms 6 (Center for Disease Control, 2016). This is often attributed to patient-level factors such as lack 7 of adherence to prescribed treatment and poor self-management. However, increasing evidence 8 indicates clinicians play a major role in national patterns of sub-optimal asthma management. In 9 particular, it has been shown that clinicians often do not assess and manage asthma 10 appropriately, and that lack of effective medication management (i.e., adherence to prescribing 11 guidelines) subsequently decreases patient adherence to controller medications (Akinbami et al., 2019). Thus, improving patient outcomes requires improving asthma management by healthcare 12 13 providers, including increasing familiarity with best-practice guidelines. Therefore, the purpose 14 of this brief report is to (1) summarize key points of current guidelines for asthma management 15 and (2) delineate important changes enacted by the recent 2020 Expert Panel Report-4 (EPR-4) 16 updates.

17 The National Asthma Education and Prevention Program (NAEPP) developed the first 18 set of U.S. asthma management guidelines in 1991. In 2007, the NAEPP Expert Panel Report-3 19 (EPR-3) released a comprehensive set of guidelines that summarized research-to-date and 20 provided detailed "best practice" guidelines for clinical asthma management (National Asthma 21 Education and Prevention Program, 2007). This included defining criteria for classification of 22 asthma *severity* and *control* based on patterns of symptoms, medication use, exacerbation 23 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 nonadherence 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.

24	(i.e., systematic, incremental increases in controller medication doses) corresponding with the
25	level of severity and control (National Heart Lung and Blood Institues, 2011).
26	From 2007 to 2020, no further updates were published. While the Global Initiative for
27	Asthma (GINA) released annual updates reflecting a rapidly-evolving global science of asthma
28	management, U.S. guidelines remained static (Global Initiative for Asthma, 2020). In December
29	2020, the long-awaited EPR-4 released a number of selected updates to EPR-3 (National Heart
30	Lung and Blood Institute, 2020). These are summarized below, along with core
31	recommendations that remain unchanged from EPR-3.
32	Unchanged core recommendations for all ages include:
33	(1) <i>Classification of asthma severity</i> quantitatively by frequency of daytime symptoms,
34	nocturnal wakening, activity limitations, short-acting beta-agonist (SABA) use,
35	exacerbations requiring oral corticosteroid (OCS) use, and FEV1%predicted;
36	(2) <i>Classification of asthma control</i> by preceding criteria but utilizing different
37	thresholds;
38	(3) Use of stepwise therapy that corresponds with level of severity and control, with
39	recommendation to seek expert help for all patients at Step 4 and above;
40	(4) <i>Treatment of non-life-threatening asthma exacerbations</i> with one SABA treatment
41	(range 2 to 6 puffs) every 20 minutes as needed based on severity, up to three times in
42	one-hour prior to seeking emergency care, and consider short course of OCS;
43	(5) <i>Emphasis on self-management training</i> to be provided at each asthma-related visit;
44	and
45	(6) <i>Reevaluation of uncontrolled asthma</i> every 2-6 weeks until controlled and every 3-6
46	months thereafter.

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48	EPR-4 changes to previous guidelines for management and treatment of asthma include
49	modifications to several therapeutic areas (Cloutier et al., 2020).
50	(1) Fractional exhaled nitric oxide testing (FeNO) should not be used to assess severity
51	of asthma exacerbations or to determine treatment. FeNO testing may be considered
52	for the diagnosis of allergic asthma in conjunction with history and exam, particularly
53	if spirometry results are unclear. FeNO may also be used as part of an ongoing
54	management plan that includes regular FeNO testing.
55	(2) Indoor allergen mitigation (e.g., dust mite covers) is not routinely recommended,
56	unless the patient has a history of atopic (allergic type) asthma. For those with atopic
57	asthma, a multimodal approach to allergen mitigation should be used to increase
58	efficacy.
59	(3) Bronchial thermoplasty (i.e., high heat directed at the bronchial walls to reduce
60	hyperresponsiveness and bronchospasm), is no longer recommended based on
61	procedural risk and limited evidence of efficacy.
62	(4) Adjunctive subcutaneous immunotherapy (SCIT) may be used in patients with
63	moderate persistent atopic asthma, but should be avoided in patients with severe
64	asthma. SCIT should not be administered during exacerbations due to increased risk
65	of adverse events. Use of sublingual immunotherapy is not recommended, based on
66	limited evidence of efficacy.
67	(5) <i>Changes to first-line medication management</i> of adults and children, will likely
68	result in major shifts in prescribing practices across the United States.

69	These important changes to medication management can be briefly summarized as
70	follows:
71	(1) For children ages 0-4 years with recurrent wheezing, consider initiating a 7-10 day
72	course of inhaled corticosteroids at onset of upper respiratory infection;
73	(2) For Step 2 (mild persistent asthma), consider use of <i>intermittent</i> low-dose inhaled
74	corticosteroids (ICS) for adults and children ages 5+ years;
75	(3) For Steps 3 and 4 (moderate persistent asthma), use of low- to medium-dose Single
76	Maintenance and Reliever Therapy (SMART) is strongly recommended as first-line
77	treatment for patients ages 5 years and older;
78	(4) For Step 5 (severe persistent asthma), in adults and children over 12 years, consider
79	adding long-acting muscarinic agonist (LAMA) to daily ICS and LABA;
80	(5) For patients with Type 2 allergic asthma, consider adjunct use of immunotherapy in
81	patients with worsening symptoms following exposure to allergens.
82	The introduction of SMART therapy and intermittent use of inhaled corticosteroids for
83	mild asthma are the most significant prescribing changes that have occurred with EPR-4.
84	SMART is the use of ICS together with formoterol (LABA) for both daily (controller) and as
85	needed (rescue), instead of SABA alone. Use of SMART has been shown to reduce
86	exacerbation risk and improve asthma control and quality of life. For this reason, SMART has
87	been the preferred treatment globally for several years, however is only recently being integrated
88	into US standards of care. Similarly, intermittent use of ICS with LABA or SABA as needed for
89	symptom relief in mild asthma has been shown to reduce total ICS exposure and improve
90	symptom control, with equivalent or superior reduction in risk of acute exacerbation. Based on
91	these changes, for patients with mild to moderate persistent asthma, it is no longer recommended

92

93

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.

94 Currently, Formoterol is the only LABA that is recommended for use in this manner, as 95 the evidence for these changes was derived from formoterol-based studies. For children ages 5-96 11 years, up to 8 total puffs of ICS with formoterol can be administered (36 mcg); for adults and 97 children older than 12 years, up to 12 total daily puffs may be administered (54 mcg). While 98 SMART is now the recommended first-line treatment for Steps 3 and 4, it is actually off-label 99 use, as these combination inhalers have not yet been FDA approved for use in this manner in the 100 United States. The lack of policy concordance poses problems for clinicians who might attempt 101 to utilize SMART, as many insurers currently cover only a single-month supply of these 102 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, 103 104 individuals with inaccurate symptom perception may be poor candidates for as needed ICS. 105 The changes implemented by EPR-4 correspond closely with current GINA guidelines, 106 with the exception that GINA also advocates the intermittent use of ICS with LABA for all 107 individuals older than 12 years at both Step 1 and 2 (mild asthma) and generally discourages use 108 of any SABA monotherapy in this population (Global Initiative for Asthma, 2020). Thus, when 109 managing teen and adult patients with asthma, nurse practitioners should consider prescribing 110 low dose ICS, either intermittent or daily, based on level of symptoms. 111 A few helpful rules can help to simplify understanding of stepwise therapy. In general, 112 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

115	generally increases the Stepwise therapy by one level. For example, an adult patient taking
116	Budesonide 180 mcg, one puff twice daily, with albuterol as needed (SABA) would be classified
117	as Step 2 (low dose ICS), whereas use of the same low dose Budesonide plus formoterol
118	(LABA) twice daily would be classified as Step 3 therapy.
119	Prescribers should also be aware that ICS dosing is non-equivalent across different
120	formulations (National Heart Lung and Blood Institues, 2011). This point cannot be over-
121	emphasized, and mistakes in this area contribute substantially to prescribing errors. For instance,
122	an adult daily dose of fluticasone propionate 200 mcg (100 mcg given twice daily) is low-dose
123	(Step 2), whereas fluticasone furoate 200 mcg (given once daily) is high-dose (Step 5). For this
124	reason, prescribers should utilize comparative dosing tables (see online e-supplement A) to
125	ensure that appropriate doses of ICS are prescribed, consistent with best-practices. Caution
126	should be used when making insurance driven formulary changes, as evidence indicates that
127	these changes might precede deterioration in lung function (Bickel, Nemer Eid, & Sayat, 2019).
128	Lastly, minimum standards for asthma-related visits should include assessment and
129	documentation of severity, control, stepwise therapy, and comparative ICS dosing (Box 1).
130	Printable, clinician-friendly pocket-guides are included in the reference list for ages 5-11 years
131	(Mammen, 2021b) and ages 12 years to adult (Mammen, 2021a) to facilitate accurate assessment
132	and classification of asthma, and appropriate step-wise medication management.
133	Conclusion. Clinical management of asthma requires increasing precision in assessment
134	and medication management. Greater familiarity with asthma management guidelines will
135	promote delivery of high-quality evidence-based care, and will help to improve patient outcomes
136	and quality of life.
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Box 1. Checklist to promote clinician compliance with U.S. National guidelines for asthma care

