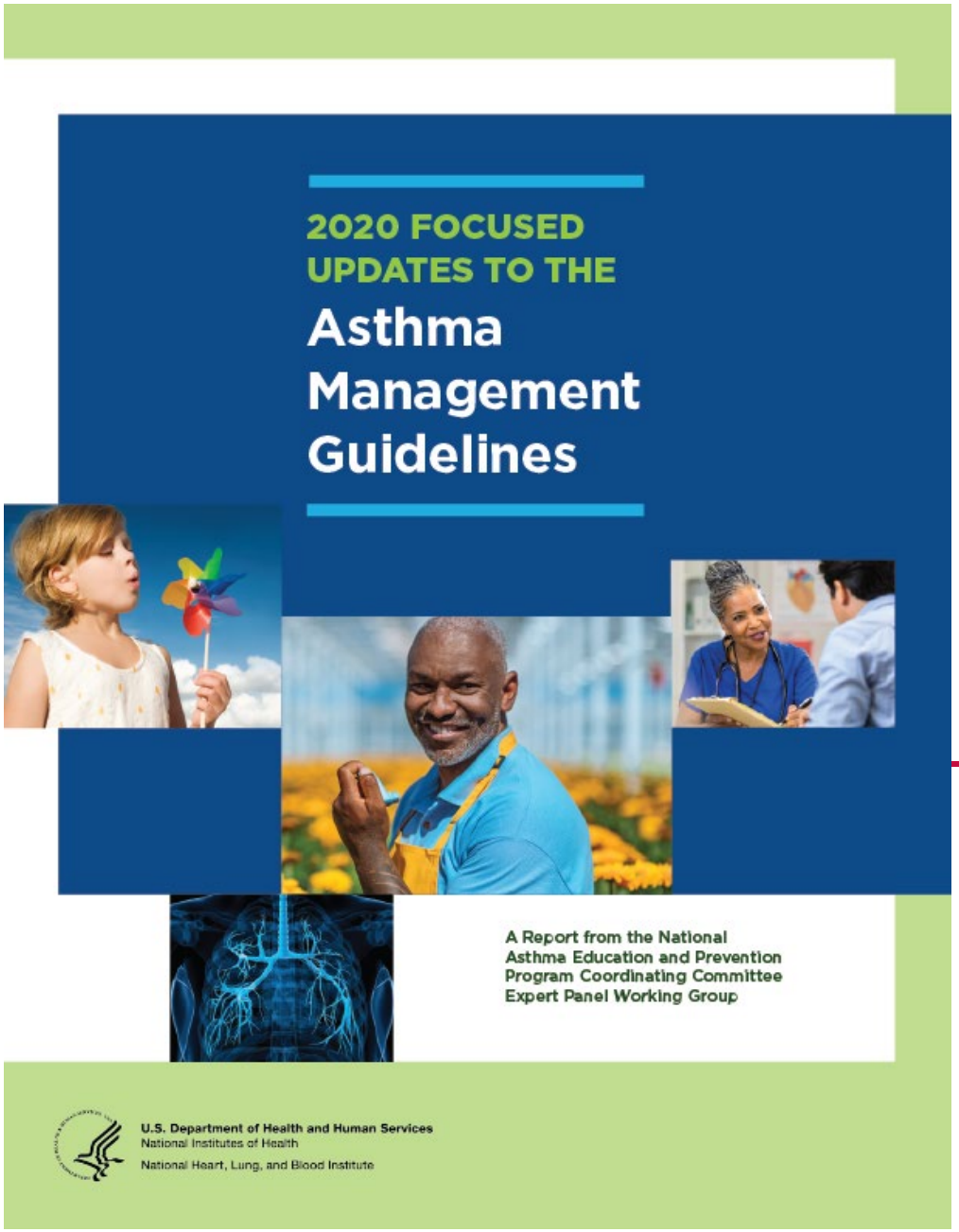

Released
December 3, 2020

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Presentation Outline

- Relevancy of the Update and Resources
- Technical Overview of the Update Development/Methodology
- Updates on Recommended Asthma Management using Stepwise Approach
- Updated Topic Areas with Comparison to 2007 Guidelines
- Questions/Discussion

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NIH National Asthma Guidelines

- Most recent guidance on asthma diagnosis, treatment, and management – 13 years ago
- Resources (www.nhlbi.nih.gov/asthmaguidelines)
  - *2020 Focused Updates to the Asthma Management Guidelines*
  - At-a-glance guides with updated stepwise tables
  - Fact sheets and FAQs
  - NHLBI's *Learn More Breathe Better*^{SM} program at www.nhlbi.nih.gov/BreatheBetter.

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Development of the 2020 Focused Update

- In 2014, the Asthma Expert Working Group of the National Heart, Lung, and Blood Advisory Council (NHLBAC) completed an assessment of the need to revise the National Asthma Education and Prevention Program (NAEPP)'s *Expert Panel Report-3: Guidelines for the Diagnosis and Management of Asthma* (EPR-3) published in 2007
- Determined 6 topics that had sufficient evidence in a systematic review to warrant an update
  - Updates based upon patient population, intervention, relevant comparators, and outcomes of interest.

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Methodology

- Multiple steps that included Expert Review Panel established – multidisciplinary panel
  - Considered input from multiple agencies (Agency for Healthcare Research and Quality (AHRQ) Evidence Based Practice Centers, National Asthma Education and Prevention Program (NAEPP)), stakeholders focus group, and public comment
- Health and Human Services (HHS) – approved guidelines and published in *Journal of Allergy and Clinical Immunology* on December 3, 2020

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AHRQ Evidence Practice Centers

- Systematic reviews on selected topic areas:
  - **The Clinical Utility of Fractional Exhaled Nitric Oxide (FeNO) in Asthma Management** (https://doi.org/10.23970/AHRQEPCCER197)
  - **Effectiveness of Indoor Allergen Reduction in Management of Asthma** (https://doi.org/10.23970/AHRQEPCCER201)
  - **Intermittent Inhaled Corticosteroids and Long-Acting Muscarinic Antagonists for Asthma** (https://doi.org/10.23970/AHRQEPCCER194)
  - **Role of Immunotherapy in the Treatment of Asthma** (https://doi.org/10.23970/AHRQEPCCER196)
  - **Effectiveness and Safety of Bronchial Thermoplasty in Management of Asthma** (https://doi.org/10.23970/AHRQEPCCER202)

Methodology

- Grading of Recommendations Assessment, Development and Evaluation (GRADE)
  - Internationally recognized approach
  - Evaluates quality of evidence
  - Guides direction and strength of recommendation
- Three critical outcomes considered:
  - Exacerbations
  - Asthma Control
  - Quality of life
- Other considerations: age group, disease severity, patient preference

Interpretation of Results

Table I.d: Certainty of Evidence of Effects

High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of the effect.

Reflects the panel's confidence in how well the estimated effect approximates the true effect

Interpretation of Results

Table I.e: Implications of Strong and Conditional Recommendations*

Implications	Strong recommendation	Conditional recommendation
For individuals with asthma	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	Most individuals in this situation would want the suggested course of action, but many would not.
For clinicians	Most individuals should receive the intervention. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Different choices will be appropriate for individuals consistent with their values and preferences. Use shared decision-making. Decision aids may be useful in helping individuals make decisions consistent with their risks, values, and preferences.
For policy makers	The recommendation can be adapted as policy or performance measure in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Policy making will require substantial debate and involvement of various stakeholders. Performance measures should assess whether decision-making is documented.
For researchers	The recommendation is supported by credible research or other convincing judgments that make additional research unlikely to alter the recommendation. On occasion, a strong recommendation is based on low or very low certainty in the evidence. In such instances, further research may provide important information that alters the recommendations.	The recommendation is likely to be strengthened (for future updates or adaptation) by additional research. An evaluation of the conditions and criteria (and the related judgments, research evidence, and additional considerations) that determined the conditional (rather than strong) recommendation will help identify possible research gaps.

*Strong recommendations are indicated by st ments that lead with "We recommend," whereas c ditional recommendations are indicated by statements that lead with "We c ditionally recommend."

Strong vs. Conditional

Mostly all agree

Some may agree

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Updated Six Topic Categories

1. Reinforce use of inhaled corticosteroids (ICS)
2. Long term asthma management: Long acting antimuscarinic agents (LAMA) with ICS
3. Reduce indoor asthma triggers with one or more methods
4. Immunotherapy for those with allergic asthma
5. Fractional exhaled nitric oxide (FeNO) test when asthma diagnosis is unclear
6. Bronchial Thermoplasty (BT) for selected adults with persistent asthma

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11 Other Relevant Topics

- Adherence
- Asthma action plans
- Asthma heterogeneity
- Biologic agents
- Biomarkers (other than FeNO)
- Classification of asthma severity
- Long-acting beta2-agonist (LABA) safety
- Physiological assessments
- Prevention of asthma onset
- Role of community health workers in asthma management
- Step-down from maintenance therapy

AGES 0–4 YEARS: STEPWISE APPROACH FOR MANAGEMENT OF ASTHMA

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 0–4 Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
Preferred	PRN SABA and At the start of RTI: Add short course daily ICS▲	Daily low-dose ICS and PRN SABA	Daily low-dose ICS-LABA and PRN SABA▲ or Daily low-dose ICS + montelukast,* or daily medium-dose ICS, and PRN SABA	Daily medium-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA + oral systemic corticosteroid and PRN SABA
Alternative		Daily montelukast* or Cromolyn,* and PRN SABA		Daily medium-dose ICS + montelukast* and PRN SABA	Daily high-dose ICS + montelukast* and PRN SABA	Daily high-dose ICS + montelukast*+ oral systemic corticosteroid and PRN SABA
			For children age 4 years only, see Step 3 and Step 4 on Management of Persistent Asthma in Individuals Ages 5–11 Years diagram.			

Assess Control

- First check adherence, inhaler technique, environmental factors,▲ and comorbid conditions.
- **Step up** if needed; reassess in 4–6 weeks
- **Step down** if possible (if asthma is well controlled for at least 3 consecutive months)

Consult with asthma specialist if Step 3 or higher is required. Consider consultation at Step 2.

Control assessment is a key element of asthma care. This involves both impairment and risk. Use of objective measures, self-reported control, and health care utilization are complementary and should be employed on an ongoing basis, depending on the individual's clinical situation.

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AGES 5–11 YEARS: STEPWISE APPROACH FOR MANAGEMENT OF ASTHMA

	Intermittent Asthma	Management of Persistent Asthma in Individuals Ages 5–11 Years				
Treatment	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6
Preferred	PRN SABA	Daily low-dose ICS and PRN SABA	Daily and PRN combination low-dose ICS-formoterol▲	Daily and PRN combination medium-dose ICS-formoterol▲	Daily high-dose ICS-LABA and PRN SABA	Daily high-dose ICS-LABA + oral systemic corticosteroid and PRN SABA
Alternative		Daily LTRA,* or Cromolyn,* or Nedocromil,* or Theophylline,* and PRN SABA	Daily medium-dose ICS and PRN SABA or Daily low-dose ICS-LABA, or daily low-dose ICS + LTRA,* or daily low-dose ICS +Theophylline,* and PRN SABA	Daily medium-dose ICS-LABA and PRN SABA or Daily medium-dose ICS + LTRA* or daily medium-dose ICS + Theophylline,* and PRN SABA	Daily high-dose ICS + LTRA* or daily high-dose ICS + Theophylline,* and PRN SABA	Daily high-dose ICS + LTRA* + oral systemic corticosteroid or daily high-dose ICS + Theophylline* + oral systemic corticosteroid, and PRN SABA
		Steps 2–4: Conditionally recommend the use of subcutaneous immunotherapy as an adjunct treatment to standard pharmacotherapy in individuals ≥ 5 years of age whose asthma is controlled at the initiation, build up, and maintenance phases of immunotherapy▲			Consider Omalizumab**▲	

Assess Control

- First check adherence, inhaler technique, environmental factors,▲ and comorbid conditions.
- **Step up** if needed; reassess in 2–6 weeks
- **Step down** if possible (if asthma is well controlled for at least 3 consecutive months)

Consult with asthma specialist if Step 4 or higher is required. Consider consultation at Step 3.

Control assessment is a key element of asthma care. This involves both impairment and risk. Use of objective measures, self-reported control, and health care utilization are complementary and should be employed on an ongoing basis, depending on the individual's clinical situation.

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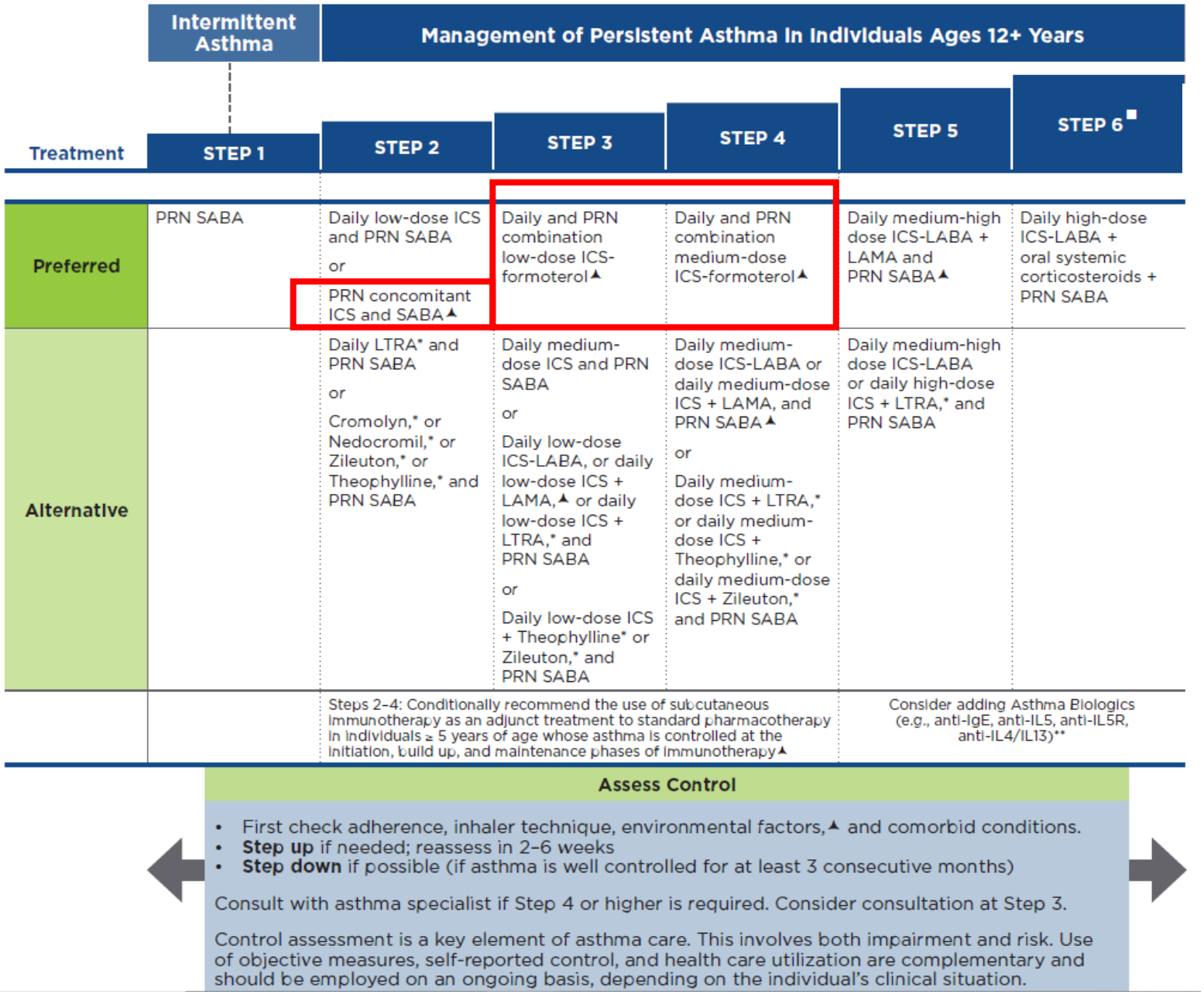
AGES 12+ YEARS: STEPWISE APPROACH FOR MANAGEMENT OF ASTHMA



Topic 1: Use of ICS

2007 Guideline

- For mild respiratory tract infection, short acting beta-agonist (SABA) every 4-6 hours
- For moderate to severe respiratory tract infection, consider a short course of oral steroids

2020 Update

- Short course of ICS with short acting beta-agonist (SABA) as needed (PRN) for children aged 0-4 yrs with intermittent asthma and a respiratory tract infection (Conditional, Moderate evidence)

Topic 1: Use of ICS

2007 Guideline

- For those age ≥ 5 yrs with mod to severe persistent asthma, daily medium-dose ICS/LABA + SABA for quick-relief therapy

2020 Update

- For those age ≥ **4 yrs** with mod to severe persistent asthma, ICS-formoterol as both daily controller and reliever therapy (Strong, High/Mod evidence)
- For those age ≥ **4 yrs** with mild to mod persistent asthma on daily ICS, recommend against short term increased in ICS dose for symptomatic relief (Conditional, Low evidence)

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Topic 1: Use of ICS

2007 Guideline

- For those age ≥ 12 yrs with mild persistent asthma, daily dose of ICS+PRN SABA

2020 Update

- For those age ≥ 12 yrs with mild persistent asthma, **EITHER** daily dose of ICS+PRN SABA **OR** ICS+SABA PRN
  (Conditional, Low)

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Topic 1: Use of ICS

2007 Guideline

- For those age ≥ 12 yrs with mod persistent asthma, daily medium-dose ICS + PRN SABA *or* low-dose ICS/LABA + PRN SABA

2020 Update

- For those age ≥ 12 yrs with mod to severe persistent asthma, ICS-formoterol as both a daily controller and reliever therapy
  (Conditional, High evidence)

Topic 2: Use of LAMA

- Recommends against the use of LAMA (Conditional, Moderate evidence)
  - If patient is **age ≥ 5 yrs with an unclear diagnosis of asthma** based upon history, clinical findings, clinical course, and spirometry or if spirometry cannot be performed

Topic 2: Use of LAMA

- Recommends against the use of LAMA and ICS compared to use of LABA and ICS (Conditional, Mod evidence)
  - If patient is **age ≥ 12 years and older with uncontrolled persistent asthma**
- If LABA is not used, LAMA may be added to ICS for a greater benefit than ICS alone for controller therapy (Conditional, Mod evidence)
  - If patient is **aged 12 years and older with uncontrolled persistent asthma**

Topic 2: Use of LAMA

- Recommends adding LAMA to ICS-LABA compared to continuing the same dose of ICS-LABA. (Conditional, Mod evidence)
  - If patient is **aged 12 years and older with uncontrolled persistent asthma**
- Special Considerations
  - Contraindicated in those with urinary retention or glaucoma
  - Small increase in risk among some individuals esp., African-Americans

Topic 3: Indoor Asthma Triggers

2007 Guideline

- Reduce exposure to allergens to which the patient is sensitized and exposed
- Effective allergen avoidance requires a multifaceted, comprehensive approach

2020 Update

- Recommends against routine allergen mitigation interventions for those who do not have sensitization to specific indoor allergens or who do not have symptoms related to exposure to specific indoor allergens (Conditional, Low evidence)
- Recommend multicomponent allergen-specific mitigation intervention in individuals with asthma who are exposed and have symptoms related to exposure to identified indoor allergens, confirmed by history taking or allergy testing (Conditional, Low evidence)

Topic 3: Indoor Asthma Triggers

2007 Guideline

- Recommended cockroach control measures if the patient is sensitive to cockroaches and the home has an infestation
- Recommend mattress and pillow covers along with washing linen in hot water weekly for dust mite mitigation

2020 Update

- IPM may be used alone or as part of a multicomponent allergen-specific mitigation intervention (Conditional, Low evidence)
- Recommend mattress/pillow covers as part of a multicomponent allergen-specific mitigation (Conditional, Mod evidence)

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Indoor Allergy Mitigation

- Mitigation Interventions examined:
  - Acaricide and air filtration/purifier systems
  - Carpet removal
  - Cleaning products
  - HEPA vacuum cleaners
  - Pillow/mattress covers
  - Integrated pest management
  - Mold mitigation
  - Pet removal

Topic 4: Immunotherapy

2007 Guideline

- Consider allergen immunotherapy for persistent asthma in the presence of symptoms and sensitization

2020 Update

- For those age ≥ 5 yrs with mild to mod allergic asthma, use SCIT if asthma is controlled at the initiation, build-up, and maintenance phases of immunotherapy (Conditional, Mod evidence)
- Recommend against use of SLIT for asthma treatment in individuals with persistent allergic asthma (Conditional, Mod evidence)

Topic 5: FeNO

- Recommend the addition of FeNO measurement as an adjunct to the evaluation process (Conditional, Moderate evidence)
  - If patient is **age ≥ 5 yrs with an unclear diagnosis of asthma** based upon history, clinical findings, clinical course, and spirometry or if spirometry cannot be performed

Topic 5: FeNO

- Recommends the addition of FeNO measurement as part of an ongoing asthma monitoring and management strategy that includes frequent assessments. (Conditional, Low evidence)
  - If patient is **age ≥ 5 yrs with persistent allergic asthma where it is uncertainty in choosing, monitoring, or adjusting anti-inflammatory therapies**

Topic 5: FeNO

- Do not use FeNO measurements in isolation to assess asthma control, predict future exacerbations, or assess exacerbation severity. If used, it should be as part of an ongoing monitoring and management strategy. (Strong, Low evidence)
  - If patient is **age ≥ 5 yrs with asthma**

Topic 5: FeNO

- Do not use FeNO measurement to predict the future development of asthma. (Strong, Low evidence)
  - If patient is **age ≤ 4 yrs with recurrent wheezing**

Topic 6: Bronchial Thermoplasty (BT)

- Do not use bronchial thermoplasty. Consider BT if the potential benefits outweigh the risks. (Conditional, Low evidence)
  - If patient is **age ≥ 18 yrs with persistent asthma**