Welcome to NAEPPCC Webinar

May 13, 2020

✓ Lines are muted to reduce background sounds
WebEx Logon

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Please hang up.

Then select “Call Me” or “I Will Call In” and follow the instructions.
NAEPPCC Membership

Dr. J. Kofi Berko (HUD)
Ms. Sheila Brown (EPA)
Dr. Kurtis S. Elward (AAFP)
Dr. Anne M. Fitzpatrick
Dr. Lynn B Gerald
Dr. Fernando Holguin (ATS)
Dr. Joy Hsu (CDC)
Dr. Elliot Israel
Dr. Robert F. Lemanske
Mr. Kenneth Mendez (AAFA)
Dr. Giselle S. Mosnaim (AAAAI)
Dr. Gary S. Rachelefsky (AAP)
Dr. Lisa M. Wheatley (NIAID)
Dr. Juan P. Wisnivesky
Dr. Darryl C. Zeldin (NIEHS)
## Meeting Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Presenter(s)</th>
</tr>
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<tbody>
<tr>
<td>12:00 – 12:10</td>
<td>Call to order and Welcome</td>
<td>Ms. Susan Shero, Dr. James Kiley, Dr. George Mensah</td>
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<tr>
<td>12:10 – 12:25</td>
<td>Overview of Public Comments</td>
<td>Dr. Michelle Cloutier</td>
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<tr>
<td>12:25 – 1:30</td>
<td>Discussion of Guidelines Update: Final Draft Report</td>
<td>Dr. Cloutier/CC/Attendees</td>
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<tr>
<td>1:30 – 1:45</td>
<td>NHLBI Communications Strategy</td>
<td>Dr. Lenora Johnson</td>
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<tr>
<td>1:45 – 1:50</td>
<td>Questions and Comments</td>
<td>Attendees</td>
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<tr>
<td>1:50 – 2:00</td>
<td>Closing Remarks</td>
<td>Drs. Kiley and Mensah</td>
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Timeline for Asthma Guidelines 2020 Update

2014
3/2014
- Needs assessment
  - Public comments solicited
  - Results published; six topics chosen

2015
2/2015
- Literature searches updated

2016
- Key questions identified
- AHRQ contract signed, protocols established, systematic reviews published
- NAEPPCC Expert Panel Working Group convened

2017
- 7/2018
  - NAEPPCC meets to discuss draft document

2018
- 10/2018
  - Literature searches updated

2019
- 12/2019
  - Draft document released for public comment

2020
- 5/2020
  - NAI/DHHS clearance
- 7/2020
  - NIH/DHHS clearance
- Expected publication

Abbreviations:
AHRQ—Agency for Healthcare Research and Quality
DHHS—U.S. Department of Health and Human Services
NAEPPCC—National Asthma Education and Prevention Program Coordinating Committee
NIH—National Institutes of Health
Overview of Public Comments

Dr. Michelle Cloutier
Chair
NAEPPCC Expert Panel Working Group
Summary of Public Comments

• Public comment period: 12/2/2019 – 1/17/2020
• Comments were submitted online and via email
• Over 500 comments were received from:
  ➢ Individuals including NAEPPCC members
  ➢ Professional societies and associations
  ➢ Public health/health care organizations
  ➢ Non-profit organizations
  ➢ Federal agencies
  ➢ Pharmaceutical/ industry
Processes for Addressing Public Comments

- Every comment was categorized by content by Westat staff as to topic area and reviewed by the Expert Panel.
- Expert Panel members reviewed the comments on calls and webinars throughout January 2020 and recommended a disposition.
- Possible dispositions included: requires further discussion, revision in document recommended, change to recommendation made, outside scope of work, no change needed.
- The Expert Panel met in-person in February 2020 to further discuss and agree upon revisions and updates to the report.
- Changes to recommendations were formally voted upon in March 2020 and consensus was reached.
- No individual responses were sent to those who submitted comments.
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<tbody>
<tr>
<td>General Comments</td>
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<tr>
<td>Need for more comprehensive update to EPR-3</td>
<td>Noted as a major gap in Introduction</td>
</tr>
<tr>
<td>Systematic reviews outdated</td>
<td>Emphasized in the report that data reviewed were through October 2018; added timeline</td>
</tr>
<tr>
<td>Differences from GINA guidelines not discussed</td>
<td>Other guidance documents were not considered in developing the recommendations</td>
</tr>
<tr>
<td>Need for clarity in recommendations; challenges understanding GRADE</td>
<td>Wrote a Clinician’s Summary in each Implementation Guidance section; strengthened GRADE background in Methods section</td>
</tr>
<tr>
<td>terminology</td>
<td></td>
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<tr>
<td>Comments about Gaps in Report</td>
<td></td>
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<tr>
<td>- Use of biologics</td>
<td>Emerging but out of scope per needs assessment; included in table of emerging areas; addressed biologics in Introduction and Step diagrams</td>
</tr>
<tr>
<td>- Adherence, asthma control, asthma severity</td>
<td></td>
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<tr>
<td>- CHWs, education tools, inhaler technique</td>
<td></td>
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<tr>
<td>Out of Scope Topics</td>
<td></td>
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<tr>
<td>Fungal therapy, cognitive impact, dehumidifiers, outdoor &amp; work</td>
<td>No changes made to report</td>
</tr>
<tr>
<td>triggers, panic disorder &amp; SABAs</td>
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### Comments and Dispositions

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<tr>
<td><strong>ICS Topic</strong></td>
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<tr>
<td>SMART off-label in US</td>
<td>No changes made to report but this was noted</td>
</tr>
<tr>
<td>Dosing information requested for SMART</td>
<td>Added information about dosing where supplied in studies</td>
</tr>
<tr>
<td>Questions regarding two types of intermittent or as needed ICS treatment:</td>
<td>Not addressed by the Key Questions in this guideline update.</td>
</tr>
<tr>
<td>1) Efficacy and safety of as-needed ICS-formoterol versus as-needed SABA in step 1 or steps 5/6</td>
<td></td>
</tr>
<tr>
<td>2) Efficacy and safety of as-needed ICS-formoterol versus low-dose ICS and as-needed SABA in step 2</td>
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<tr>
<td><strong>LAMA Topic</strong></td>
<td><strong>Concerns regarding apparent contradiction between Recommendations #14 and #15 as written (i.e., recommend against adding LAMA to ICS vs. adding LABA to ICS; but recommend for adding LAMA to ICS vs. ICS alone)</strong></td>
</tr>
<tr>
<td><strong>Why recommendations did not include use of LAMA in children ages 6-11 years</strong></td>
<td></td>
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<tr>
<td><strong>Report did not reference RESPIMAT®</strong></td>
<td></td>
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<tr>
<td><strong>Concerns that harm signal from one real-world study in African Americans (BELT Study) may be overstated</strong></td>
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Report did not reference RESPIMAT®

Added note that tiotropium bromide (RESPIMAT®) was the only formulation of LAMA with FDA approval for asthma at time of the report.
## Comments and Dispositions

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<td><strong>Immunotherapy Topic</strong></td>
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<tr>
<td>FDA approved vs. non-FDA approved therapies (SLIT [tablets or drops] is not FDA-approved specifically for asthma)</td>
<td>No change was made to the recommendation; comment was added about limited evidence</td>
</tr>
<tr>
<td>Need to differentiate between SLIT tablets and SLIT drops</td>
<td>Clarified SLIT forms in the report; expanded on the use of tablets for concurrent comorbid conditions in Implementation Guidance</td>
</tr>
<tr>
<td>Comparisons to other guidance documents (e.g., approval of SLIT for a specific asthma phenotype by GINA)</td>
<td>Other guidance documents were not considered in developing the recommendations</td>
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<td><strong>Allergen Mitigation Topic</strong></td>
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<tr>
<td>Scope is limited with focus on home allergens, particularly exclusion of environmental irritants and ETS</td>
<td>Acknowledged limited scope and important role of irritants in asthma exacerbations</td>
</tr>
<tr>
<td>Recommendations should be sensitive to inequities in access to care for allergy specialists and allergy testing</td>
<td>Revised recommendation language to indicate that history of symptoms upon allergen-specific exposure may be sufficient in lieu of testing</td>
</tr>
<tr>
<td>Lack of clarity about recommendation against mattress/pillow covers as a single intervention, but for mattress/pillow covers as part of a multi-component intervention</td>
<td>Refined recommendation to clarify language and expanded Implementation Guidance</td>
</tr>
<tr>
<td>Comments regarding terminology used (e.g. allergen reduction, mold removal, allergen sensitivity, pest control)</td>
<td>Revised terminology (e.g. allergen mitigation, mold mitigation, allergen sensitization, integrated pest management)</td>
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<tr>
<td>Use of FeNO in specific groups (e.g. atopic individuals and non-asthmatic conditions)</td>
<td>Revised Summary of Evidence statement to be more precise about the nature of evidence since non-atopic patients were included in many of the adult studies</td>
</tr>
<tr>
<td>Identifying Type 2 inflammation and role in selecting biologics</td>
<td>Out of scope for this update; noted as an important area for future research</td>
</tr>
<tr>
<td>Questions about studies evaluated for the diagnostic use of FeNO in children</td>
<td>No change was made to the recommendation; however, summary of evidence was revised for completeness</td>
</tr>
<tr>
<td>Use of FeNO for prediction of asthma in children</td>
<td>Indicated in Future Research Opportunities the need to define possible role of FeNO measurements in young children</td>
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<td>Disposition</td>
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<td>---------------------------------------------------------------</td>
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<tr>
<td>Bronchial Thermoplasty Topic</td>
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<tr>
<td>Concerns regarding clarity of a</td>
<td>Moved statement about patient values to implementation</td>
</tr>
<tr>
<td>recommendation against BT being</td>
<td>guidance section to clarify the explanation</td>
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<tr>
<td>accompanied by a statement about</td>
<td></td>
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<tr>
<td>patient choice based on patient</td>
<td></td>
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<tr>
<td>values</td>
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• NAEPPCC comments and discussion – Dr. Cloutier and CC

• Comments from other attendees/public representatives - All

• Move to accept report – Dr. Kiley
Report Release Plans

Lenora Johnson, DrPH
Director,
Office of Science Policy Engagement, Education and Communications

National Heart, Lung, and Blood Institute’s
NAEPPCC
May 13, 2020
Update Report Communication Goals

To introduce, disseminate and encourage adoption of recommendations in the 2020 Focused Updates to the Asthma Management Guidelines by:

- Raising awareness about the recommendations outlined in the 2020 Focused Updates
- Engaging our partners and stakeholders to broadly disseminate the recommendations to asthma communities
  - Special focus on populations of greatest need
Planning to use a phased communication approach that:

- Focuses on specific needs of audiences
- Can be adjusted to consider current environment – more virtual communications channels
- Relies upon innovative collaborations and mutually beneficial partnerships to expand our reach
- Uses continuous reassessment and effectiveness of tactics/approaches
Guidelines Rollout: A Phased Approach

Phase 1: Spring 2020
- Strategic Communications and Outreach Planning & Coordination

Phase 2: Summer 2020 – Spring 2022
- Development of Supportive Materials & Clearance

Phase 3: Fall 2020 – Winter 2021
- Announce Release of Update Report & Build Awareness

Post Release: 2021 – 2022
- Implementation & Adoption
Phase 1: Strategic Communications and Outreach Planning & Coordination

- Developed a comprehensive communications plan
- Identified appropriate spokespeople for the report
- Create workflows and timelines
- Connect with AAAAI’s journal (JACI) to develop coordinated Report release plans
- Ensure accessibility of the Report (online and print)
- Identify and develop complementary products that support understanding of Report
Phase 2: Materials Development

The following Report related supplementary products are under consideration:

- Hard copy of JACI journal issue for those unable to access online
- Summary/overview fact sheet highlighting key take-aways
- A pull-out, stand-alone version of the Report’s Step-Wise Chart
- A quick reference guide for use in the clinical setting
- Materials for partners and stakeholder dissemination needs (tool kit)
  - Including digital/social partner toolkit, sample social media posts/images/info cards/animations for sharing
- Media related products (release)
- Updated landing page on nhlbi.nih.gov
  - Work toward a digitally compliant version over time
Major Milestones by Phase

**Phase 3: Announce Release of Update Report & Build Awareness**

- NHLBI will:
  - Issue a media advisory
  - Hold telebriefing for stakeholders & media
  - Issue a news release in coordination with JACI
  - Release a digital/social partner toolkit
  - Launch updated landing page linking to Report
  - Push social media posts that build awareness
Phase 4: Post-Release Phase

Distributed responsibilities for implementation activities beyond the Report release

- Provider-focused presentation content
- Partner with CME offerors to co-produce professional education webinar
- Health Professional Toolkit content
- Video series/training tutorials
- Materials for dissemination at appropriate medical meetings and exhibit booths
- Consideration of Decision Support Tools development in 2021
- Asthma and Allergy Awareness opportunities in 2021
Assumptions

- Federal clearance process will proceed as expected
- NAEPP members (and other stakeholders) will also be supporting the release and implementation of the updates to the guidelines in ways aligned with their own constituents’ needs
Guidelines Rollout: A Phased Approach

Phase 1: Spring 2020

Strategic Communications and Outreach Planning & Coordination

Development of Supportive Materials & Clearance

Phase 2: Summer 2020 – Spring 2022

Announce Release of Update Report & Build Awareness

Phase 3: Fall 2020 – Winter 2021

Post Release: 2021 – 2022

CLEARANCES

Intended Release

Implementation & Adoption
Questions, Thoughts, Inputs?
Thank you!