March 14, 2024

Coffee with Colleagues

Asthma

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VIRTUAL COFFEE With Colleagues: Updated Management of Pediatric Asthma

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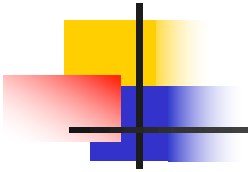
Common Abbreviations

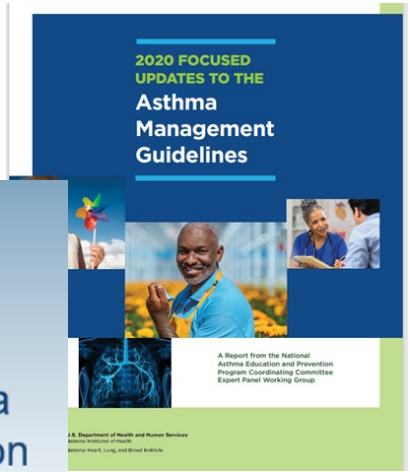
- GINA-- Global Initiative for Asthma
- NAEPP— National Asthma Education & Prevention Pr
- ICS— Inhaled corticosteroid
- LABA— Long-acting beta agonist (ex. salmeterol)
- SABA— Short acting beta agonist (ex. albuterol)
- LAMA— Long-acting muscarinic antagonist
- AIR— Anti-inflammatory reliever
- DPI— Dry powder inhaler
- MDI— Metered dose inhaler
- HFA– Hydrofluoroalkane (inhaler propellant)
- MART/ SMART— (Single) Maintenance And Reliever Therapy
- LTRA— Leukotriene receptor antagonist (ex. Montelukast or Singulair)



Background

GINA

- **Global Initiative for Asthma**
  - International committee
  - Primarily based in Europe
  - Annual updates
  - Most recent 2023
  - ***Focused on risk***
    - *Reducing morbidity & side effects*



NAEPP (NHLBI)

- **National Asthma Education and Prevention Program**
  - US based
  - Responsible for the familiar guidelines that we know
  - Updated less frequently
  - 2007→2010→2020
  - Addressed 6 priority topics including
    - Intermittent Inhaled Corticosteroids and ICS/LABA
    - Long-acting Muscarinic Antagonists (LAMA)

- **Age ranges slightly different**
  - NAEPP: 0-4, 5-11, 12+
  - GINA: 0-5, 6-11, 12+
- **Number of steps of therapy**
  - NAEPP 6 steps
  - GINA 5 steps
- **NAEPP endorses:**
  - **Use of high dose ICS in youngest age group**
  - **Introduces ICS/LABA at younger age**

GINA Ages 6-11

Asthma medication options:
Adjust treatment up and down for individual child's needs

	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
PREFERRED CONTROLLER to prevent exacerbations and control symptoms	Low dose ICS taken whenever SABA taken	Daily low dose inhaled corticosteroid (ICS) (see table of ICS dose ranges for children)	Low dose ICS-LABA, OR medium dose ICS, OR very low dose* ICS-formoterol maintenance and reliever (MART)	Medium dose ICS-LABA, OR low dose† ICS-formoterol maintenance and reliever therapy (MART). Refer for expert advice	Refer for phenotypic assessment ± higher dose ICS-LABA or add-on therapy, e.g. anti-IgE
Other controller options	*Consider daily low dose ICS*	*Daily leukotriene receptor antagonist (LTRA), or low dose ICS taken whenever SABA taken*	*Low dose ICS + LTRA*	*Add tiotropium or add LTRA*	*Add-on anti-IL5, or add-on low dose OCS, but consider side-effects*
RELIEVER	*As-needed short-acting beta2-agonist (or ICS-formoterol reliever for M*				

NAEPP

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**▲	

Both updates outline *preferred* and *alternative* tracks of management

GINA Updates are Focused on ***Reduction of Risk***

- Risks of albuterol alone as asthma treatment
  - Increased risk of *progression to severe exacerbation*
  - Increased risk of *severe exacerbation*
  - Increased risk of *death from asthma*
- Risks of use of high dose ICS in very young children even for short periods of time

Risks of SABA

- SABA alone even for short periods of time
  - β-receptor downregulation
  - ↓ bronchodilator response
  - ↓ bronchoprotection
  - Rebound bronchial hyperresponsiveness (Hancox, Respir Med 2000)
- Increased SABA use → higher risk of severe exacerbation and death from asthma (even with daily ICS)
  - > 3 canisters/yr incr exacerbation risk (Stanford, AAAI, 2012; Nwaru, Eur Resp J, 2020)
  - > 12 canisters /yr incr risk of death (Suissa, AJRCCM, 1994, NEJM, 2000, 2002; Pauwels, Lancet 2003, Nwaru, Eur Resp J, 2020)

Rationale for ICS as part of rescue

- Adherence to daily ICS is poor for poor perceivers, pts with occasional symptoms
- Even patients with mild asthma can have severe exacerbations→overuse of SABA
  - 15-20% of adult asthma deaths
  - 16% of near fatal exacerbations (Dusser, Allergy, 2007)
- Both groups at risk of progression to severe exacerbation

New Concept: ICS and Rescue

- **ICS must be used EVEN in intermittent asthma**
- Reliever medications for infrequent asthma*
  - Age 4-11 years***:*** **Albuterol + inhaled steroids at the time of symptoms**
  - Age 12+ years**:** **ICS + formoterol at the time of symptoms**
  - Albuterol alone as rescue ONLY if taking daily ICS or ICS/LABA as maintenance

*GINA (NAEPP endorses albuterol alone in Step 1)

New Concept: ICS-formoterol as rescue

- As needed ICS-formoterol compared to
- Either prn SABA OR daily ICS + prn albuterol
  - *Reduces severe exacerbations*
  - *Same or better reduction in EIB*
  - *Decreased ICS dose*
  - *Similar symptom control*

Anti-inflammatory Reliever (AIR)

- **Steroids are part of the rescue regimen in mild asthma across all age groups**
  - Preschool—*high dose ICS with albuterol during URI*
  - School age—*ICS + albuterol prn symptoms*
  - Adolescents/adults—*ICS + formoterol prn*

Recommendations by Age: Age 6-11 years

Case 1: 10-year-old boy

- Mild persistent asthma
- Current therapy:
  - fluticasone 44mcg 2 puffs twice daily
  - Increases to 4 puffs twice daily and adds albuterol prn during URI
- Today presents with increased frequency of asthma symptoms over the past 6 weeks
  - Good adherence to daily fluticasone
  - Good MDI and spacer technique

Case 1: 10-year-old boy

- What changes would you make?
  1) Increase daily maintenance from low dose to medium dose ICS
  2) Change daily controller from fluticasone to ICS/LABA such as budesonide-formoterol or fluticasone-salmeterol and continue SABA as reliever
  3) Initiate (S)MART with budesonide-formoterol 80/4.5 (2 puffs once daily and 1 puff as needed)

- *If this child was well controlled, are changes needed?*

Children 6-11 years of age

New recommendations:

- **Step 1 Low dose** ICS + albuterol prn symptoms
- Step 2 Daily low dose ICS + prn albuterol
- **Steps 3, 4**

  ICS-formoterol daily *AND* as needed = SMART

  OR

  Daily ICS-formoterol + prn albuterol

  OR

  Medium dose ICS + prn albuterol
- Step 5 NO SMART

(S)MART:
(Single) Maintenance And Reliever Therapy

- Budesonide/formoterol (Symbicort, Breyna, generic)

- Mometasone/ formoterol (Dulera)

Not All LABAs are the Same!

FORMOTEROL: rapid onset of action AND extended length of action

ICS/formoterol

- can serve as rescue and controller
- now known as an anti-inflammatory reliever
- most data with budesonide/formoterol

ANTI-INFLAMMATORY RELIEVER = AIR

(ICS+SABA inhaler (Airsupra™) approved for ≥ 18 yrs which is also AIR)

Case 1: Debrief

- Best option based on NAEPP & GINA: Initiate (S)MART with budesonide-formoterol 80/4.5 (2 puffs once daily and 1 puff as needed)
- Step up from step 2 (low dose ICS)→Step 3 (ICS-LABA)
- Step 3 preferred use of ICS LABA is SMART

- Evidence that ICS-formoterol as rescue decreases risk of progression to severe exacerbation, admission, death compared to SABA alone ***across all asthma severities***

Case 1: Debrief

- Change daily controller from fluticasone to ICS/LABA such as budesonide-formoterol or fluticasone-salmeterol and continue SABA as reliever—*A possible best answer*
  - *if ICS-formoterol is not covered by insurance*
  - *If insurance will not cover enough inhalers per month for SMART (OH, IN and KY Medicaid now cover!)*
  - *If family has difficulty understanding concept*
- Remember if using ICS-LABA that does not contain formoterol, albuterol is the rescue
- Increase daily maintenance med from low dose to medium dose ICS—Acceptable alternative

Case 1: Debrief

- If this child was well controlled, are changes needed? Yes

- NAEPP *DOES NOT* recommend increasing dose of ICS monotherapy with SABA during exacerbations
  (Low level of evidence supporting this practice)

- If well controlled, recommendation = continue daily low dose ICS and add SABA for rescue

Low, medium and high ICS doses: children 6-11 years

Children 6–11 years			
Inhaled corticosteroid	Total daily ICS dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100–200	>200–400	>400
Beclometasone dipropionate (pMDI, extrafine particle*, HFA)	50-100	>100-200	>200
Budesonide (DPI)	100–200	>200–400	>400
Budesonide (nebules)	250–500	>500–1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	>100-200	>200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	>100-200	>200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC); * see product information

GINA 2023, Box 3-14

Fluticasone Brand Alternatives 0-5 yrs

- Brand name Fluticasone taken off market 12/2024
- Children < 5 yrs typically need to take ICS with MDI/mask spacer
- Alternatives:
  - Mometasone (Asmanex) 50 MDI 1-2 puffs/daily low dose
  - Generic fluticasone 44 1 puff once daily low dose

DPI=dry powdered inhaler; ICS=Inhaled Corticosteroids

Fluticasone Brand Alternatives 6+ yrs

- Brand name Fluticasone taken off market 12/2024
  - Beclomethasone (Qvar™) Redihaler breath actuated 40, 80mcg
  - Budesonide (Pulmicort™) flexhaler DPI 90, 180mcg
  - Ciclesonide (Alvesco™) MDI 80, 160mcg doesn't fit many spacers
  - Fluticasone generic MDI 44, 110, 220mcg
  - Fluticasone generic diskus 50, 100, 250mcg
  - Fluticasone furoate (Arnuity™) ellipta DPI 50, 100, 200mcg 1 puff once daily
  - Fluticasone (ArmonAir™) respiclick or digihaler breath actuated 55, 113, 232mcg 1 p BID
  - Mometasone (Asmanex™) MDI 50, 100, 200mcg
  - Mometasone (Asmanex™) Twisthaler 110, 220mcg

DPI=dry powdered inhaler; MDI=Metered Dose Inhaler

Important (S)MART Points!!

- ICS/LABA must include *formoterol*
- **Maintenance** dose in SMART is 1-2 puffs
- Very low dose is 1 puff budesonide/formoterol 80/4.5
- Low dose is 1 puff budesonide/formoterol 160/4.5

- **Rescue** dose in SMART is 1 puff
- ***NO SMART FOR STEP 5 or Severe Asthma (this age group)***

More updates for ages 5 or 6-11 years

- *No specific amount of time between rescue doses for SMART*
- *Maximum number of puffs per day = 8 (age 5-11)*
- *Dose of ICS-formoterol is lower if using SMART*

STEP 4	SMART	NOT SMART	
Maintenance	Very low dose ICS-formoterol	Low dose ICS-formoterol	Medium dose ICS
Reliever	Very low dose ICS-formoterol *Max 8 puffs per day*	Albuterol prn	Albuterol prn

More updates for ages 5 or 6-11 years

- **Albuterol is the reliever UNLESS using SMART**
- Consider tiotropium at Step 4
- Step 4,5 refer for expert advice +/- biologic

Ages 5-6 to 11 Years: Step 4 Asthma Action Plan scenarios

Green Zone Take Symbicort 80/4.5 2 puffs twice daily

Rescue or Yellow Zone

Take Albuterol 4 puffs with spacer every 4 hours

OR ***SMART***

Green Zone Take Symbicort 80/4.5 1 puff twice daily

Rescue or Yellow Zone

Take Symbicort 80/4.5 1 puff as needed up to maximum of 8 puffs per day (including Green Zone puffs)

Ages 5 or 6 to 11 Years: Step 5 Asthma Action Plan scenarios

Green Zone Take Advair 230/21 1 puff twice daily

Rescue or Yellow Zone

Take Albuterol 4 puffs q 4 hours prn

OR

Green Zone Take Breo 100/25 1 puff once daily

Rescue or Yellow Zone

Take Albuterol 4 puffs q 4 hours prn

Recommendations by Age: Age 12 years and older

Case 2: 14-year-old female

- History of mild persistent asthma, well controlled on mometasone (Asmanex) 110mcg 1 puff twice daily (low dose ICS) and albuterol prn.
- Has mild exacerbations during Spring and Fall
- Has been worse this Winter and required one course of oral steroids
- *Is a change in therapy needed?*

≥ 12 years of age

New recommendations:

- **Steps 1-2: As needed low dose ICS + formoterol**
- **Steps 3, 4:**

  ICS-formoterol daily *AND* as needed = SMART

  OR

  Daily ICS-formoterol + albuterol

- **Step 5**: ICS-formoterol daily + LAMA + prn albuterol (NAEPP) or as needed ICS-formoterol (GINA)

  Add biologic

≥ 12 years of age

New recommendations:

- ICS-formoterol is preferred *reliever*
- ICS-formoterol is preferred *maintenance*

- This approach **reduces severe exacerbations across all treatment steps compared with using albuterol as reliever**

SMART in age 12+ years

- **Maintenance** dose in SMART is 1-2 puffs
- Starting dose is low dose budesonide-formoterol
- **Rescue** dose is always 1 puff of low dose budesonide-formoterol
- Maximum number of puffs per day is 12 puffs (including maintenance puffs)
- ***No specific amount of time between rescue doses for SMART***

More updates for ages 12+ years

STEP 4	SMART	NOT SMART	
Maintenance	Low dose ICS-formoterol	Low dose ICS-formoterol	Low ose ICS/LABA
Reliever	Llow dose ICS-formoterol *Max 8 puffs per day*	Albuterol prn	Albuterol prn

- If not using ICS-formoterol for maintenance→ albuterol should be reliever

Benefits of ICS/formoterol as reliever

- ICS-formoterol used as a reliever with or without maintenance ICS-formoterol is the preferred treatment approach for children 12+ years of age and adults.
- This approach **reduces severe exacerbations across all treatment steps compared with using albuterol as reliever**.

Age Based Doses for AIR & SMART

Step	Age (years)	Medication and strength (per 2 puffs of pMDI)	Dosage (number of puffs)
Steps 1-2 (AIR only)	6 - 11 12 - 17 >18	NO EVIDENCE TO DATE Budesonide-formoterol 160/4.5 Budesonide-formoterol 160/4.5	1 puff whenever needed
Step 3 ((S)MART)	6 – 11 12 - 17 >18	Budesonide-formoterol 80/4.5 Budesonide-formoterol 160/4.5 Budesonide-formoterol 160/4.5	1 puff once or twice daily (once daily for children), PLUS 1 puff whenever needed
Step 4 ((S)MART)	6 – 11 12 - 17 >18	Budesonide-formoterol 80/4.5 Budesonide-formoterol 160/4.5 Budesonide-formoterol 160/4.5	2 puffs twice daily (1 puff twice daily for children), PLUS 1 puff whenever needed
Step 5-6 ((S)MART)	6 – 11 12 - 17 >18	NOT RECOMMENDED Budesonide-formoterol 160/4.5 Budesonide-formoterol 160/4.5	2 puffs twice daily, PLUS 1 puff whenever needed

*Table adapted from GINA 2023, Box 3-15, p. 80. Available at *ginasthma.org*.

Low, medium and high ICS doses: adults/adolescents

Adults and adolescents (12 years and older)			
Inhaled corticosteroid	**Total daily ICS dose (mcg)**		
	Low	**Medium**	**High**
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (pMDI, extrafine particle*, HFA)	100–200	>200–400	>400
Budesonide (DPI)	200–400	>400–800	>800
Ciclesonide (pMDI, extrafine particle*, HFA)	80–160	>160–320	>320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100–250	>250–500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100–250	>250–500	>500
Mometasone furoate (DPI)			
Mometasone furoate (pMDI, standard particle, HFA)	200-400		>400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC); * see product information

GINA 2023, Box 3-14

Case 2: Debrief

- Patient is well controlled so no change in therapy is needed
- However new NAEPP guidelines offer an alternative therapy in children ≥ 12 years old with well controlled mild persistent asthma (Step 2)
  - As needed ICS + SABA taken together for symptoms (NAEPP)
  - Step down to ICS/formoterol as needed (GINA guidelines)
  - Not a good option for poor perceivers

≥ 12 years of age

(S)MART therapy preferred, but not the only option

- Daily low dose ICS-LABA with albuterol as reliever
- If any ICS-LABA other than ICS-formoterol is maintenance→ albuterol should be reliever
- Decision about implementing SMART should take multiple factors into account

Limitations to implementation of SMART

- *Intermittent ICS use may be less efficacious in patients with low or high perception of asthma symptoms*
  - Too rare or too frequent use of ICS

- Cost of medications/insurance coverage
- Need for increased volume of medication per month with SMART
- Patient/family preference
- Patient/family understanding
- Medication intolerance

Pros to implementation of SMART

- It uses a single inhaler for both maintenance and reliever which is less confusing for patients
- A patient's treatment can be stepped up or down according to clinical need without changing the medication or device.
- This cannot be done with any other ICS-LABA combination except ICS-formoterol.
- ICS-formoterol can also be used prior to exercise or allergen exposure.

Age 12+: Step 4
Asthma Action Plan scenarios

Green Zone Take Symbicort 160/4.5 2 puffs with spacer twice daily

Rescue or Yellow Zone

Take Albuterol 4 puffs with spacer every 4 hours

OR ***SMART***

Green Zone Take Symbicort 160/4.5 2 puffs with spacer twice daily

Rescue or Yellow Zone

Take Symbicort 160/4.5 1 puff as needed up to maximum of 12 puffs per day (including Green Zone puffs)

Age 12+: Step 4
Asthma Action Plan scenarios

Green Zone Take Breo 200 1 puff once daily

Rescue or Yellow Zone

Take Albuterol 4 puffs with spacer every 4 hours

OR ***SMART***

Green Zone Take Dulera 100/5 2 puffs with spacer twice daily

Rescue or Yellow Zone

Take Dulera 100/5 1 puff as needed up to maximum of 12 puffs per day (including Green Zone puffs)

New Management Strategy Reduces Risk

- ***Steps 1-2 (AIR only): low dose ICS-formoterol is used as needed for symptom relief without any maintenance treatment***.
  - **Reduces risk** of severe exacerbations and ED visits/admissions by **65% compared with SABA alone**
  - **Reduces risk** of severe exacerbations and ED visits/admissions by **37% compared to daily ICS with SABA as reliever.** Starting ICS-formoterol as reliever avoids training patients to regard SABA as their main asthma treatment.

- ***Steps 3-5 (S)MART):*** maintenance and reliever therapy with ICS-formoterol
  - **Reduces risk** of severe exacerbations **by 32% compared with the same dose of ICS-LABA**
  - **Reduces risk by 23% compared with higher dose ICS-LABA**
  - **Reduces risk by 17% compared with the usual care**
  - Concerns with poor perceivers

- (S)MART is also an option for children ages 6-11 in Steps 3-4

Summary of Major Changes

- No albuterol alone for asthma management even in mild asthma
- Mild asthma anti-inflammatory *reliever*:
  - 0-5yr: high dose ICS + albuterol x 7-10 days with URI (NAEPP & GINA)
  - 6-11yr: Low dose ICS + albuterol prn in step 1 (GINA)
  - 12+ yr: Low dose ICS-formoterol prn in steps 1,2 (GINA)
- (S)MART with ICS-formoterol in steps 3 & 4 in age > 5 (NAEPP & GINA) and Step 5 (GINA)

NAEPP Reliever Philosophy

- Albuterol alone as rescue in Step 1 for ages 5+
- Albuterol is preferred reliever except in SMART
- Doesn’t endorse as needed prn ICS + SABA until age 12 as alternative to daily low dose ICS + prn SABA
- Doesn’t endorse ICS-formoterol as reliever except as part of SMART
- (S)MART with ICS-formoterol in steps 3 & 4 in age ≥ 4

NAEPP and GINA Agree

If the patient is *well controlled* on current regimen that includes inhaled steroids as maintenance therapy and short acting beta-agonist as rescue,

THERE IS NO NEED TO ALTER THERAPY

DON'T ROUTINELY STEP-UP ICS DOSE in YELLOW ZONE (ONLY SMART APPROACH)

Caveats about (S)MART

- Evidence supports its use
- Must be ICS-formoterol
  - Budesonide-formoterol (Symbicort, Breyna)
  - Mometasone-formoterol (Dulera)
- Not necessarily the best regimen for all families or situations
  - Insurance may not cover ICS-formoterol
  - Insurance may not cover 2 ICS-formoterol inhalers (e.g. 1 for home, 1 for school) but OH, IN, KY Medicaid now do!
  - Maintenance dose of 2 puffs twice daily = 1 inhaler, need a 2nd inhaler to have any rescue puffs
  - Family preference, uncomfortable with paradigm shift
  - Child/family may be poor perceivers or overly anxious

Caveats about (S)MART

- Easiest scenario if insurance doesn't cover:
  - When maintenance is 1 puff twice daily
  - Child old enough to self carry at school or home schooled
- Workaround
  - Use ICS-formoterol (S)MART therapy at home
  - Have SABA available as rescue at school

References

- Global Initiative for Asthma (GINA) www.ginasthma.org
  - Pocket Guide
  - Slides
- National Asthma Education and Prevention Program (NAEPP) www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates
  - At-A-Glance-Guide
  - Clinician's Guide
- NAEPP updates: Cloutier, et. al. *JACI*, 2020

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Coffee with Colleagues

Asthma

Theresa Guilbert, MD

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