

New Approaches to Asthma Selection and Assessment Pre-Presentation Survey



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New Approaches to Asthma Treatment, Selection, and Assessment

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Therapeutic areas covered by PCRG include:

- Asthma
- COPD
- Infectious respiratory disease
- Tuberculosis
- Pleural and bronchial disorders



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Disclosures

- **Stephen Brunton, MD, FAAFP**, advisory board and speakers bureau for AstraZeneca, and the advisory board for Haleon.
- **Austin Ulrich, PharmD**, medical writer, and **Michael Hanak, MD**, CME Reviewer, have no disclosures to report.
- All relevant financial relationships have been mitigated.

Learning Objectives

At the end of this presentation, participants will be able to...

Select optimal inhaled therapy for asthma based on patient characteristics, clinical evidence, and guideline recommendations.

Evaluate asthma control and treatment response routinely using validated assessment tools.

Apply effective strategies for helping patients adhere to the treatment regimen.

Resource Toolkit

Additional asthma information

Links to resources

A PDF of this slide deck

A recording of this presentation

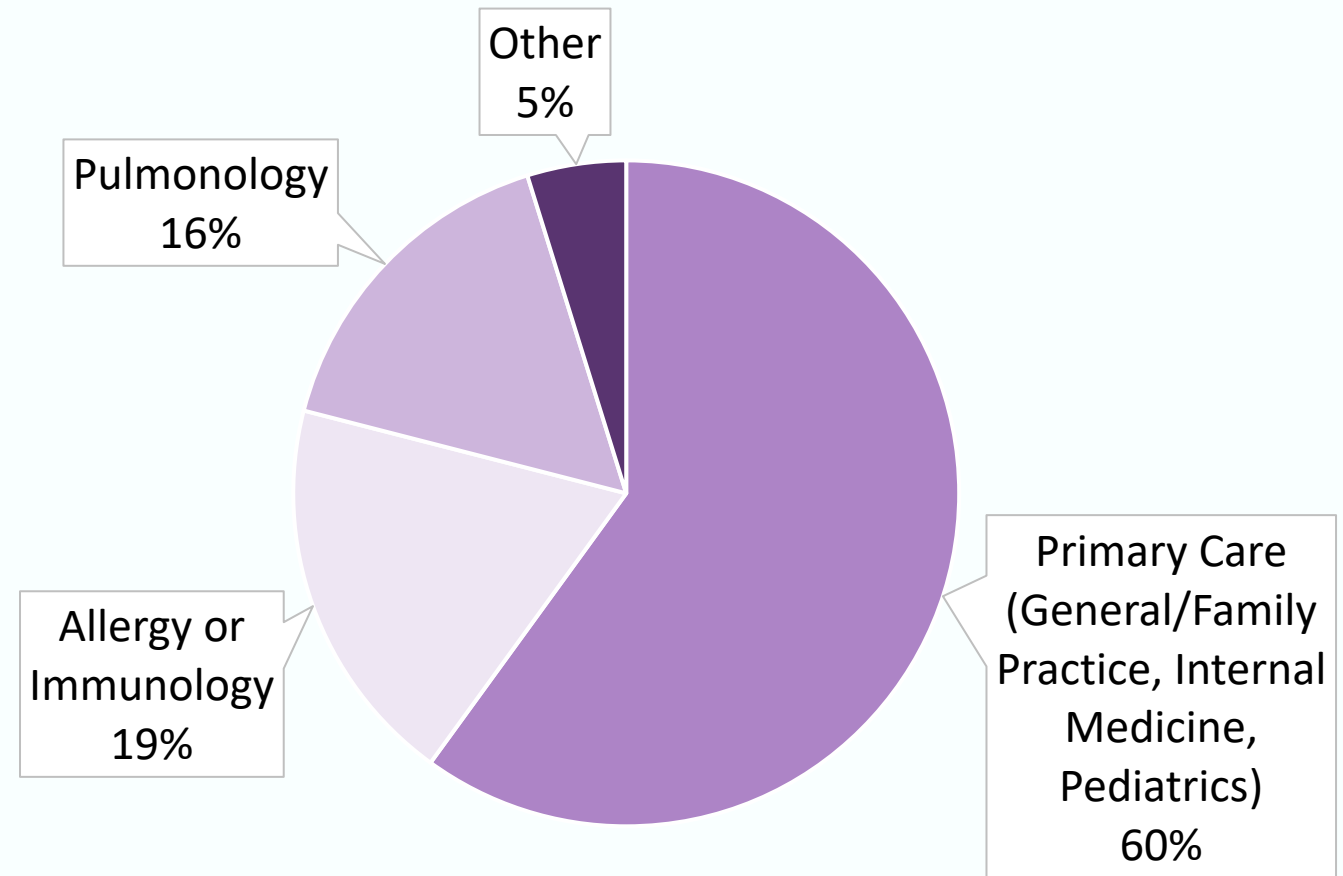


Visit <https://www.pcr-g-us.org/toolkit/newapproaches> or use the QR code to the right.

Asthma – The Role of PCCs

60% of all asthma visits conducted by PCCs

- The majority of patients with asthma can successfully be managed by PCCs



PCCs, primary care clinicians

Case #1

A 36-year-old female presents to her PCC for an asthma follow-up visit

- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection

What additional information do you need to assess this patient's asthma control?

Case #1 – Initial Assessment

A 36-year-old female presents to her PCC for an asthma follow-up visit

- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection
- She initially states that she is adherent to her medications
- She acknowledges that she often skips 1 of the 2 doses of her maintenance inhaler, and sometimes misses using the inhaler all together
- She says that the albuterol inhaler seems to really help her breathe better, so she carries this with her and uses it most days of the week

How would you assess this patient's asthma control?

Managing Asthma in Primary Care

International guidance: 2023 GINA Report

US Guidelines: NAEPP 2020

- Major components of asthma management:
 - Selection of initial therapy
 - Based on assessment of current asthma severity
 - Assessment of asthma control and risk of exacerbations
 - Adjusting therapy based on a stepwise approach

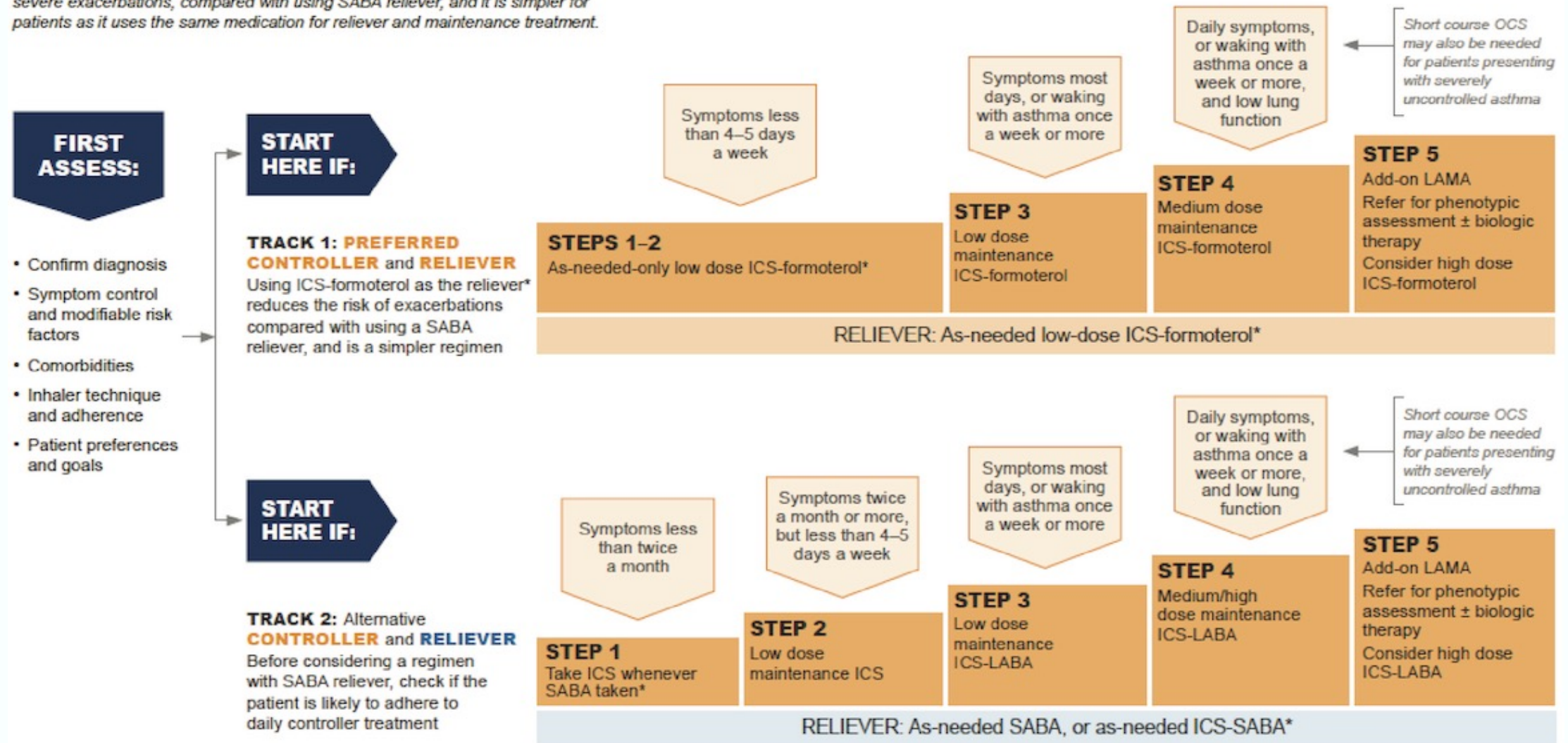
GINA, Global Initiative for Asthma; NAEPP, National Asthma Education and Prevention Program

Cloutier MM, et al. *J Allergy Clin Immunol*. 2020;146(6):1217-1270. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023.
Available from: www.ginasthma.org

GINA 2023 – STARTING TREATMENT in adults and adolescents with a diagnosis of asthma

Track 1 using ICS-formoterol reliever is preferred because it reduces the risk of severe exacerbations, compared with using SABA reliever, and it is simpler for patients as it uses the same medication for reliever and maintenance treatment.

GINA Treatment Approach



*Anti-inflammatory relievers (AIR)

ICS, inhaled corticosteroids; SABA, short-acting beta₂-agonist; LABA, long-acting beta₂-agonist; OCS, oral corticosteroids; LAMA, long-acting muscarinic antagonist

GINA Treatment Approach – Initial Assessment

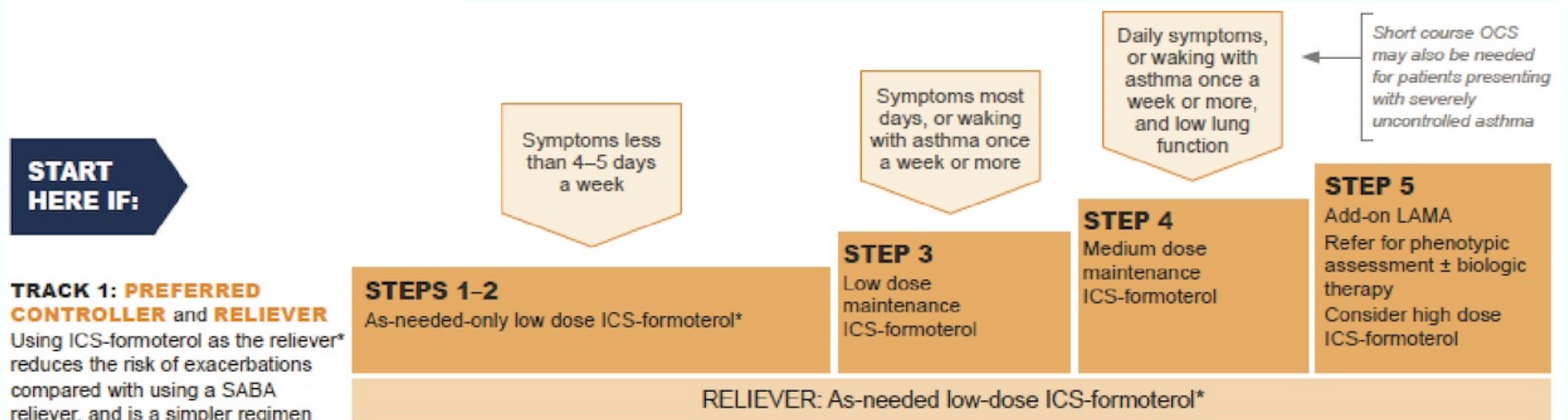
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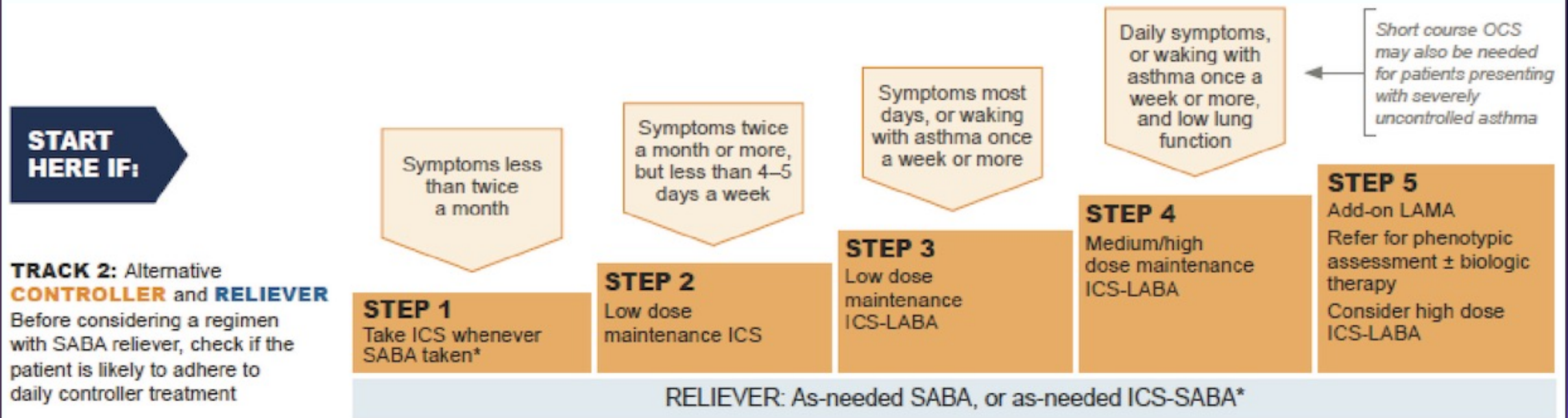
FIRST ASSESS:

- Confirm diagnosis
- Symptom control and modifiable risk factors
- Comorbidities
- Inhaler technique and adherence
- Patient preferences and goals

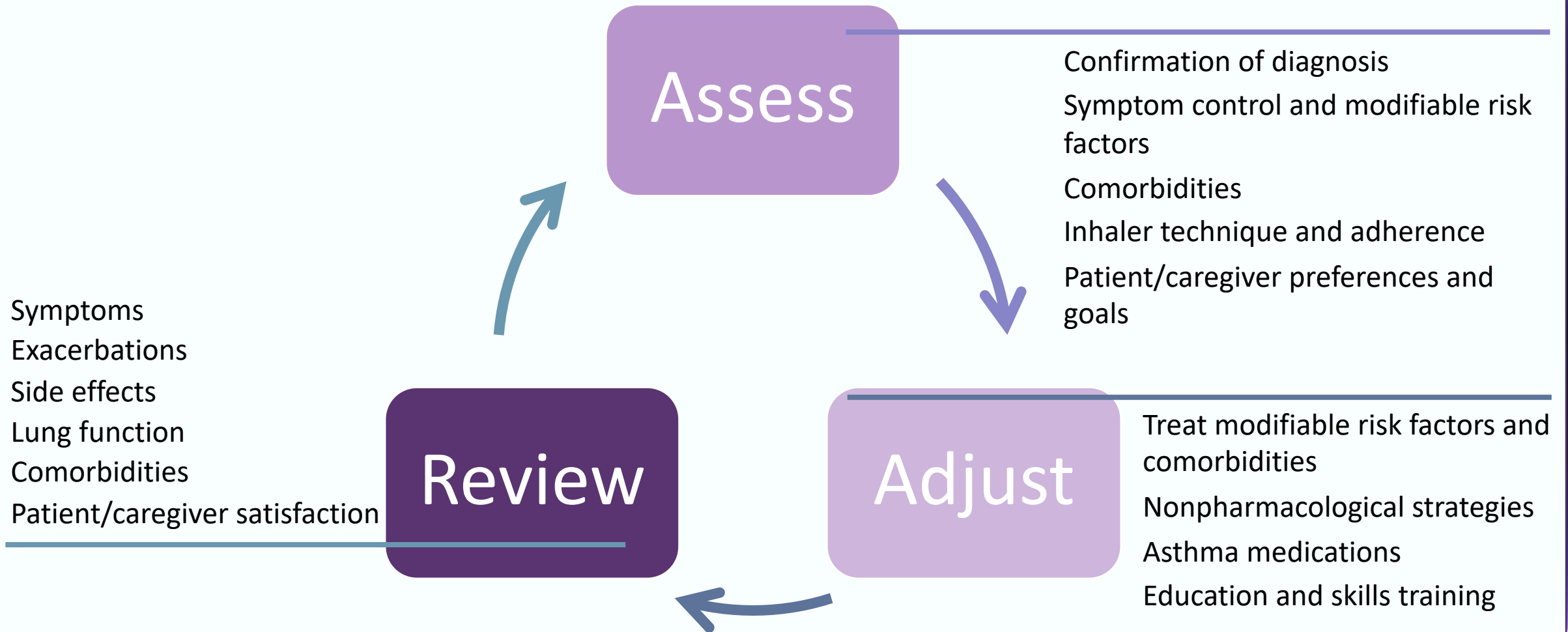
GINA Treatment Approach – Track 1



GINA Treatment Approach – Track 2



Ongoing Asthma Management Strategy (GINA)



Asthma – When to Refer

- While many patients with asthma can be successfully managed in primary care, it requires adequate training and equipment
- Specialist referral is warranted in some cases
 - Involving specialists (pulmonologists, allergists) can lead to improved outcomes for certain patients

Common Reasons for Specialist Referral

Suspected alternative pulmonary diagnosis

Unable to confirm asthma diagnosis by usual means

Suspicion of occupational asthma

Persistently uncontrolled disease

Severe disease requiring specialized therapy

Assessing Asthma Control

- Determining asthma control is essential for optimizing therapy and achieving treatment goals
 - Validated asthma assessment tools acknowledged in GINA and NAEPP
 - GINA and NAEPP each also have a separate set of questions to assess control
-
- GINA: symptom control should be assessed “at every opportunity”
 - NAEPP: periodic assessments at 1–6-month intervals and “ongoing”

Assessing Exacerbations

- Exacerbations are asthma episodes with a **progressive increase in symptoms and progressive decrease in lung function**
 - Represent a change from the patient's usual status sufficient to require a change in treatment
- Decrease in expiratory flow can be quantified by **lung function measurements**
- **Symptoms** are a sensitive measure of exacerbation onset
 - Small portion of patients with poor perception of airflow limitation may have significant lung function decline without change in symptoms - consider routine lung function monitoring, as this especially affects patients with a history of near-fatal asthma

Exacerbation Self-Management

- **All patients with asthma should receive self-management education**
- The written action plan includes specific instructions about rescue and/or maintenance medications, OCS, and how/when to access medical care
- For patients with an **anti-inflammatory reliever (ICS-formoterol or ICS-SABA), use of this inhaler should be the first step in the action plan** to reduce the risk of progressing to severe exacerbation and requiring OCS

Asthma self-management education requires:

- Self-monitoring of symptoms and/or lung function
- Written asthma action plan
- Regular medical review

Patients with Increased Risk of Fatal Exacerbation

Factors that increase the risk of asthma-related death

A history of near-fatal asthma requiring intubation and mechanical ventilation

Hospitalization or emergency care visit for asthma in the past year

Currently using or having recently stopped using oral corticosteroids

Not currently using ICS

Overuse of SABA, especially more than one canister per month

Poor adherence with ICS-containing medication

Poor adherence with, or lack of, a written action plan

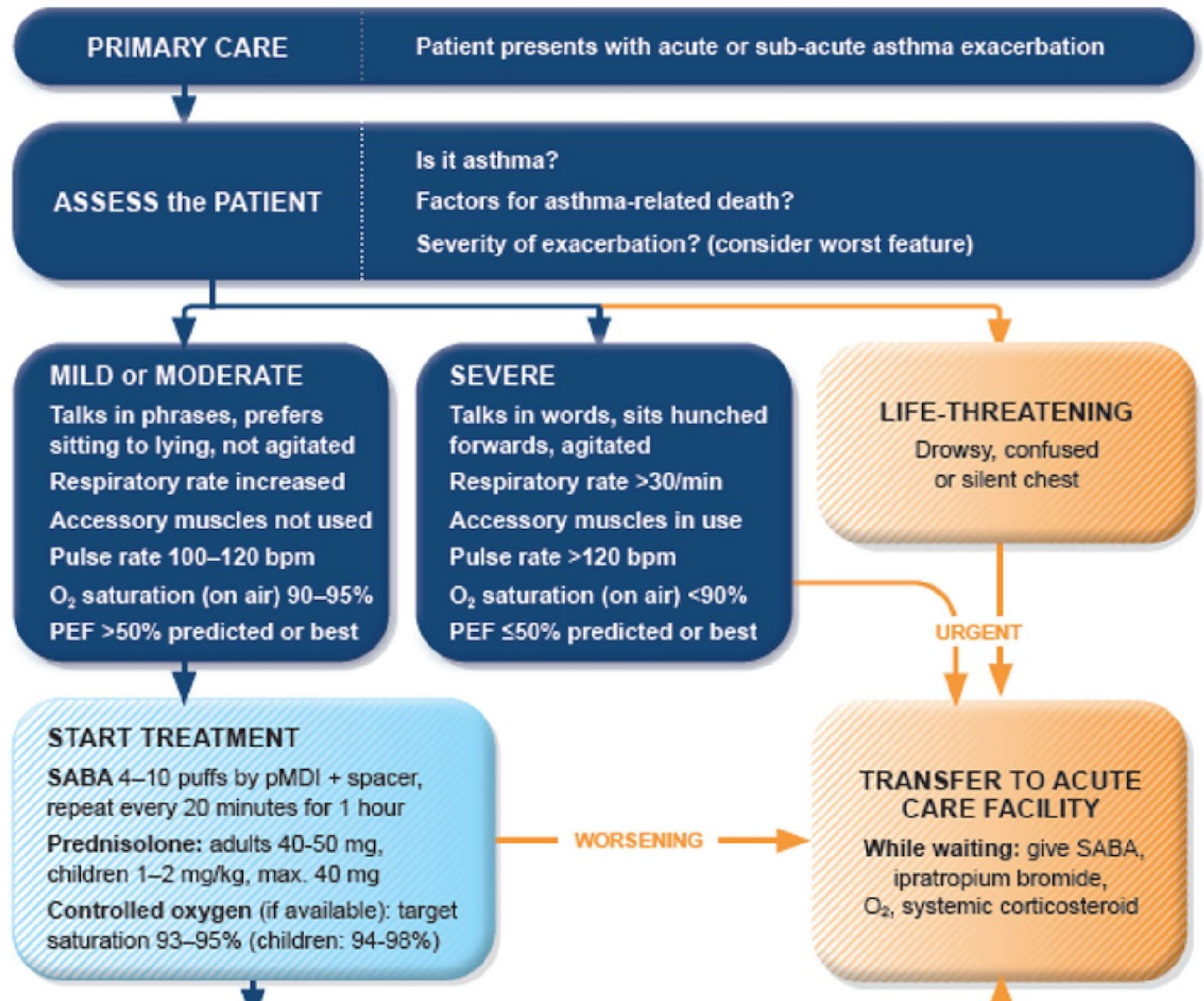
A history of psychiatric disease or psychosocial problems

Food allergy in a patient with asthma

Comorbidities such as pneumonia, diabetes, and arrhythmia

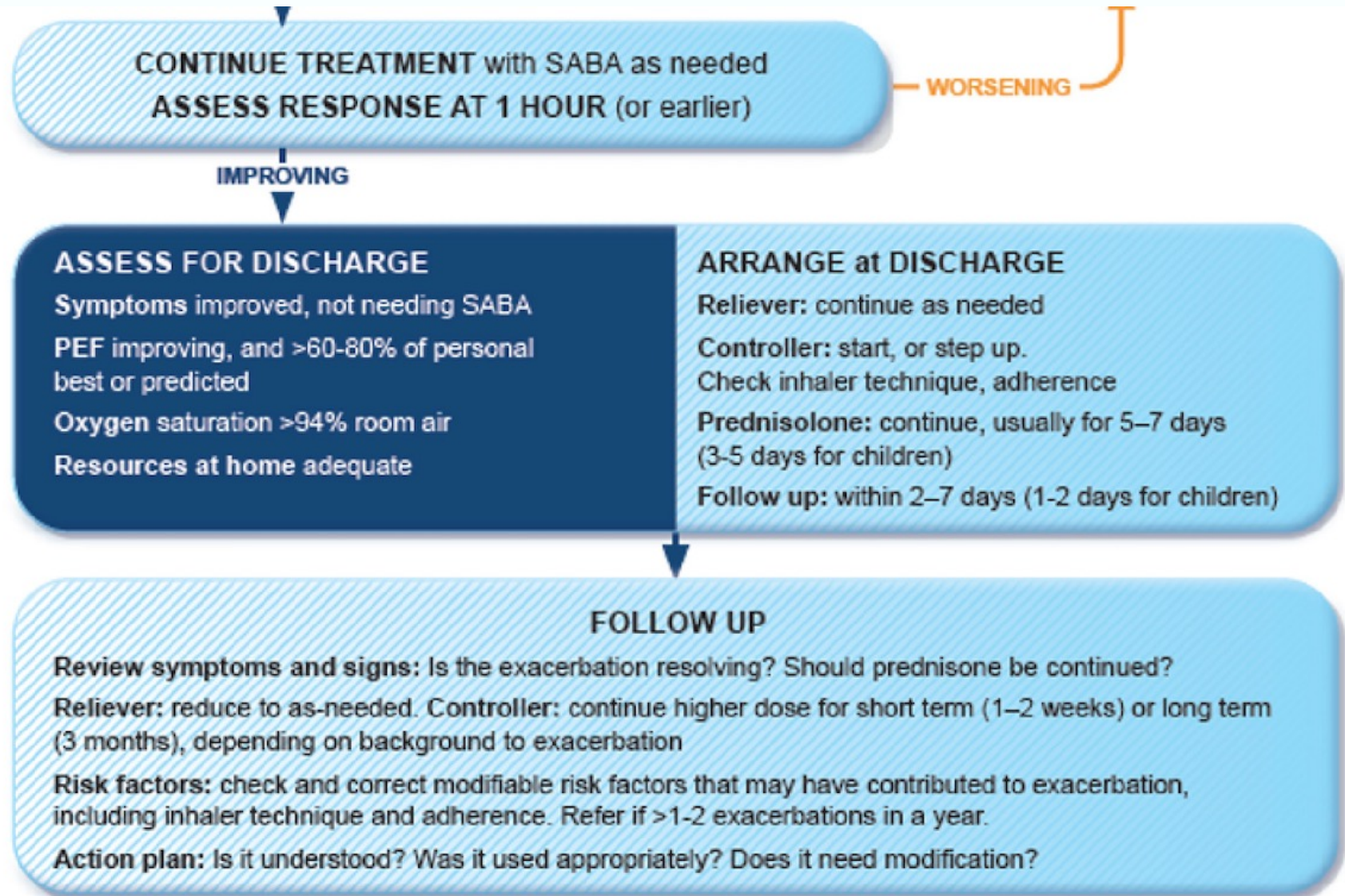
Patients with any of these factors should be encouraged to seek urgent medical care early in the course of an exacerbation

Managing Exacerbations in Primary Care - GINA



O₂, oxygen; PEF, peak expiratory flow

Managing Exacerbations in Primary Care – GINA (cont)



Preventing Asthma Exacerbations

Preventing exacerbations is a key outcome for treating asthma

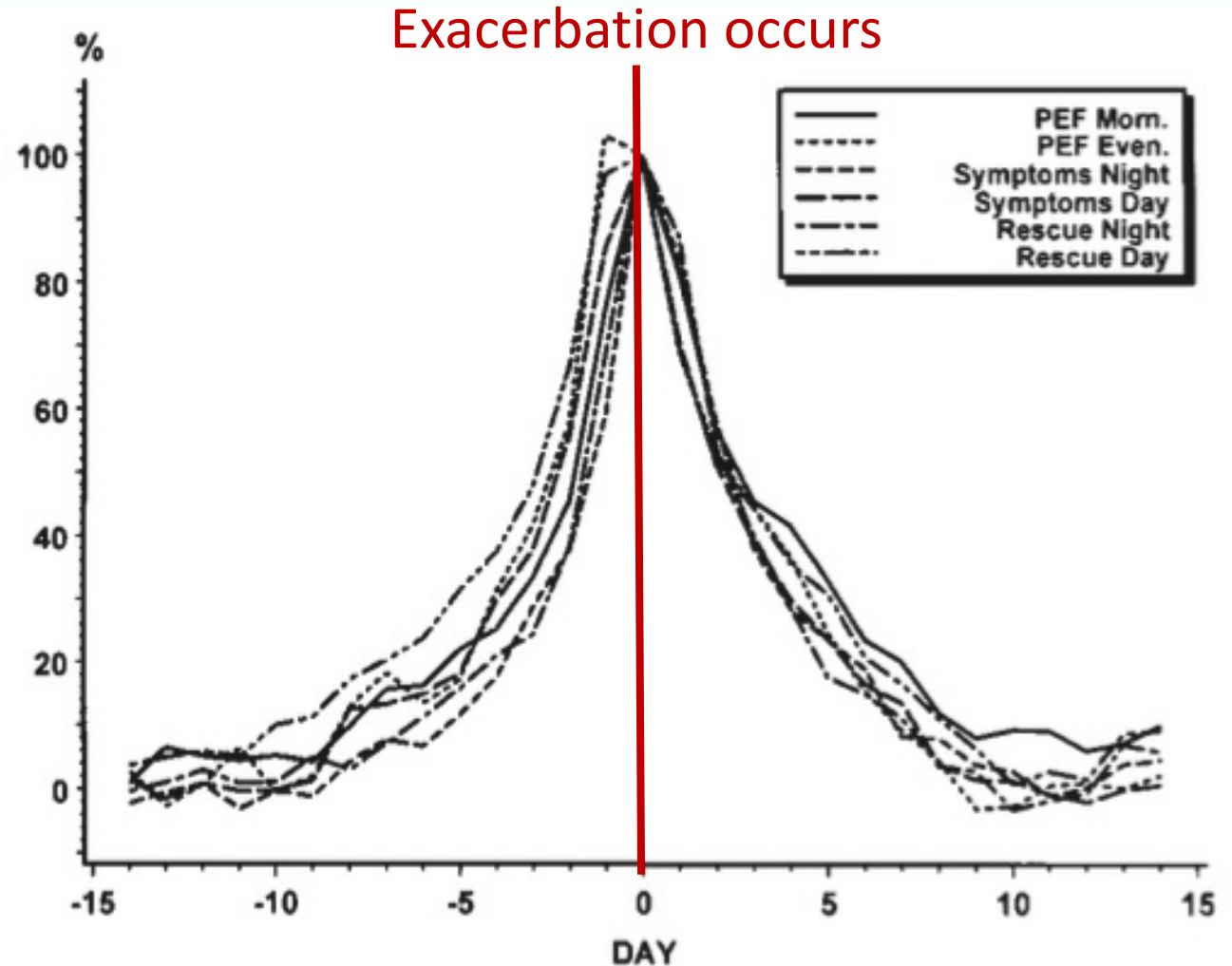
- Fewer exacerbations leads to:
 - Fewer visits to the emergency department
 - Lower rates of hospitalization
 - Lower mortality rates
 - Improvement in quality of life
- Regular ICS use leads to reductions in exacerbations across asthma severity levels
- Adding a fast-acting bronchodilator to ICS as rescue or maintenance and rescue therapy has demonstrated additional benefit

Preventing Asthma Exacerbations: The Window of Opportunity

10-14 days before an exacerbation:

- Peak expiratory flow worsens
 - (inverse relationship shown in figure)
- Symptoms increase
- SABA use increases

The time leading up to an exacerbation may offer a window of opportunity to mitigate exacerbation occurrence or severity with anti-inflammatory therapy (ICS)



Disparities in Asthma Care

The burden of asthma uniquely affects patients across different age, socioeconomic, and minority groups

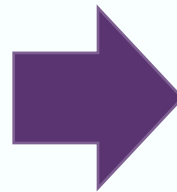
- Black and/or Hispanic/Latinx individuals of Puerto Rican origin have the highest rates of asthma and the highest asthma death rates in the US
- Black individuals are nearly 3 times more likely to die from asthma than White individuals
- Refugees and other immigrants face unique barriers in accessing the health care system
 - Language barriers
 - Lack of familiarity with the health care system
 - Cultural barriers, such as misinformed fears of ICS being addictive

Addressing Disparities – Challenges and Solutions

Clinicians

Challenges

- Availability of asthma specialist care
- Linguistic and cultural competency
- Limitations from payors



Solutions

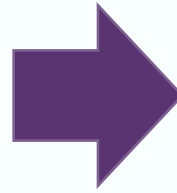
- Assess access of specialist asthma care
- Telemedicine and technology use
- Improve medication coverage

Addressing Disparities – Challenges and Solutions

Patients

Challenges

- Treatment preferences
- Adherence issues
- Limited health literacy
- Social environment
- Economic instability
- Health behavior
- Risk behavior



Solutions

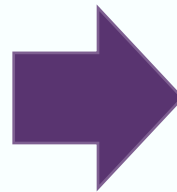
- Telemedicine
- Care coordination
- Referral to local services
- Improve opportunities for higher education and employment
- Improve access to social work services

Addressing Disparities – Challenges and Solutions

Health Care System

Challenges

- Medication coverage
- Asthma health literacy
- Limited access to quality asthma services
- Inequitable receipt of care



Solutions

- Care coordination
- Collaborate with pharmaceutical agencies
- Combat implicit and explicit bias
- Address health equity
- Enhance community-based programming
- Telemedicine

Access to Asthma Care and Treatments

- Free clinics often available to patients who are uninsured or underinsured
- Many pharmaceutical companies offer financial assistance programs for asthma medications that have high out-of-pocket cost
- Increased focus on adherence to therapy
 - May be improved by digital health interventions and telemedicine
 - More frequent touchpoints
- Community-based asthma education programs can improve health literacy and cultural competency

Case #2 – Patient with commercial insurance

48-year-old female with moderate asthma (GINA Step 4)

- Insured commercially through her employer-sponsored insurance
 - Prescription insurance coverage
 - \$50 co-pay for preferred brand medications
- Currently prescribed medium-dose maintenance ICS-LABA
- Presents with complaints of worsening shortness of breath
- Asks for a refill of her albuterol inhaler

What might contribute to problems with medication access for this patient?

How could her asthma regimen be optimized to better align with current evidence?

Case #2 – Patient with commercial insurance

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- Currently prescribed medium-dose maintenance ICS-LABA
- Presents with complaints of worsening shortness of breath
- Asks for a refill of her albuterol inhaler
- Further investigation finds that she only uses her ICS-LABA 2-3 times a week because she doesn't like paying \$50 every time she picks up the ICS-LABA inhaler, and albuterol is less expensive

What could you do to improve this patient's medication access for the ICS-LABA inhaler?

Case #3 – Patient with government insurance

70-year-old Black female with mild asthma (GINA Step 2)

- Has Medicare Part D prescription insurance
 - \$50 copay for preferred brand medications
- Currently prescribed low-dose ICS and as-needed SABA
 - Instructed to take her ICS when she uses her SABA
 - Says she follows her regimen as prescribed
- She states that she's having trouble affording her ICS inhaler because she's on a fixed income
- She expresses concern that she'll be "treated differently because of her situation"

What asthma care disparities does this patient have (or is at risk for)?

How could you improve her access to her asthma treatments?

Case #4 – Patient without insurance

35-year-old Hispanic male with moderate asthma (GINA Step 3)

- Presents to your federally-qualified health center (FQHC) to establish care; he has been in the US for about 3 years
- His asthma has not been well-managed previously
 - Several emergency department visits in the last 3 months
- He's currently not taking any asthma medication because his inhalers have all run out, including those he received at the hospital
- He's feels that in the past, his "doctors haven't paid enough attention to his health"

What asthma care disparities does this patient have (or is at risk for)?

What regimen might you consider for this patient's asthma, and how could you help ensure access to treatments?

Improving Adherence: Patient Perspectives

- **Emphasize clinician-patient collaboration**
 - Patients who are educated and engaged have reduced asthma morbidity^{1,2}
 - Shared decision-making associated with better adherence and asthma outcomes³
- **INSPIRE – 3415 adults with asthma asked about their perceptions of treatment⁴**
 - Most patients (90%) wanted treatments that work quickly
 - About 74% used a SABA daily despite being prescribed maintenance therapy
 - 38% thought they didn't need to take asthma medication daily when they were feeling well
- **Patients often prefer symptom-driven treatment, creating a paradox**
 - Historically, SABA-only rescue therapy has been the main symptom-driven treatment
 - Does not help decrease exacerbations if used without ICS

The Importance of ICS in Rescue/Reliever Therapy

ICS have both nongenomic and genomic anti-inflammatory effects

- Both contribute to role for lowering airway inflammation related to an exacerbation

Nongenomic Effects (Rapid onset – seconds to minutes)	Genomic Effects (Delayed onset – 4–24 hours)
Decreased airway mucosal blood flow	Increased transcription of anti-inflammatory genes Decreased transcription of inflammatory genes
Decreased airway edema	
Immune cell activity modulation	
Potentialiation of bronchodilator effects	

The Role of ICS + Fast-acting Bronchodilator

Budesonide-formoterol studies

- Budesonide-formoterol as a fixed-dose combination inhaler evaluated for use as rescue and rescue and maintenance therapy across asthma severities
- Compared with PRN SABA, budesonide maintenance therapy, or budesonide-formoterol maintenance therapy with PRN SABA:
 - Reduced ICS exposure
 - Better symptom control
 - Improved lung function
- Collectively, trials demonstrate reductions in asthma exacerbations with PRN budesonide-formoterol compared to PRN SABA alone

Formoterol is considered a LABA; however, onset of action is within 3 minutes

Budesonide-formoterol is not currently FDA-approved for PRN use in the US

The Role of ICS + Fast-acting Bronchodilator

Select budesonide-formoterol studies

SYGMA Trials (mild asthma)

SYGMA 1

- 65% reduction in annualized exacerbation rate compared to PRN terbutaline
- Equally effective as budesonide maintenance therapy for preventing exacerbations
- Post-hoc analysis: a single day of treatment with ≥ 2 PRN inhalations of budesonide-formoterol reduced short-term risk of severe exacerbations

SYGMA 2

- Equally effective compared to budesonide maintenance therapy for preventing exacerbations
- 75% reduction of inhaled corticosteroid exposure

Note: Although most maintenance and rescue therapy studies of ICS + fast-acting bronchodilator were conducted with budesonide-formoterol, mometasone-formoterol is also an ICS + fast-acting bronchodilator combination inhaler. It also lacks approval for PRN use in the US.

ICS + SABA Studies

PREPARE Trial

Adults with moderate-to-severe asthma

Randomly assigned to:

- Patient-activated ICS + SABA for rescue therapy along with usual maintenance therapy
- or
- Usual maintenance or SABA for rescue therapy along with usual maintenance therapy

Patients who were instructed to take ICS every time they used rescue therapy had a **lower annualized rate of severe exacerbations** than the control group (HR 0.85; 95% CI 0.72–0.999; $P = .048$)

Intervention group also had better asthma control and fewer missed days of work, school, and usual activities

ICS + SABA Studies

MANDALA Trial

Note: all data are from the pre-planned efficacy analysis

3132 adolescent and adult patients with moderate-to-severe asthma

Key patient groups:

- PRN fixed-dose combination of albuterol 180 mcg + budesonide 160 mcg along with routine therapy
- PRN albuterol 180 mcg along with routine therapy

Patients in the fixed-dose group compared to albuterol-alone group experienced:

- 27% reduction in risk of severe exacerbations (HR 0.73; 95% CI 0.61–0.88)
- Lower mean annualized total dose of SCS (86.2 ± 262.9 mg prednisone equivalents versus 129.3 ± 657.2 mg)
- Improvement in asthma control (ACQ; OR, 1.22; 95% CI, 1.02 to 1.47)
- Improved asthma-related quality of life (AQLQ+12; OR, 1.23; 95% CI 1.02–1.48)

AQLQ+12, Asthma Quality of Life Questionnaire validated for persons ≥ 12 years of age

ICS + SABA Studies

DENALI Trial

989 patients aged ≥ 12 years with mild-to-moderate asthma

Patients were randomized 1:1:1:1:1 for 12 weeks to receive four-times-daily:

- Fixed-dose combination of albuterol 180 mcg + budesonide 160 mcg
 - Fixed-dose combination of albuterol 180 mcg + budesonide 80 mcg
 - Albuterol 180 mcg
 - Budesonide 160 mcg
 - Placebo
-
- Change from baseline in FEV_1 AUC_{0-6h} over 12 weeks was greater with albuterol-budesonide 180/160 mcg vs budesonide 160 mcg ($P = .003$)
 - Change in trough FEV_1 at week 12 was greater with albuterol-budesonide 180/160 and 180/80 μg vs albuterol 180 μg ($P < .001$)
 - Both monocomponents contributed to albuterol-budesonide lung function efficacy

FEV_1 , forced expiratory volume in 1 second; AUC, area under the curve

FDA Approval of Albuterol/Budesonide

January 2023

- The FDA approved the combination inhaler albuterol/budesonide “for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older.”
- **Strength:** albuterol 90 mcg and budesonide 80 mcg per inhalation
- **Dosing:** 2 inhalations as needed for asthma symptoms
 - Maximum dose: 12 inhalations in 24 hours
- Current availability and place in therapy to be determined
- Will be an option for ensuring patients have an ICS with their rescue/reliever treatment
- The approval fills a long-time gap in asthma management in the US

Case #1 – Initial Assessment (revisited)

A 36-year-old female presents to her PCC for an asthma follow-up visit

- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection
- She initially states that she is adherent to her medications
- She acknowledges that she often skips 1 of the 2 doses of her maintenance inhaler, and sometimes misses using the inhaler all together
- She says that the albuterol inhaler seems to really help her breathe better, so she carries this with her and uses it most days of the week

How would you assess this patient's asthma control?

Case #1 – AIRQ Results

A 36-year-old female presents to her PCC for an asthma follow-up visit

- The patient's AIRQ score is 4, indicating not well-controlled



Case #1 – Treatment Approach

A 36-year-old female presents to her PCC for an asthma follow-up visit

- Currently taking a medium-dose ICS maintenance inhaler (two doses per day) along with an albuterol rescue inhaler
- Has had two urgent care visits in the last year for asthma exacerbations, one of which was during a concomitant upper respiratory infection
- She initially states that she is adherent to her medications
- She acknowledges that she often skips 1 of the 2 doses of her maintenance inhaler, and sometimes misses using the inhaler all together
- She says that the albuterol inhaler seems to really help her breathe better, so she carries this with her and uses it most days of the week

How would you approach discussing the patient's treatment regimen?

Case #1 – Evaluating Treatment Response

A 36-year-old female presents to her PCC for an asthma follow-up visit

- You decide to continue the medium-dose ICS maintenance inhaler and prescribe ICS-SABA instead of her albuterol inhaler for improved symptom control and to reduce the risk of severe exacerbations
- She comes back for a follow-up visit 3 months later

How would you assess the patient's response to therapy?

Case #1 – Follow-up AIRQ Results

A 36-year-old female presents to her PCC for an asthma follow-up visit

- The patient's follow-up AIRQ score is 1, indicating well-controlled



Summary and Key Takeaways

- Most asthma visits (60%) are conducted in primary care – PCCs play a significant role in asthma management
- The GINA 2023 Report provides the most updated guidance for asthma care based on current evidence
- GINA step therapy approaches emphasize the use of ICS with SABA for rescue/reliever therapy
- Several validated tools are available to assess asthma control
- Early intervention with ICS can prevent asthma exacerbations
- Disparities in asthma care contribute to different risks based on age, socioeconomic status, and among minority groups

Summary and Key Takeaways (cont)

- Solutions for addressing disparities from the perspective of clinicians, patients, and the healthcare system can improve asthma care equity
- Options for improved access to asthma care and treatments include government-subsidized care settings, copay cards, and patient assistance programs
- There is a large body of evidence supporting the use of a fast-acting bronchodilator + ICS combination to reduce exacerbations
- FDA approval of albuterol/budesonide represents the first approval of a fast-acting bronchodilator + ICS combination inhaler indicated for as-needed therapy to reduce the risk of exacerbations

Reminder:

Resource Toolkit

Additional asthma information
Links to resources
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A recording of this presentation



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<https://www.pcr-g-us.org/survey/post/approaches3>