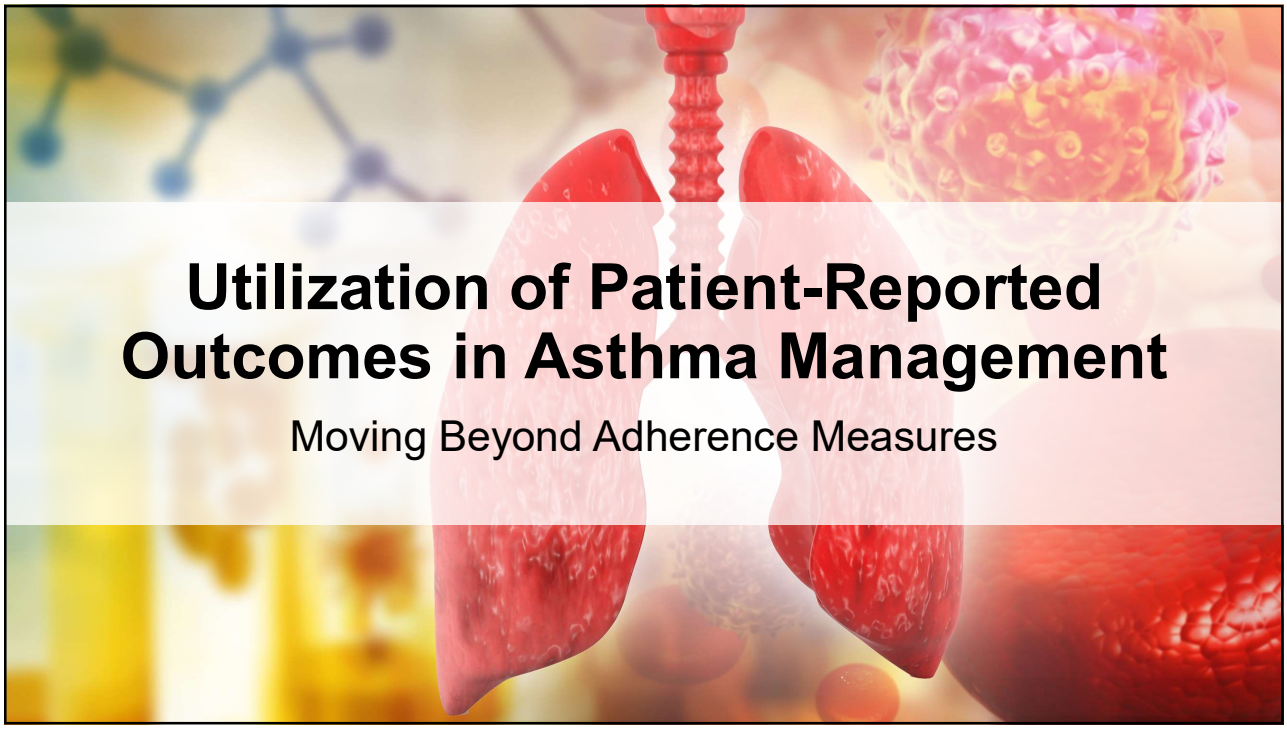

Utilization of Patient-Reported Outcomes in Asthma Management

Moving Beyond Adherence Measures

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Postgraduate Healthcare Education, LLC
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Sanofi Genzyme and Regeneron Pharmaceuticals.

Faculty

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Chief Clinical Officer
Therigy, LLC
Maitland, FL

Dr. Lily Duong is the Chief Clinical Officer at Therigy. She has dedicated the more than 20 years of her pharmacy career to specialty pharmacy services, clinical programs, and outcome measures. Lily provides clinical expertise and oversees the development team on drug therapy management and outcome reporting for multiple disease states.

Before joining Therigy in 2013, Lily held a variety of upper management positions and served on the Therapeutic Assessment Committee at Express Scripts. Lily received both her BS and PharmD degrees from Temple University School of Pharmacy and completed residencies at hospitals and clinics in New Jersey and New York City.

Faculty

Darrell Hulisz, PharmD, RPh
Associate Professor
Department of Family Medicine & Community Health
Case Western Reserve University, School of Medicine
Cleveland, OH

Dr. Darrell Hulisz is Associate Professor of Family Medicine and Community Health in the School of Medicine at Case Western Reserve University in Cleveland, Ohio. He also holds a clinical faculty appointment at Ohio Northern University College of Pharmacy and practices as a clinical pharmacy specialist with University Hospitals Medical Group, Family Medicine Residency Program.

Darrell received his BS in Pharmacy from the University of Toledo and his PharmD from the Medical University of South Carolina. He has published over 70 papers, has lectured extensively, and has served as an investigator in several clinical trials.

Faculty

Meghann Randolph, PharmD
Ambulatory Retail Clinical Pharmacist
Specialty Pharmacy & Infusion Services
University of Kentucky
Lexington, KY

Dr. Meghann Randolph is a Clinical Pharmacist at the University of Kentucky Specialty Pharmacy in Lexington. She completed a BS in Chemistry at Morehead State University, followed by a PharmD at the University of Kentucky College of Pharmacy. She is currently pursuing an MBA at the University of Kentucky Gatton College of Business and Economics.
Since joining the University of Kentucky Specialty Pharmacy, Meghann has worked in a variety of disease states, including bleeding disorders, cardiology, and asthma/immunology. Her research interests include assessing specialty pharmacy's impact on patient adherence, prevention of disease complications, and access to specialty medications.

Disclosures

Drs. Duong, Hulisz, and Randolph state that they have no relevant affiliation or financial relationship or relationship to products or devices with a commercial interest related to the content of this activity to disclose.

The clinical reviewer, **Dennis Williams, PharmD**, BCPS, AE-C has disclosed that his spouse is employed by and he owns stock in GlaxoSmithKline.

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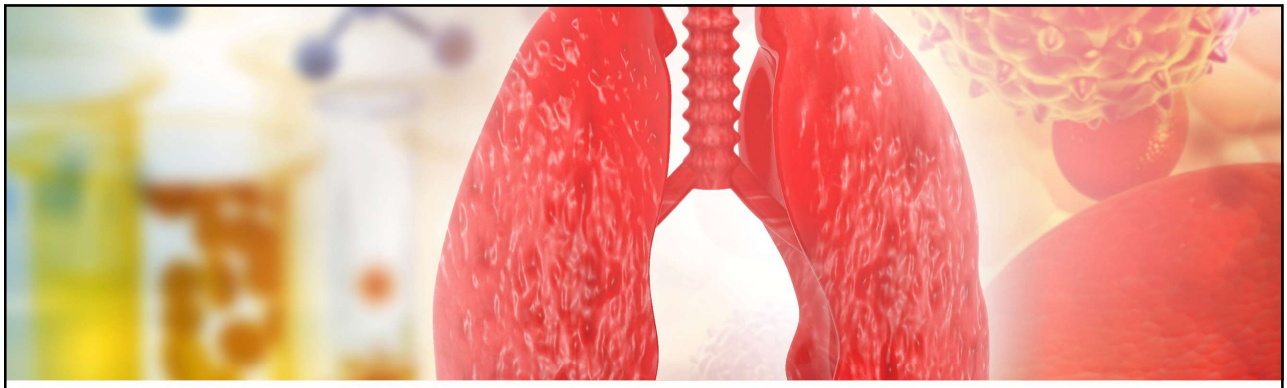


Asthma Overview

Darrell Hulisz, PharmD, RPh

Learning Objectives

- **Describe** asthma's ideal clinical value compass of medical outcomes, patient satisfaction, functional status, and cost
- **Compare** adherence monitoring programs and outcomes measurement programs for asthma, and explain the need to have both types of programs
- **Analyze** outcomes measurement programs for asthma and how they represent an important expansion to adherence monitoring programs
- **Select** appropriate measures for healthcare plans that move patients who have asthma toward realistic, achievable outcomes
- **Use** patient-reported outcomes data to tailor treatment for patients who have asthma

Asthma Defined

- Asthma is a heterogeneous disease characterized by chronic airway inflammation
- It is defined by a history of respiratory symptoms such as wheeze, dyspnea, chest tightness, and cough that vary over time and in intensity
- Patients have variable expiratory airflow limitations
- Symptomatic episodes are often triggered by factors such as exercise, allergen or irritant exposure, change in weather, or viral respiratory infections
- Airway inflammation leads to bronchial hyper-responsiveness to these various triggers and is variable over time

Asthma Epidemiology

- Asthma affects approximately 300 million individuals worldwide

In the United States…

- 19.2 million adults (aged 18 years and over) have asthma
  - 7.7% of U.S. adults
- 5.5 million patients with asthma are under 18 years of age
  - 7.5% of U.S. children
- 10.6 million individuals experienced an asthmatic episode during the previous 12 months
  - 3.8 million were children
- Each year, asthma causes:
  - 10.5 million physician office visits
  - 1.8 million hospitalizations
  - Approximately 5,000 deaths

Centers for Disease Control. Asthma Facts 2018. https://www.cdc.gov/nchs/fastats/asthma.htm
Morris MJ, Pearson DJ. Asthma Treatment and Management – Medscape, Dec 2019. Available at: https://emedicine.medscape.com/article/296301
Global Initiative for Asthma. 2020 Main GINA Report, Global Strategy for Asthma Management and Prevention. https://ginasthma.org/gina-reports/

Asthma Epidemiology

- Asthma prevalence, especially morbidity and mortality, is higher in blacks than in whites in the U.S.
- Genetic factors help determine a predisposition to the development of asthma, but environmental factors play an important role in asthma onset
- Increased morbidity in ethnic minorities is seen in the U.S. and is multifactorial
- Larger asthma-associated lung function deficits are reported in Hispanics, especially females

Asthma Epidemiology

- Atopy (genetic predisposition to develop specific IgE antibodies against common allergens) is the strongest identifiable risk factor for the development of asthma
- Numerous environmental risk factors also exist
- Most asthma cases are diagnosed before the patient is 18 years old
- Children living in poverty and/or inner cities have higher rates of hospitalizations and mortality from asthma
- Children miss 13.8 million days of school each year due to asthma

Pathophysiology and Pathogenesis of Asthma

- Usually associated with airway hyper-responsiveness to direct or indirect stimuli with chronic airway inflammation
- Both airway hyper-reactivity and inflammation persist even when symptoms are absent or lung function is normal
- Asthma phenotypes are recognizable clusters of demographic, clinical, and pathophysiological characteristics used to help guide management
- Airway inflammation involves cells (eosinophils, lymphocytes, mast cells, and neutrophils) and is commonly initiated by allergen-dependent release of histamine and other mediators

Pathophysiology and Pathogenesis of Asthma

- In atopic asthma, responses are mediated by allergen-specific IgE, which is generated during allergic sensitization, bound to mast cells, and activated by re-exposure to allergen
- Elevated levels of pro-inflammatory cytokines IL-4, IL-5, and IL-13 are observed in asthmatics
- Airway inflammation leads to airway obstruction by promoting mucosal infiltration, edema, mucus secretion, and airway hyper-responsiveness
- Neutrophil infiltration and activation contribute to the severity of uncontrolled and severe asthma

IL, interleukin.

Characterizing Asthma Patients at Baseline

▪Components of Severity		▪Classification of Asthma Severity (Youths ≥12 of Age and adults)			
		▪Intermittent	▪Persistent		
			▪Mild	▪Moderate	▪Severe
▪Impairment	▪Symptoms	▪≤2 days/week	▪>2 days/week but not daily	▪Daily	▪Throughout the day
	▪Nighttime awakenings	▪<2x/month	▪3-4x/month	▪>1x/week but not nightly	▪Often 7x/week
▪Normal FEV_1/FVC: ▪ 8-19 yr 85% ▪20-39 yr 80% ▪40-59 yr 75% ▪60-80 yr 70%	▪Short-acting $beta_2$-agonist use for symptom control	▪≤2 days/week	▪>2 days/week but not daily, and not more than 1x on any day	▪Daily	▪Several times per day
	▪Interference with normal activity	▪None	▪Minor limitation	▪Some limitation	▪Extremely limited
	▪Lung function	▪ Normal FEV_1 between exacerbations ▪ FEV_1 >80% predicted ▪ FEV_1/FVC normal	▪ FEV_1 <80% predicted ▪ FEV_1/FVC normal	▪ FEV_1 >60% but <80% predicted ▪ FEV_1/FVC reduced 5%	▪ FEV_1 <60% predicted ▪ FEV_1/FVC reduced >5%
▪Risk	▪Exacerbations requiring OSC	▪ 0-1/year	▪≥2/year		
		▪Consider severity and interval since last exacerbation. ▪Frequency and severity may fluctuate over time for patients in any severity category. ▪Relative annual risk of exacerbations may be related to FEV_1.			
▪Recommended Step for Initiating Therapy		▪ Step 1	▪Step 2	▪Step 3	Step 4 or 5 and consider short course of systemic corticosteroids
		▪In 2-6 weeks, evaluate level of asthma control that is achieved, and adjust therapy accordingly.			

National Asthma Education and Prevention Program, National Heart, Lung, and Blood Institute (NHLBI). Expert panel report 3: guidelines for the diagnosis and management of asthma. NHLBI https://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf

Pharmacist's Role in Assessing Asthma Patients

- Goals include symptom relief, minimal use of SABA rescue, maintenance of normal activity, and prevention of asthma exacerbations
- Measures of the following are recommended:
  - Signs and symptoms of asthma
  - Pulmonary function (peak flow demonstration)
  - Quality of life/functional status
  - History of asthma exacerbations
  - Pharmacotherapy review
  - Adherence, potential side effects
  - Proper inhaler technique
  - Discussion of patient follow-up plan

SABA, short-acting beta$_2$ agonist.

Asthma Triggers and Environmental Control

- Aeroallergens: pollens, molds, dust mite antigen, cockroach allergen, animals (especially cats)
- Irritants: cigarette smoke, spray cleaners, colognes
- Nonspecific stimuli: changes in weather, exercise
- Infections: viral and bacterial URIs
- Others: sulfites, shellfish, aspirin, NSAIDs, ACE-Is, misoprostol, wood dusts, flour dust, latex

✓*Strict environmental control measures must become a cornerstone for treating asthma*

✓*Address any comorbid conditions: GERD, allergic rhinitis, anxiety, obstructive sleep apnea, smoking cessation*

ACE-Is, angiotensin-converting enzyme inhibitors; GERD, gastroesophageal reflux disease; NSAIDs, non-steroidal anti-inflammatory drugs; URIs, upper respiratory infections.

Asthma Pharmacotherapy Overview

- Short-acting beta$_2$ agonists (SABAs): e.g., albuterol
- Long-acting beta$_2$ agonists (LABAs): e.g., formoterol
- Long-acting muscarinic antagonists (LAMAs): e.g., tiotropium
- Inhaled corticosteroids (ICS): e.g., fluticasone
- Leukotriene receptor antagonists (LTRAs): e.g., montelukast
- Mast cell stabilizers: e.g., cromolyn
- Methylxanthines: e.g., theophylline
- Systemic corticosteroids: e.g., prednisone
- Immunotherapy: e.g., omalizumab, reslizumab, mepolizumab, benralizumab, dupilumab

GINA 2020 Treatment Overview

	Step 1	Step 2	Step 3	Step 4	Step 5
Preferred Controller	PRN low dose ICS-formoterol	Daily low dose ICS or PRN low dose ICS-formoterol	Low dose ICS-LABA	Medium dose ICS-LABA	High dose ICS-LABA Refer for phenotypic assessment +/- add on therapy (e.g tiotropium, anti-IgE, anti-IL5/5R, anti-IL4R)
Other Controller	Low dose ICS taken with SABA	LTRA, or low dose ICS taken with SABA	Medium dose ICS or low dose ICS + LTRA	High dose ICS, add on tiotropium, or add on LTRA	Add low dose OCS but consider side effects
Reliever	PRN low dose ICS-formoterol	PRN low dose ICS-formoterol	PRN low dose ICS-formoterol for patients prescribed maintenance and reliever therapy	PRN low dose ICS-formoterol for patients prescribed maintenance and reliever therapy	PRN low dose ICS-formoterol for patients prescribed maintenance and reliever therapy
Other Reliever	PRN SABA	PRN SABA	PRN SABA	PRN SABA	PRN SABA

ICS = inhaled corticosteroid; SABA = short-acting beta2-agonist; LABA = long-acting beta2-agonist

GINA, Global Initiative for Asthma.
Global Initiative for Asthma. 2020. https://ginasthma.org/gina-reports/

GINA 2020 Treatment Pearls

- GINA no longer recommends starting with SABA-only treatment
- GINA recommends that all adults and adolescents receive ICS-containing controller treatment
- For mild asthma, as-needed low-dose ICS-formoterol is first line or, if not available, low-dose ICS whenever SABA is used
- Formoterol is the only LABA recommended for use with ICS (preferably budesonide) when used as a reliever
- Formoterol has an onset comparable to a SABA versus other LABAs
- Studies (SYGMA, START, PRACTICAL) demonstrated that ICS-formoterol maintenance and reliever regimen significantly reduces exacerbations and provides similar results at relatively low doses of ICS compared with a fixed dose of ICS-LABA as maintenance (or higher dose of ICS), both with PRN SABA
- GINA does not recommend use of ICS-formoterol as the reliever for patients taking combination ICS-LABA medications with a different LABA
  - These patients should use a PRN SABA

PRN, as needed.

GINA 2020 Treatment Pearls

- Provide guided self-management education
  - self-monitoring + written action plan + regular review
- Treat modifiable risk factors and comorbidities
  - e.g., smoking, obesity, anxiety
- Advise about non-pharmacological therapies and strategies
  - e.g., physical activity, weight loss, avoidance of sensitizers
- Consider stepping up pharmacotherapy if uncontrolled symptoms, exacerbations, or risks
  - Check diagnosis, inhaler technique, and adherence first
- Consider adding sublingual immunotherapy in adult HDM-sensitive patients with allergic rhinitis who have exacerbations despite ICS treatment, provided FEV1 is > 70% predicted
- Consider stepping down pharmacotherapy if symptoms are controlled for 3 months and patients have a low risk for exacerbations
  - Stopping ICS is not advised
- The 2020 guidelines include the option of adding an IL-4 receptor alpha (IL-4Rα) antagonist (dupilumab) for severe asthma

FEV1, forced expiratory volume in 1 second; HDM, house dust mite.

Pharmacotherapy for Asthma

- Treatment with regular, daily, low-dose ICS is highly effective in reducing asthma symptoms and reducing the risk of asthma-related exacerbations, hospitalization, and death
- In adults and adolescents with mild asthma, treatment with PRN low-dose ICS-formoterol reduces the risk of severe exacerbations by about two-thirds compared with SABA-only treatment and is non-inferior to daily low-dose ICS
- For patients with persistent symptoms and/or exacerbations despite low-dose ICS, consider step up
  - First check inhaler technique, adherence, allergen exposure, and comorbidities
  - Step up if asthma remains uncontrolled despite good adherence and inhaler technique

Pharmacotherapy for Asthma

- For adults and adolescents with exacerbations despite other therapies, the risk of exacerbations is reduced with combination low-dose ICS-formoterol as both maintenance and reliever
- For children 6 to 11 years old, Step 3 options include medium-dose ICS and combination low-dose ICS-LABA as maintenance therapy with PRN SABA
- Consider step down once good asthma control has been achieved and maintained for 3 months
  - Find the patient's lowest treatment that controls both symptoms and exacerbations
- Provide inhaler skills training and asthma self-management training, including self-monitoring of symptoms (peak flows), written asthma action plan, and regular medical review
- Patients with poor symptom control and/or exacerbations despite Step 4-5 treatment should be assessed for contributing factors and asthma treatment should be optimized

Short-Acting Beta$_2$ Agonists

- *Albuterol (ProAir, Proventil, Ventolin) and levalbuterol (Xopenex)*
- MOA: β2-agonists relax bronchial smooth muscle and cause bronchodilation
  - Lack significant anti-inflammatory activity
- β1-receptor stimulation produces excessive cardiac stimulation resulting in tachycardia
- Patients may experience transient skeletal muscle tremor, hypokalemia, and CNS stimulation
- There is no rationale for using non-β2-selective agonists in the treatment of asthma
- Patients using SABAs for rescue should be instructed to carry an MDI at all times

CNS, central nervous system; MDI, metered dose inhaler; MOA, mechanism of action.

Short-Acting Beta$_2$ Agonists

- Overall, SABAs are the most effective medication for relief of acute bronchospasm in asthma
- Use of more than 1 canister per month or more than 3 per year suggests inadequate control
- Regularly scheduled use of SABAs is not generally recommended
  - Mostly given PRN for rescue
  - Scheduled use may lower effectiveness and increase airway hyper-responsiveness
  - Chronic administration of β2-agonists causes downregulation (decreased number of β2 receptors) and decreased receptor-binding affinity

Long-Acting Beta$_2$ Agonists

- *Formoterol, arformoterol, indacaterol, salmeterol, olodaterol, vilanterol*
- Not a substitute for anti-inflammatory therapy and not appropriate for monotherapy
- Beneficial when added to ICS
  - Often commercially available as combination MDI
- Formoterol has unique advantages over other LABAs
  - Faster onset
  - Only LABA to be used with ICS as a PRN reliever
- Choice of LABA is often dictated by payer formulary

Inhaled Corticosteroids

- Most effective long-term control therapy for persistent asthma
- Small risk for adverse events at recommended dosages
- Although effects of ICS on growth velocity are seen in pre-pubertal children in the first 1 to 2 years of treatment, this is not progressive nor cumulative
- Slight increase in incidence of “earlier” cataract formation with high-dose ICS
- Reduce potential for adverse events by:
  - Using spacer and rinsing mouth
  - Using lowest dose possible
  - Using in combination with LABA
  - Demonstrating correct inhaler technique
  - Monitoring growth in children

Leukotriene Modifiers

- Leukotrienes
  - Augment neutrophil and eosinophil migration, neutrophil and monocyte aggregation, and leukocyte adhesion
  - Increase capillary permeability and smooth muscle contraction
  - Contribute to inflammation, edema, mucous secretion, and bronchoconstriction in the airway
- *Montelukast (Singulair) and zafirlukast (Accolate) are selectively competitive LTRAs of leukotriene D4 and E4*
  - *Components of slow-reacting substance of anaphylaxis*
- *Zileuton (Zyflo) is a 5-lipoxygenase inhibitor*
  - *Inhibits leukotriene formation*

Leukotriene Modifiers: Indications

- Not as effective as ICS
- May be effective as add-on therapy
  - Not effective as monotherapy in asthma
- May be beneficial in patients with aspirin sensitivity and food allergies
- Consider in patients with allergic rhinitis and asthma
- Long-term control therapy in mild persistent asthma
  - Improve lung function
  - Prevent need for SABA
  - Prevent exacerbations

Long-Acting Muscarinic Antagonists

- *Ipratropium (short-acting), tiotropium, aclidinium, glycopyrrolate umeclidinium (LAMA), revefenacin (nebulizer)*
- Anticholinergic agents have emerged as first-line therapy for COPD but are used less often for asthma
- When given by inhalation, LAMAs produce bronchodilation by competitively inhibiting cholinergic receptors in bronchial smooth muscle
- Tiotropium shown effective as “add on” therapy in asthma patients on maximal therapy
- LAMAs lack systemic absorption, decreasing the anticholinergic side effects associated with atropine
  - Blurred vision, urinary retention, nausea, and tachycardia
  - *LAMAs cause dry mouth*

COPD, chronic obstructive pulmonary disease.

Potential Candidates for Biologics

- *Omalizumab, reslizumab, mepolizumab, benralizumab, and dupilumab* indicated for GINA Step 5
- Patients with severe asthma with excessive morbidity (comorbid illness, multiple hospitalizations) and high consumers of medical resources (ED visits, sick visits, etc.)
- Patients who are steroid-dependent (systemic)
- Severe asthmatics with IgE levels 30-700
- Severe asthmatics with positive skin-prick test or positive RAST
- Patients who are adherent to meds and avoid triggers

ED, emergency department; RAST, radioallergosorbent test.

Biologics for Asthma

- Omalizumab is an IgG monoclonal antibody that inhibits IgE binding to the high-affinity IgE receptor on mast cells and basophils
- By decreasing bound IgE, the activation and release of mediators in the allergic response (early and late phase) is limited
- Serum free IgE levels and the number of high-affinity IgE receptors are decreased
- Long-term treatment showed a decrease in asthma exacerbations and corticosteroid usage

Omalizumab Doses (mg) Administered Subcutaneously Every 2 or 4 Weeks

Every 4 weeks

Pretreatment serum IgE (IU/mL)	Actual body weight (kg)			
	30-60	> 60-70	> 70-90	> 90-150
≥ 30-100	150	150	150	300
> 100-200	300	300	300	
> 200-300	300			

Every 2 weeks

Pretreatment serum IgE (IU/mL)	Actual body weight (kg)			
	30-60	> 60-70	> 70-90	> 90-150
> 100-200				225
> 200-300		225	225	300
> 300-400	225	225	300	
> 400-500	300	300	375	
> 500-600	300	375		
> 600-700	375			

Reslizumab vs. Mepolizumab

	Reslizumab	Mepolizumab
FDA-approved indications	Indicated as add-on maintenance treatment of severe asthma in adults with an eosinophilic phenotype	Indicated as add-on maintenance treatment of severe asthma in adults and children 6 years and older
Year approved	2016	2015
Usual dose	3 mg/kg Q month	Adults: 100 mg Q month Children: 40-100 mg Q 4 weeks
Available dosage forms	100 mg/10 mL vials	100 mg powder (to be reconstituted) auto-injector and pre-filled syringe 100 mg/mL
Administration	Intravenous injection	Subcutaneous injection
Mechanism of action	IL-5 antagonist (IgG4 kappa)	IL-5 antagonist (IgG1 kappa)

FDA, United States Food and Drug Administration.

Reslizumab vs. Mepolizumab

	Reslizumab	Mepolizumab
Contraindications/major warnings	Hypersensitivity to reslizumab or any component of the formulation; Must be administered by qualified HCP; Do not discontinue corticosteroid use abruptly; Limited use for eosinophilic conditions; Boxed warning of anaphylaxis with administration; Contraindicated in patients with helminth infections because unknown effects	Hypersensitivity to mepolizumab or any component of the formulation
Contraindicated concomitant drug therapy	Do not administer IV with other agents (non-specific) concomitantly	No significant contraindications with other medications
Half-life	24 days	16 to 22 days
Metabolism	Proteolytic degradation via enzymes into small peptides and amino acids	Proteolytic degradation via enzymes that are widely distributed in the body and not restricted to hepatic tissue
Renal/hepatic dose adjustments	None	None
Drug interactions	No significant interactions reported at this time	No significant interactions reported at this time

HCP, healthcare professional; IV, intravenous.

Benralizumab

- MOA: Monoclonal antibody (IgG1, kappa) that binds to the alpha subunit of the IL-5 receptor
  - IL-5 is responsible for eosinophil activity
  - By inhibiting IL-5 signaling, the drug reduces production and survival of eosinophils and basophils
- Indication: Add-on treatment of severe asthma in adults and children ≥ 12 years old with eosinophilic phenotype
- Dosage: 30 mg SQ (upper arm, thigh, or abdomen) every 4 weeks for first 3 doses, then once every 8 weeks
- ADRs: Headache, fever, hypersensitivity reactions
- Availability: Pre-filled syringe AND auto-injector, SQ Fasenra Pen: 30 mg/mL (1 mL)

ADRs, adverse drug reactions; SQ, subcutaneously.

Dupilumab

- MOA: Human monoclonal IgG4 antibody that inhibits IL-4 and IL-13 signaling by binding to the IL-4Rα subunit
  - Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of pro-inflammatory cytokines, chemokines, nitric oxide, and IgE
- Indication: Add-on treatment of moderate to severe asthma in adults and pediatric patients ≥ 12 years old with eosinophilic phenotype or steroid-dependent asthma
- Dose: 400-600 mg SQ loading dose, followed by 300 mg Q every other week
- Local ADRs: Injection-site reaction (6% to 18%)

Role of Pharmacists in the Care of Asthma Patients

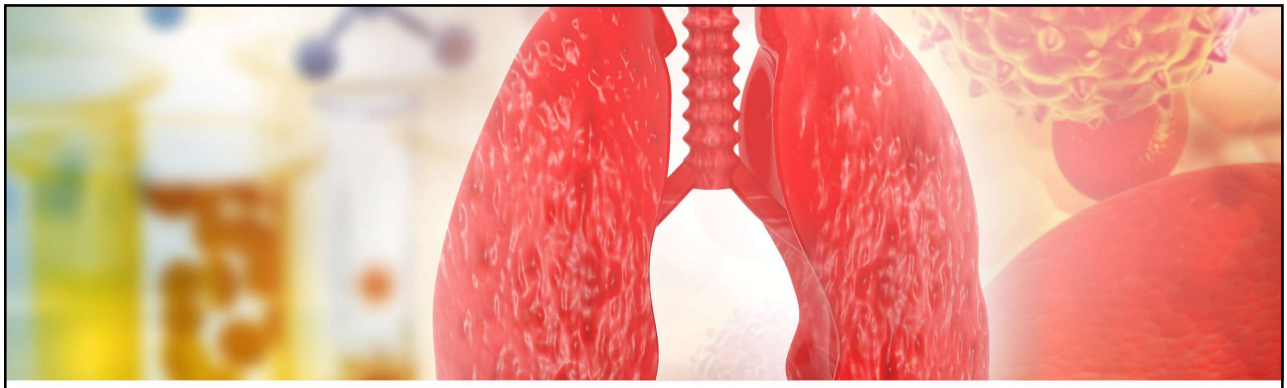
- Asthma disease state education
- Counseling for trigger avoidance and risk factor reduction
  - Address asthma comorbidities
- Medication counseling for adverse effects
- Prevent drug misadventures, such as overuse of SABAs, poor adherence to controllers, and LABA use without a controller (monotherapy)
- Monitor for potential adverse effects of medications (e.g., oral candidiasis with ICS)
- Assess and/or demonstrate proper inhaler technique

Role of Pharmacists in the Care of Asthma Patients

- Monitor medication refill patterns
- Monitor for potential overuse of SABAs
- Coach patients for adherence to controller medications
- Monitor for LABA monotherapy use without a controller
- Provide guidance for prescribers for formulary compliance
- Provide referral for patients when financial assistance is necessary
- Provide smoking cessation intervention

Role of Pharmacists in the Care of Asthma Patients

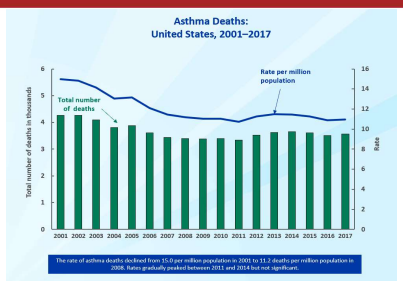
- Arrange for holding chamber or spacing device for MDIs when needed
- Explain and/or assess patient understanding of asthma action plan
- Monitor for adverse effects of oral corticosteroids
- Explain the role of medications (quick relief vs. long-term controller)
- Assess/review respiratory device technique
- Assist patient understanding and technique with self-monitoring methods, such as use of peak flowmeter
- Provide feedback to prescriber/provider as needed

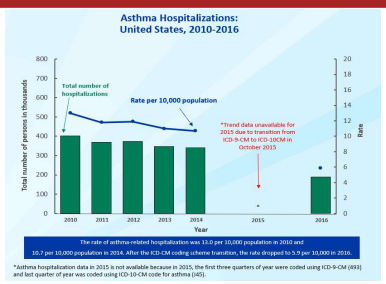


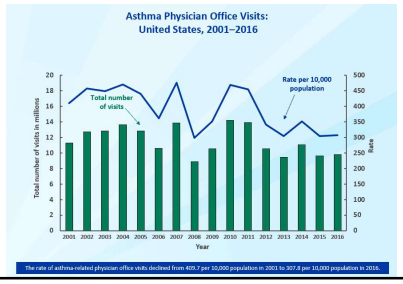
Asthma Outcome Measures

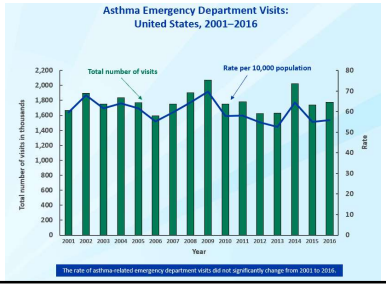
Lily P. Duong, PharmD, RPh

Asthma Surveillance Data







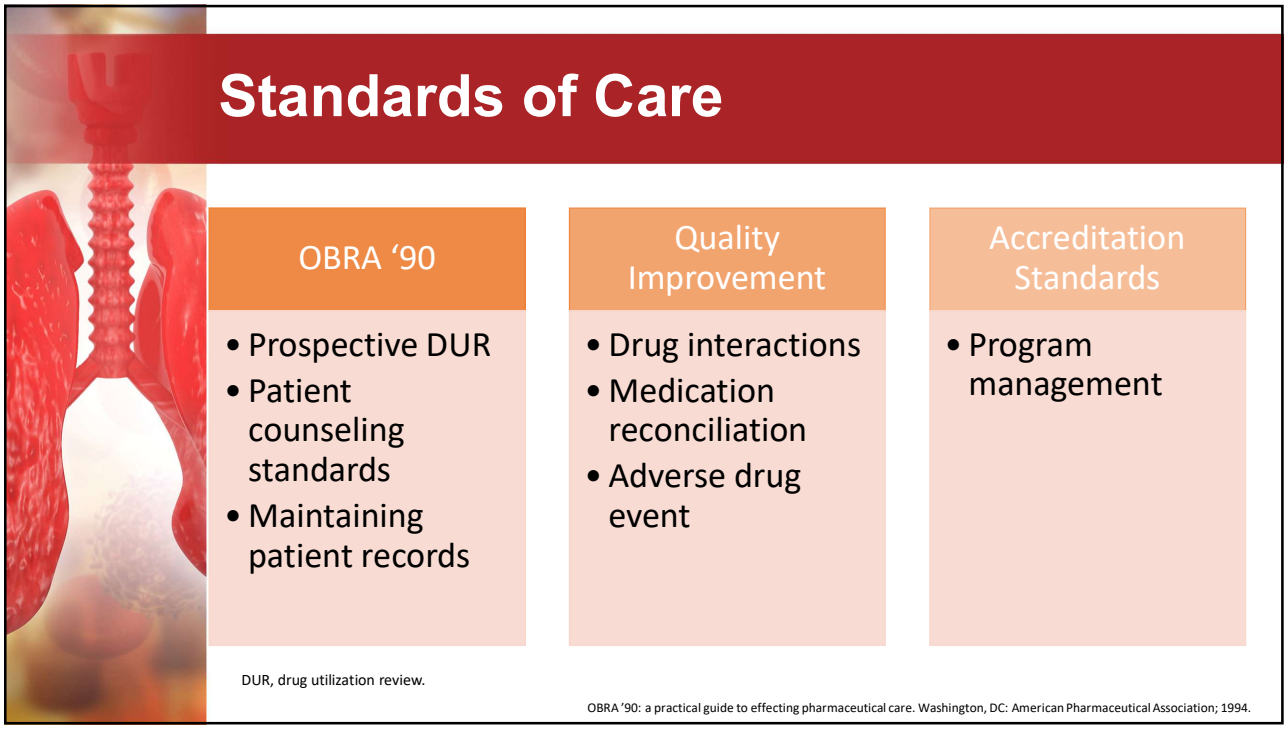


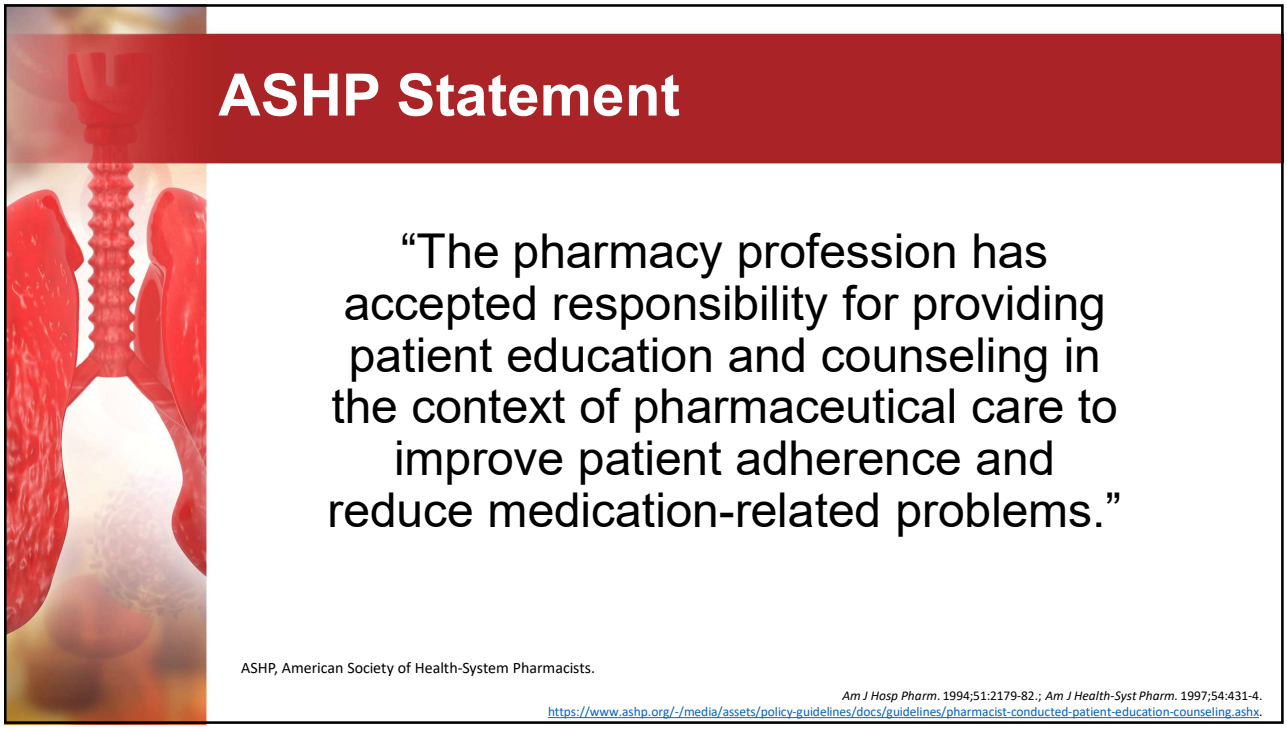
Centers for Disease Control and Prevention. 2019. https://www.cdc.gov/asthma/national-surveillance-data/default.htm.

Burden of Asthma to Patients

- Missed days of work/school
- Limited ability to perform daily activities
- Fear of exacerbations and avoidance of certain daily activities
- Embarrassment about exacerbations and using an inhaler
- Sleep disturbances and lack of sleep
- Worry and stress on parents and family members
- Medication cost

Schmier JK, et al. *J Asthma*. 1998;35(7):585-97.


Standards of Care
OBRA '90
• Prospective DUR
• Patient counseling standards
• Maintaining patient records
Quality Improvement
• Drug interactions
• Medication reconciliation
• Adverse drug event
Accreditation Standards
• Program management
DUR, drug utilization review.
OBRA '90: a practical guide to effecting pharmaceutical care. Washington, DC: American Pharmaceutical Association; 1994.

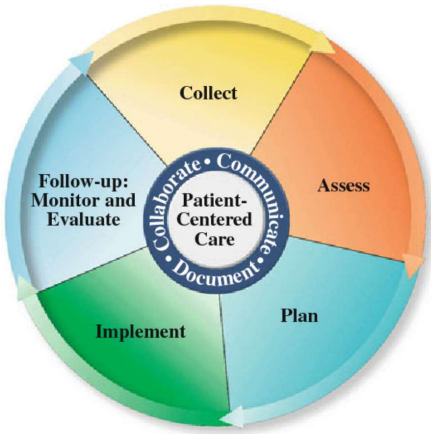

ASHP Statement
"The pharmacy profession has accepted responsibility for providing patient education and counseling in the context of pharmaceutical care to improve patient adherence and reduce medication-related problems."
ASHP, American Society of Health-System Pharmacists.
Am J Hosp Pharm. 1994;51:2179-82.; Am J Health-Syst Pharm. 1997;54:431-4.
https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/pharmacist-conducted-patient-education-counseling.ashx.

Care Management Program

Patient Onboarding	Patient Care Plan	Outcome Measures
• Appropriate drug selection • Initial patient interaction for essential education • Initial counseling on proper medication use, adherence, and side effects	• Initial and re-assessment of drug therapy and monitoring plan for appropriateness and effectiveness • Adherence management • Side effect management	• Effectiveness of prescribed drug therapy • Reduction on disease severity • Quality of life

Am J Health-Syst Pharm. 1997;54:431-4. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/pharmacist-conducted-patient-education-counseling.ashx.

Pharmacist Patient Care Process



Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.

Using principles of evidence-based practice, pharmacists:

Collect
The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

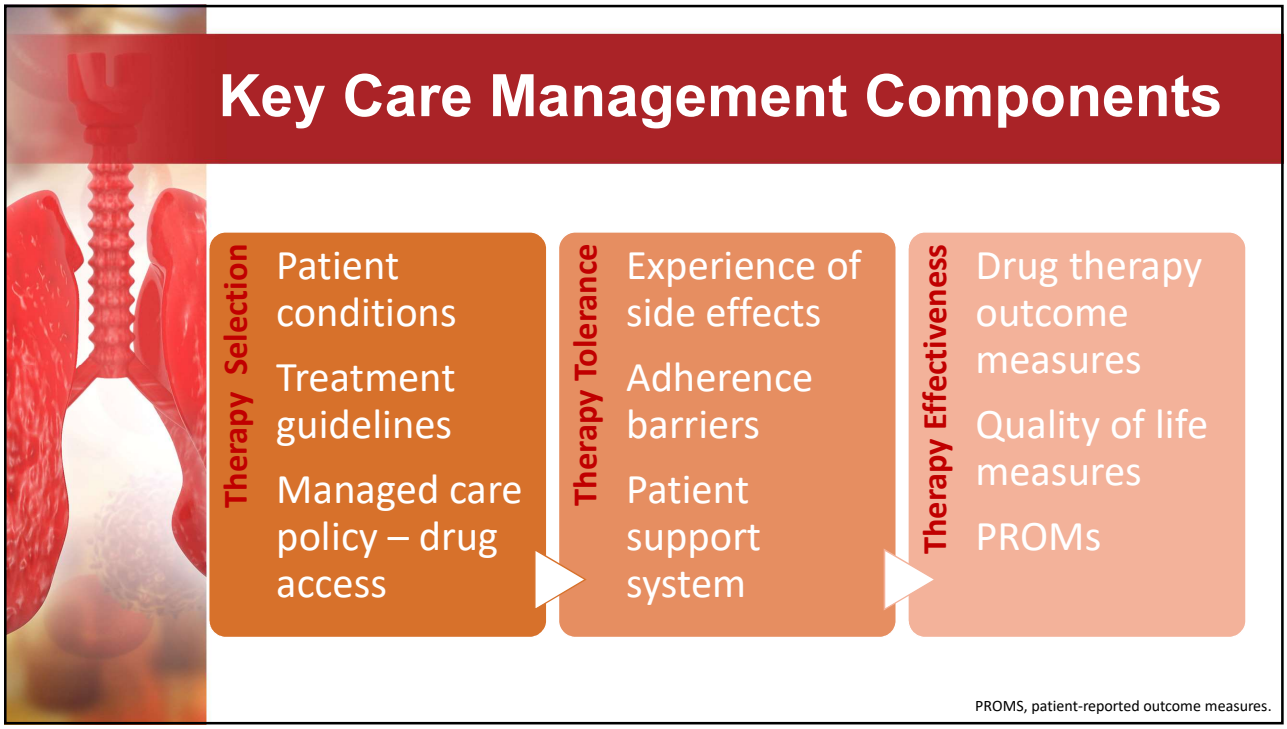
Assess
The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

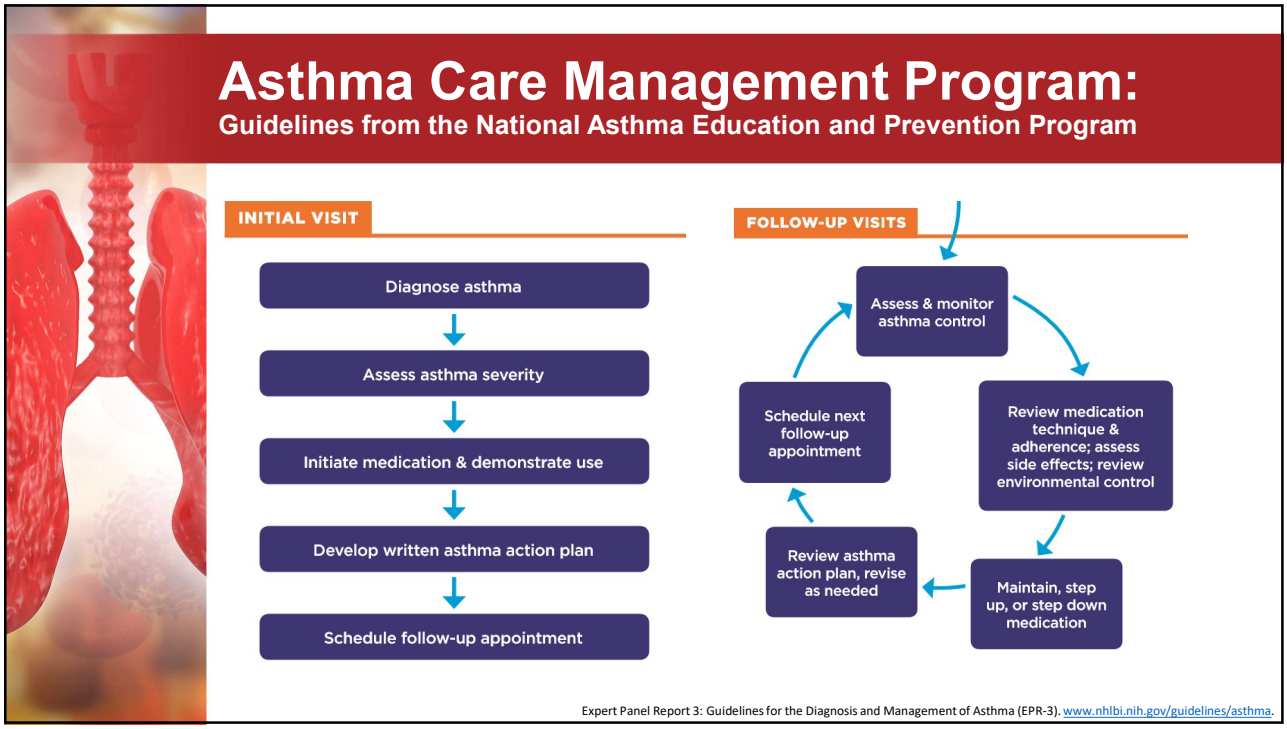
Plan
The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

Implement
The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Follow-up: Monitor and Evaluate
The pharmacist monitors and evaluates effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

Joint Commission of Pharmacy Practitioners. Pharmacists' Patient Care Process. May 29, 2014. https://jcpp.net/wp-content/uploads/2016/03/PatientCareProcess-with-supporting-organizations.pdf.


Key Care Management Components
Therapy Selection
Patient conditions
Treatment guidelines
Managed care policy – drug access
Therapy Tolerance
Experience of side effects
Adherence barriers
Patient support system
Therapy Effectiveness
Drug therapy outcome measures
Quality of life measures
PROMs
PROMS, patient-reported outcome measures.


Asthma Care Management Program:
Guidelines from the National Asthma Education and Prevention Program
INITIAL VISIT
Diagnose asthma
Assess asthma severity
Initiate medication & demonstrate use
Develop written asthma action plan
Schedule follow-up appointment
FOLLOW-UP VISITS
Assess & monitor asthma control
Review medication technique & adherence; assess side effects; review environmental control
Maintain, step up, or step down medication
Review asthma action plan, revise as needed
Schedule next follow-up appointment
Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). www.nhlbi.nih.gov/guidelines/asthma.

Asthma Action Plan

For: _____ Doctor: _____ Date: _____

Doctor's Phone Number _____ Hospital/Emergency Department Phone Number _____

GREEN ZONE

Doing Well

- No cough, wheeze, chest tightness, or shortness of breath during the day or night
- Can do usual activities

And, if a peak flow meter is used,

Peak flow: more than _____
(80 percent or more of my best peak flow)

My best peak flow is: _____

Take these long-term control medicines each day (include an anti-inflammatory).

Medicine	How much to take	When to take it
Before exercise	❒ _____	❒ 2 or ❒ 4 puffs _____ 5 minutes before exercise

YELLOW ZONE

Asthma Is Getting Worse

- Cough, wheeze, chest tightness, or shortness of breath, or
- Waking at night due to asthma, or
- Can do some, but not all, usual activities

-Or-

Peak flow: _____ to _____
(50 to 79 percent of my best peak flow)

First **Add: quick-relief medicine—and keep taking your GREEN ZONE medicine.**

_____ (short-acting $beta_2$-agonist) ❒ 2 or ❒ 4 puffs, every 20 minutes for up to 1 hour ❒ Nebulizer, once

Second **If your symptoms (and peak flow, if used) return to GREEN ZONE after 1 hour of above treatment:**
❒ Continue monitoring to be sure you stay in the green zone.

-Or-

If your symptoms (and peak flow, if used) do not return to GREEN ZONE after 1 hour of above treatment:
❒ Take: _____ (short-acting $beta_2$-agonist) ❒ 2 or ❒ 4 puffs or ❒ Nebulizer
❒ Add: _____ (oral steroid) mg per day For _____ (3–10) days
❒ Call the doctor ❒ before/ ❒ within _____ hours after taking the oral steroid.

RED ZONE

Medical Alert!

- Very short of breath, or
- Quick-relief medicines have not helped, or
- Cannot do usual activities, or
- Symptoms are same or get worse after 24 hours in Yellow Zone

-Or-

Peak flow: less than _____
(50 percent of my best peak flow)

Take this medicine:

❒ _____ (short-acting $beta_2$-agonist) ❒ 4 or ❒ 6 puffs or ❒ Nebulizer

❒ _____ (oral steroid) mg

Then call your doctor NOW. Go to the hospital or call an ambulance if:
- You are still in the red zone after 15 minutes AND
- You have not reached your doctor.

DANGER SIGNS
- **Trouble walking and talking due to shortness of breath**
- **Lips or fingernails are blue**

- **Take ❒ 4 or ❒ 6 puffs of your quick-relief medicine AND**
- **Go to the hospital or call for an ambulance _____ (phone) NOW!**

Pharmaceutical Care Plan:

Incorporating the National Asthma Management guidelines in the pharmacy scope of practice

➔ LONG-TERM ASTHMA MANAGEMENT

GOAL:
Asthma Control

Reduce Impairment

- Prevent chronic symptoms.
- Require infrequent use of short-acting $beta_2$-agonist (SABA).
- Maintain (near) normal lung function and normal activity levels.

Reduce Risk

- Prevent exacerbations.
- Minimize need for emergency care, hospitalization.
- Prevent loss of lung function (or, for children, prevent reduced lung growth).
- Minimize adverse effects of therapy.

STEPWISE APPROACH FOR MANAGING ASTHMA LONG TERM

The stepwise approach tailors the selection of medication to the level of asthma severity (see page 5) or asthma control (see page 6).
The stepwise approach is meant to help, not replace, the clinical decisionmaking needed to meet individual patient needs.

ASSESS CONTROL:

STEP UP IF NEEDED (first, check medication adherence, inhaler technique, environmental control, and comorbidities)

STEP DOWN IF POSSIBLE (and asthma is well controlled for at least 3 months)

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6

At each step: Patient education, environmental control, and management of comorbidities

What are the Measurable Outcomes?

Outcome measures	Executable	Means to measure	Quantifiable	Opportunities
Asthma symptoms	Possible	Patient self-report	Symptom scores	Various surveys available
Use of SABA	Possible	Pharmacy records	Patient diary	Implement treatment guidelines
Exacerbations	Possible	Patient self-report	Number of attacks	Clinical care program
Emergency care visits	Possible	Medical records	Number of visits	Clinical care program
Hospitalization	Possible	Medical records	Number of visits	Clinical care program
Loss of lung function	Challenging	Doctor visits	Medical notes	Collaboration w/ medical team
Adverse drug events	Possible	Patient care plan	Therapy management metrics	Clinical care program
Quality of life	Possible	Patient survey	Depending on surveys	12 PROMs surveys available
Work productivity	Possible	Patient survey	% impairment	WPAI-asthma

WPAI, Work Productivity and Activity Impairment.

Patient Reported Outcome Measures
by the Asthma Outcomes Consensus Group – University of Oxford

Appendix C

iii: Summary of ge

Instrument	Physical function
SF-36 (36)	x
SF-12 (12)	x
EQ-5D (5+1)	x
SIP (136)	x
HUI	x
SF-6D	x

Appendix Diii

Summary of asthma-specific instruments: health status domains *(after Fitzpatrick et al., 1998)*

Instrument	*Instrument domains*								
	Physical function	Symptoms	Global judgement	Psychol. well-being	Social well-being	Cognitive functioning	Role activities	Personal construct	Treatment satisfaction
AQLQ		x		x			x		
MiniAQLQ		x		x			x		
AQLQ(S)		x		x			x		
Acute AQLQ		x		x					
ACQ		x							x
ACD		x							
MAQLQ		x		x	x			x	
LWAQ		x		x	x			x	
SGRQ	x	x		x	x		x		x
ACT		x					x	x	x
AIS-6	x	x		x					
ATAQ								x	x
PCAQ								x	
AOMS									
ASCC		x							
AQL-5D									
ASUI		x							
AQ 20	x	x		x					
RCP		x					x		
LASS		x							
ASES								x	
WPAI							x		

Asthma PROMs
by the Asthma Outcomes Consensus Group – University of Oxford

APPENDIX

PROM	Domains (items)	Response options	Score	Administration/ Completion (time)
ACT	*5 items* Symptoms	5 point Likert	Summation 5= poor control	Self-report
AQL-5D	Utility measure derived from the AQLQ and psychometric evidence		5 attributes, each with 5 levels.	
ASUI	*1 domain/11 items* Symptoms (11)	4 point Likert scale	Preference-weighted scores generating a single utility: 0 to 1.0. Lower scores indicate greater symptom problems	Self-report
AQ 20	*3 domains/ 20 items* 1. Symptoms 2. Activities 3. Impacts		Total score expressed as a percentage. High scores indicate poor quality of life.	Self-report
RCP	Three questions assessing impact of asthma	Yes/no	One "yes" indicates medium morbidity and two or three "yes" answers indicate high morbidity	Self-report
LASS	*1 domain/ 8 items* Symptoms (8)	5 point Likert	Total scores range from 8 to 40.	Self-report
ASES	1 domain/80 items Self-efficacy and locus of control	5 point Likert	Patients report level of confidence in avoiding an asthma attack. 1= no confidence, 5= very confident	Self-report
WPAI	*3 domains/ 9 items* 1. Work impairment (4) 2. School impairment (4) 3. Activity impairment (1) Only 1 or 2 is answered	Percentage	Percentage impairment obtained for each domain. Higher scores indicate higher impairment	Self-report
measurement				

PROM: AQLQ, MiniAQLQ, AQLQ(S), Acute AQLQ, ACQ, ACD, MAQLQ, LWAQ, SGRQ, AIS-6, ATAQ, PCAQ, AOMS, ASCC

Asthma PROMs Recommendations:
by the Asthma Outcomes Consensus Group – University of Oxford

Most favorable option for the measurement of asthma control

The Asthma Control Questionnaire (ACQ)

1 domain / 8 items

- Symptoms (7) (1 clinician assessed)
- Sleep related (2)
- Breathlessness (1)
- Wheeze (1)
- Activity limitations (1)
- Use of bronchodilators (1)
- FEV % of predicted (clinician assessed) (1)

Highly rated for the measurement of the quality of NHS services

The Asthma QoL Questionnaire (miniAQLQ)

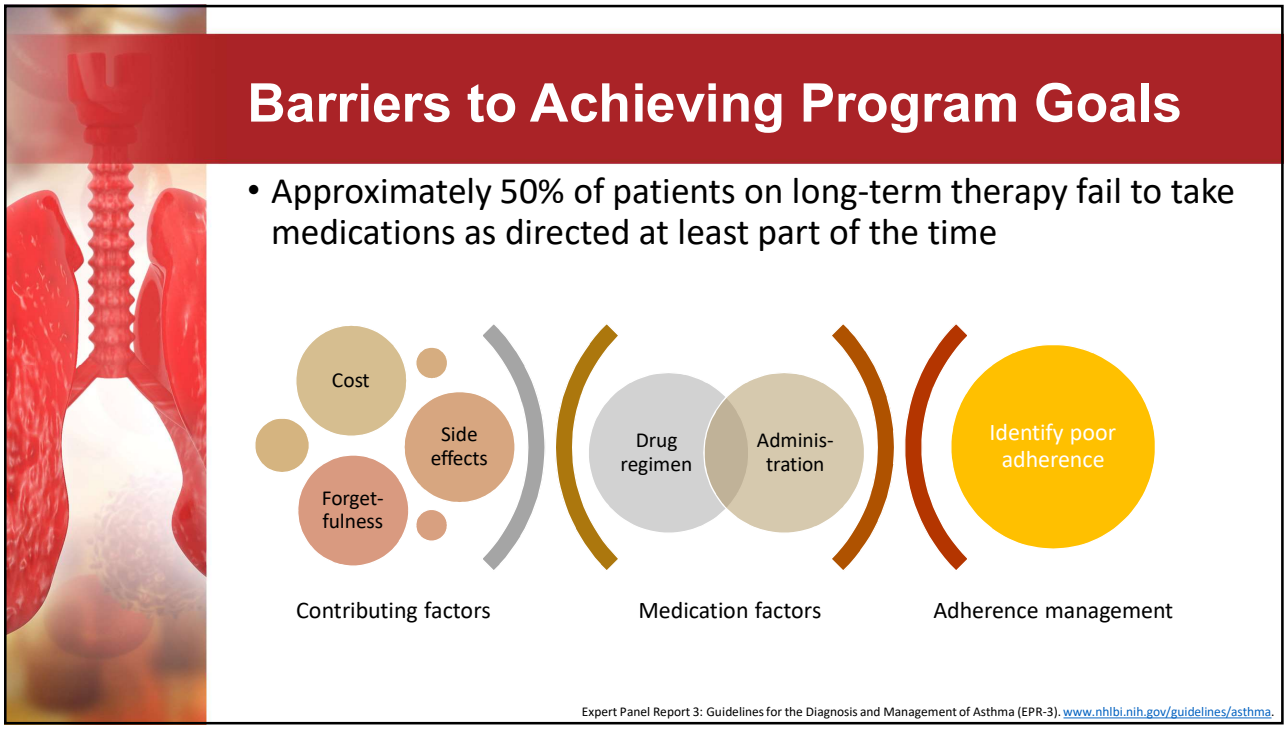
4 domains / 15 items

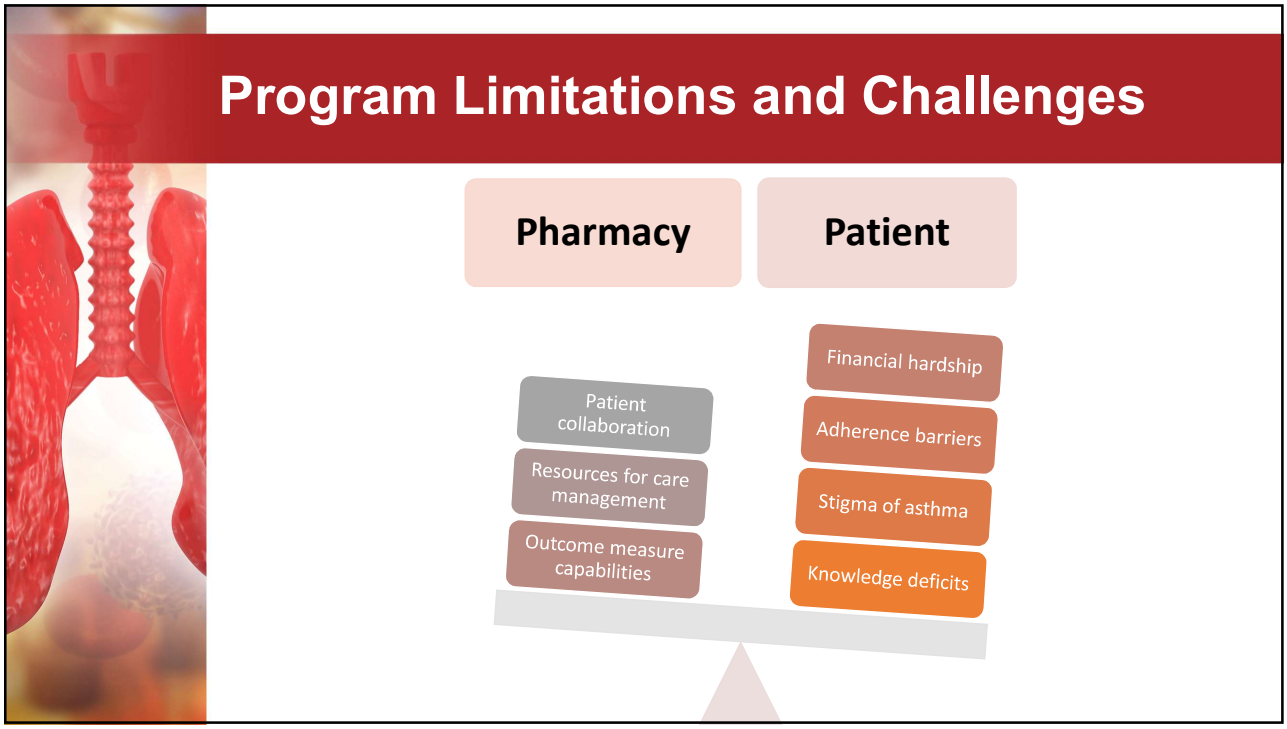
- Symptoms (12)
- Emotions (5)
- Environment (4)
- Activities (11)

7-point Likert scale

7 minutes to complete at first visit,

3-5 minutes at follow-ups


Barriers to Achieving Program Goals
• Approximately 50% of patients on long-term therapy fail to take medications as directed at least part of the time
Cost
Side effects
Forget-fulness
Drug regimen
Adminis-tration
Identify poor adherence
Contributing factors
Medication factors
Adherence management
Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). www.nhlbi.nih.gov/guidelines/asthma.


Program Limitations and Challenges
Pharmacy
Patient
Patient collaboration
Resources for care management
Outcome measure capabilities
Financial hardship
Adherence barriers
Stigma of asthma
Knowledge deficits

Tailoring Program to Engage Patient

Level 1

- **Standard**

- Proactive refill reminders to patient
- Initial patient education and counseling on therapy initiation
- Simple therapy goal
- Follow up as needed
- Track and measure interventions and outcomes

Level 2

- **High Touch**

- Proactive management patient care
- Initial and follow-up assessments
- Proactive adherence and side effect management
- Track and measure intervention outcomes
- Therapy outcome tracking

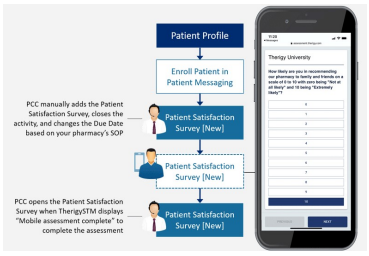
Level 3

- **Custom**

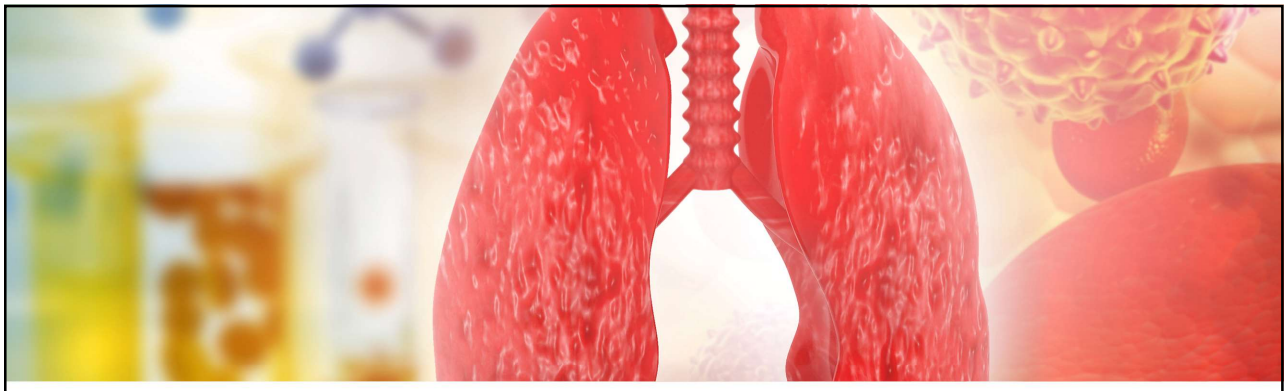
- High Touch care plan above & beyond standard
- High-risk patient care services
- Complications prevention
- Targeted outcome tracking designated for high-risk patients

Mobile Patient Engagement

- Reach patients faster and improve adherence
  - ✓ Increase adherence through customized refill reminders
  - ✓ Decrease average handle time through mobile-enabled assessments
    - Quality-of-life survey
    - Patient satisfaction
  - ✓ Unbiased patient satisfaction results



60



Specialty Pharmacy: Asthma Management Program

Meghann Randolph, PharmD

What is Specialty Pharmacy?

"A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies"

-National Association of Specialty Pharmacy, 2016

National Association of Specialty Pharmacy. http://naspnet.org/wp-content/uploads/2017/02/NASP-Defintions-final-2.16.pdf.

Specialty Pharmacy Disease States

- Infectious disease
  - Hepatitis B
  - Hepatitis C
- Inflammatory conditions
  - Rheumatoid arthritis
  - Psoriatic arthritis
  - Inflammatory bowel disease
- Pulmonary conditions
  - Cystic fibrosis
  - Idiopathic pulmonary fibrosis
  - Asthma
- Others
  - Multiple sclerosis
  - Oncology
  - Bleeding disorders
  - Solid organ transplant
  - Human growth hormone deficiencies
  - HIV/AIDS

Specialty Pharmacy Therapies

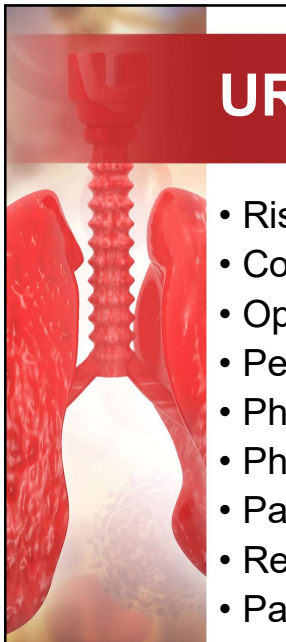
- Administration (oral, injectable, infused)
- Special handling requirements
- Complex side effect profile
- Used to treat rare diseases
- Special access conditions set by the manufacturer
- Payor authorization requirements
- Can be quite costly

National Association of Specialty Pharmacy. http://naspnet.org/wp-content/uploads/2017/02/NASP-Defintions-final-2.16.pdf.

Specialty Pharmacy Accreditation

- URAC
- Accreditation Commission for Health Care (ACHC)
- Center for Pharmacy Practice Accreditation (CPPA)
- The Joint Commission

http://www.urac.org; https://www.achc.org/pharmacy.html; https://www.pharmacypracticeaccredit.org/; https://www.jointcommission.org/accreditation-and-certification/health-care-settings/pharmacy/.



URAC Focus Areas, v4.0

- Risk management
- Consumer protection and empowerment
- Operations and infrastructure
- Performance monitoring and improvement
- Pharmacy operations
- Pharmacy product handling and security
- Patient service and communication
- Reporting performance measures to URAC
- Patient management

URAC. https://www.urac.org/programs/specialty-pharmacy-accreditation.

ACHC Standards

- Organization and administration
- Program/service operations
- Fiscal management
- Human resource management
- Provision of care and record management
- Quality outcomes/performance improvement
- Risk management: infection and safety control

ACHC ACCREDITED

Accreditation Commission for Health Care. https://www.achc.org/about-accreditation.html.

Specialty Therapies in Asthma Management

Xolair Omalizumab FOR SUBCUTANEOUS USE 150 mg

DUPIXENT (dupilumab) Injection 200mg · 300mg

CINQAIR (reslizumab) Injection 100 mg/10 mL

Fasenra (benralizumab) Subcutaneous Injection 30 mg

Nucala (mepolizumab) Injection 100 mg/mL

https://www.xolairhcp.com/; https://www.dupixent.com/asthma; https://www.cinqair.com/; https://www.nucala.com/; https://www.fasenrahcp.com/.

Healthcare Provider-Administered Therapies

Omalizumab (Xolair®)

- Anti-IgE monoclonal antibody
- SQ injection every 2 or every 4 weeks
- Black box warning: anaphylaxis
- Other indications: chronic idiopathic urticaria

Reslizumab (Cinqair®)

- IL-5 antagonist
- IV infusion every 4 weeks
- Black box warning: anaphylaxis

Self-Administered Therapies

Dupilumab (Dupixent®)

- IL-4 and IL-13 inhibitor
- SQ injection
  - Initial: Loading dose (2 injections)
  - Maintenance: 1 injection every 2 weeks
- Preparations
  - 200 mg/1.14 mL (moderate to severe asthma)
  - 300 mg/2 mL (oral steroid-dependent asthma)
- Other indications
  - Atopic dermatitis
  - Chronic rhinosinusitis with nasal polyposis

Mepolizumab (Nucala®)

- IL-5 antagonist
- SQ injection administered every 4 weeks
- Preparations: Auto-injector, prefilled syringe, or vial

Benralizumab (Fasenra®)

- IL-5 receptor antagonist
- SQ injection
  - Every 4 weeks x 3 doses
  - Every 8 weeks thereafter
- Preparations: Auto-injector, prefilled syringe

Referral Process

New referral
- Prior authorization
- Appeals process*
- Benefits investigation
- Financial assistance*

Initial fill
- Coordination with outside facilities*
- Initial education and fill
- Patient begins therapy

Subsequent fills
- Proactive refill management
- Periodic clinical follow-up assessment

*if applicable

Therapy Considerations

Healthcare provider-administered therapies

- Reimbursement through medical or pharmacy benefit
  - J-codes/units
  - Facility/site of care
- Coordination with outside infusion centers
  - White bagged vs. brown bagged products
- Management of injection appointments

Self-administered therapies

- Counseling methods
  - Telephonic
  - Retail pharmacy locations
  - Infusion center appointments
- Written educational materials
- Ancillary supplies

Access to Asthma Biologics

- **Prior authorization criteria**
  - Usually payor-specific
  - Age requirements
  - Positive skin test or in vitro reactivity to a perennial aeroallergen (omalizumab)
  - Absolute eosinophils > 150 cells/µL (for anti-IL-5 therapies)
  - FEV_1 < 80% predicted
  - Inadequate control with inhaled therapies
- **Manufacturer assistance**
  - Copay assistance (commercial insurance)
  - Free drug programs
    - Government-funded insurance
    - Rendered uninsured through prior authorization denial and appeal
    - No active prescription drug insurance
- **Foundational support**
  - Patient Access Network Foundation (PANF)
  - HealthWell Foundation
  - Patient Advocate Foundation

UK Specialty Pharmacy Asthma Management: Patient Demographics

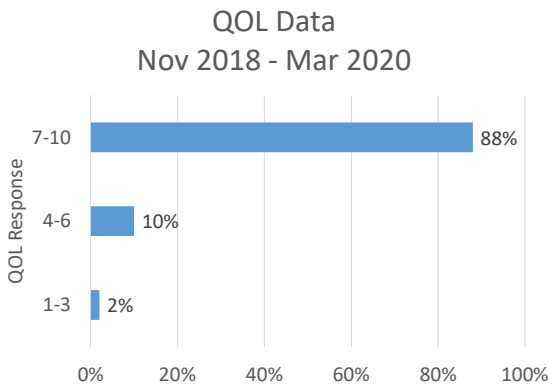
- Clinics
  - Pediatric allergy/immunology
  - Allergy, asthma, and sinus
  - Pulmonary medicine specialties
- Geography
  - Lexington, KY: 51%
  - Surrounding areas: 49%

- Diagnosis

Moderate persistent asthma (J45.4*)	10 (17%)
Severe persistent asthma (J45.5*)	34 (58%)
Other types of asthma (J45.90*)	14 (24%)
Pulmonary eosinophilia (J82)	1 (2%)

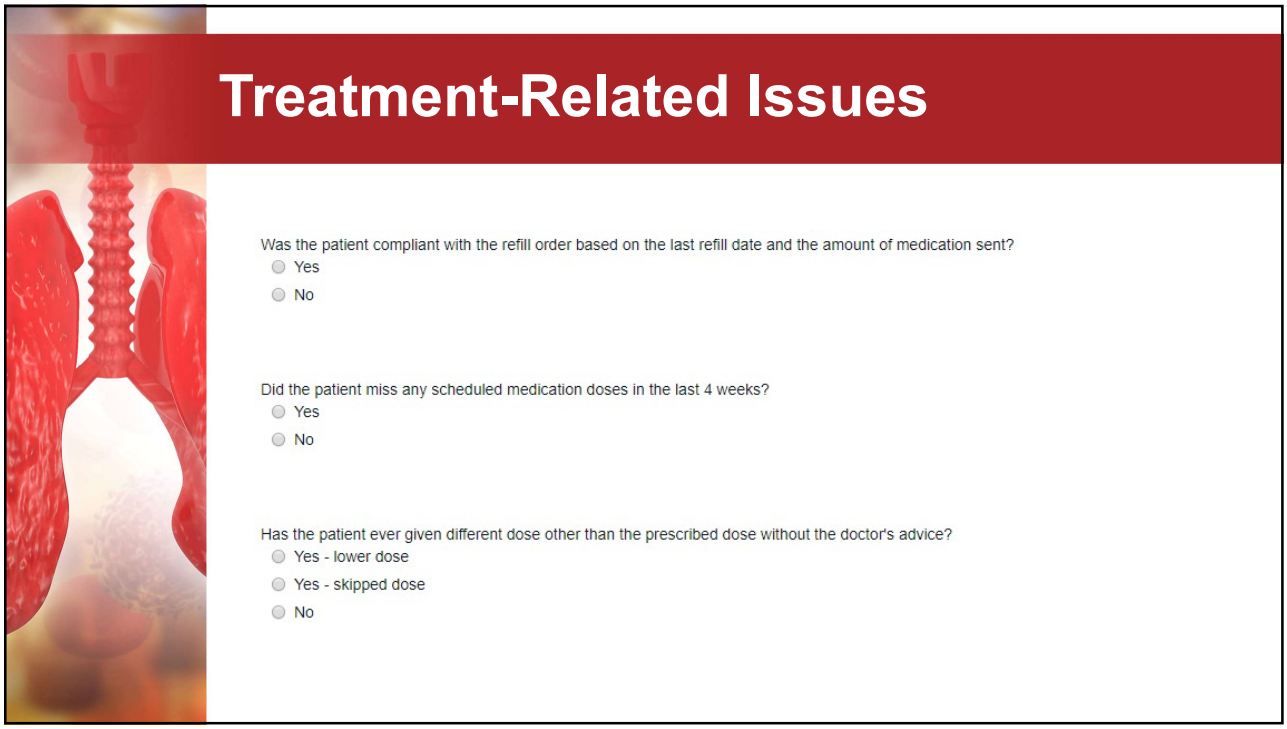
Refill Assessment

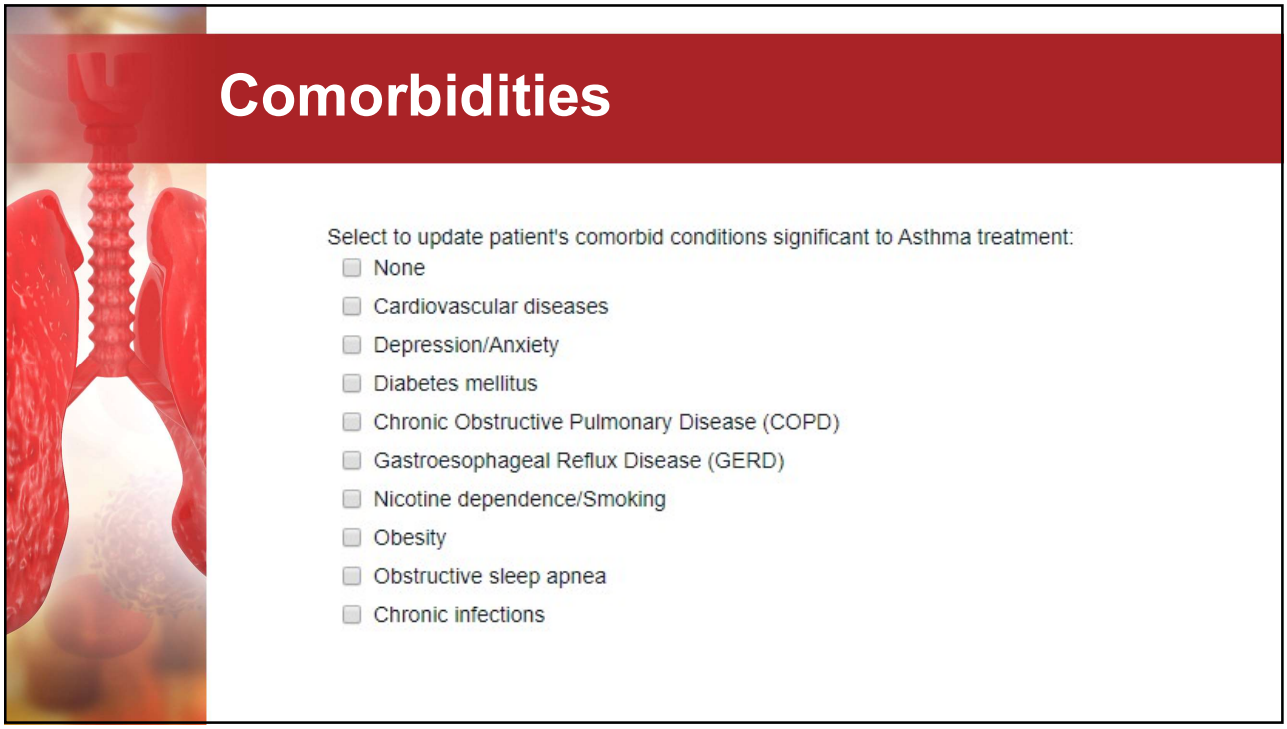
- Medication reconciliation
- Clinical history (new allergies or medical conditions)
- Administration issues
- Reported adverse effects
- Adherence
  - Last dose
  - Number of doses on hand
- Quality of life (QOL) assessment
  - 1 = very poor
  - 10 = very well



Clinical Assessment

- Treatment-related issues
  - Adherence
  - Adverse effects
- Comorbidities
- Asthma symptom control
  - Daytime asthma symptoms
  - Any night awakenings due to asthma
- Activities of daily living


Treatment-Related Issues
Was the patient compliant with the refill order based on the last refill date and the amount of medication sent?
Yes
No
Did the patient miss any scheduled medication doses in the last 4 weeks?
Yes
No
Has the patient ever given different dose other than the prescribed dose without the doctor's advice?
Yes - lower dose
Yes - skipped dose
No


Comorbidities
Select to update patient's comorbid conditions significant to Asthma treatment:
None
Cardiovascular diseases
Depression/Anxiety
Diabetes mellitus
Chronic Obstructive Pulmonary Disease (COPD)
Gastroesophageal Reflux Disease (GERD)
Nicotine dependence/Smoking
Obesity
Obstructive sleep apnea
Chronic infections

Asthma Symptom Control

During the past month, approximately how many times has the patient experienced asthma-related symptoms, such as a chronic cough, difficulty breathing, chest tightness, or shortness of breath?

- ≤2 days/week
- >2 days/week, but not daily
- Daily
- Multiple times each day

During the past month, approximately how many times has the patient experienced asthma-related nighttime awakenings?

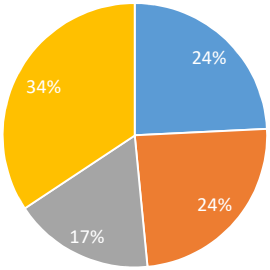
- 0
- 1-2 times/month
- Weekly
- >1 time/week

Is the patient up to date on all their immunizations, including Influenza and pneumococcal immunizations?

- Yes
- No

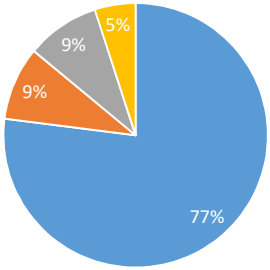
Asthma Symptom Control: Frequency of Symptoms

Initial assessment

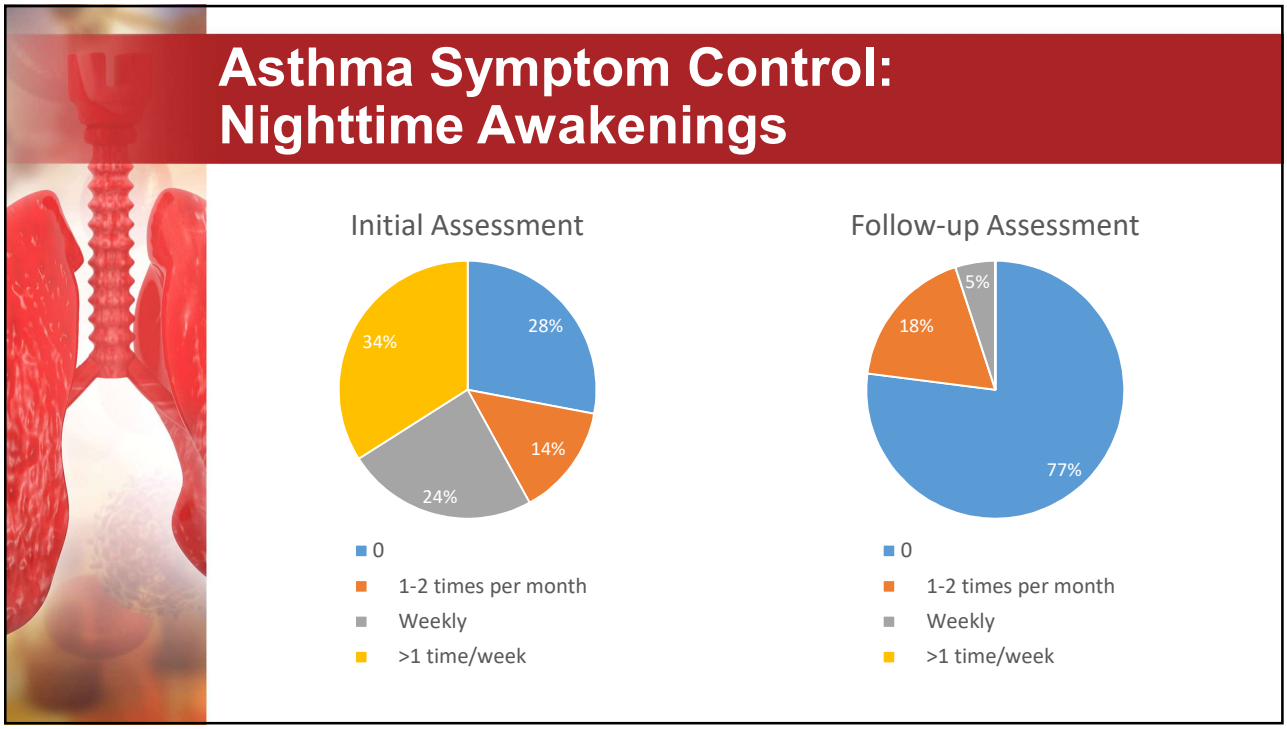


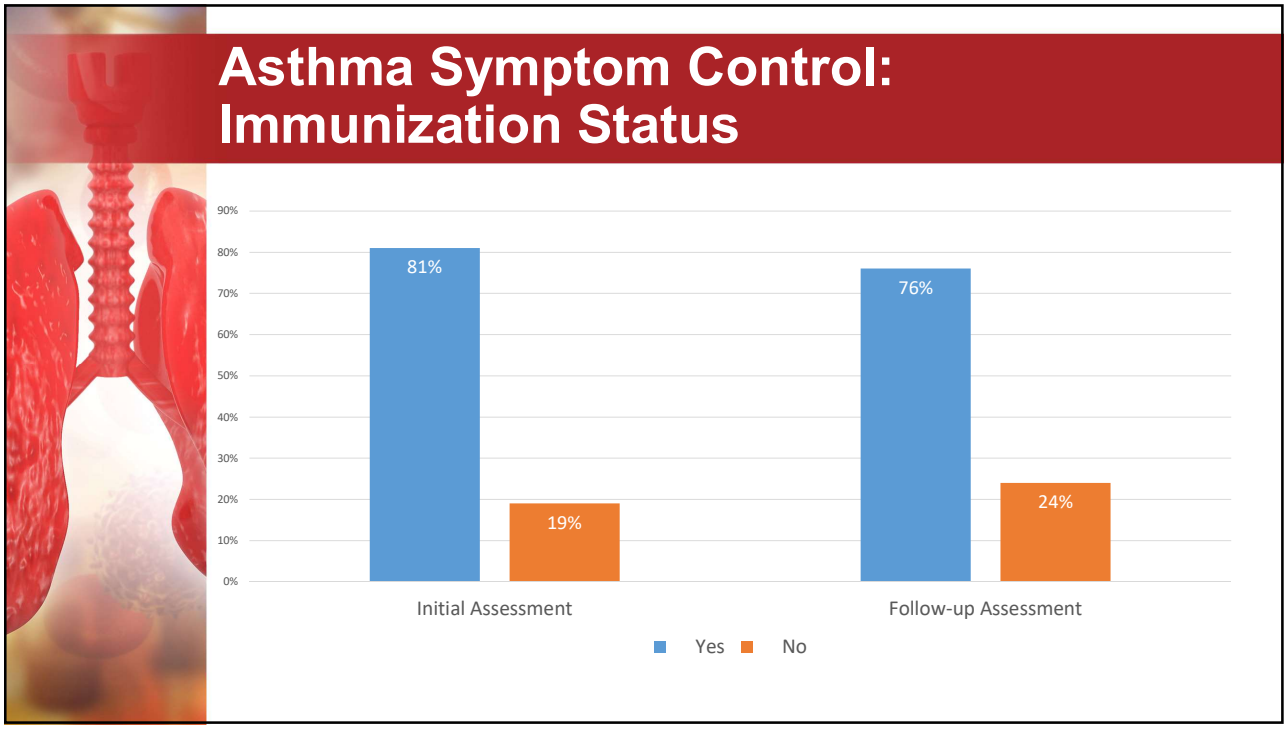
- ≤2 days/week
- >2 days/week, but not daily
- Daily
- Multiple times per day

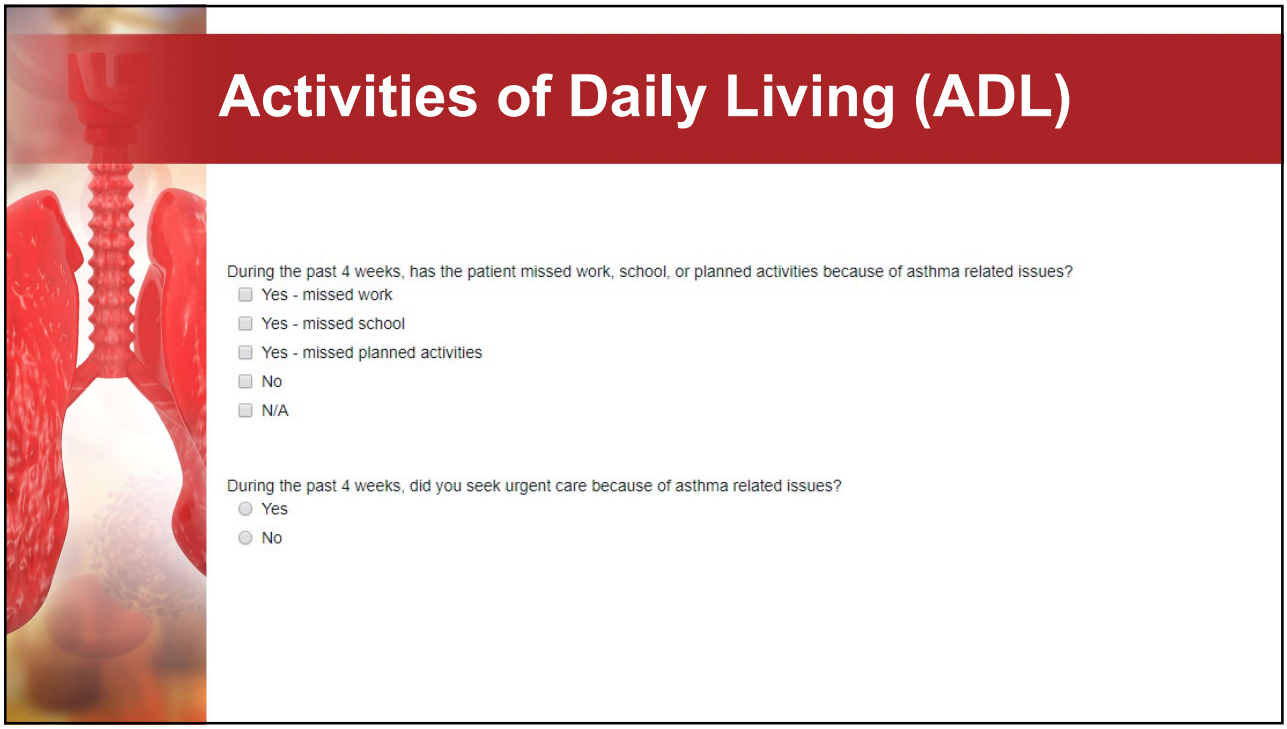
Follow-up assessment

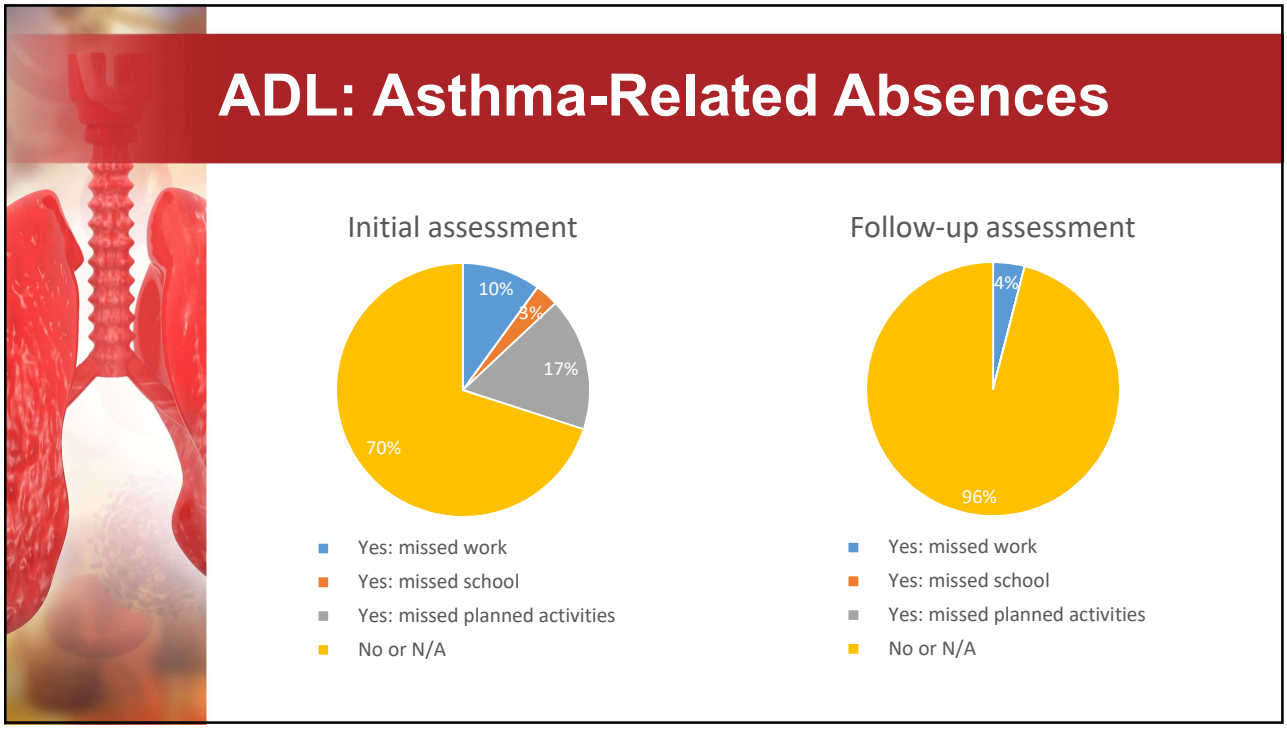


- ≤2 days/week
- >2 days/week, but not daily
- Daily
- Multiple times per day

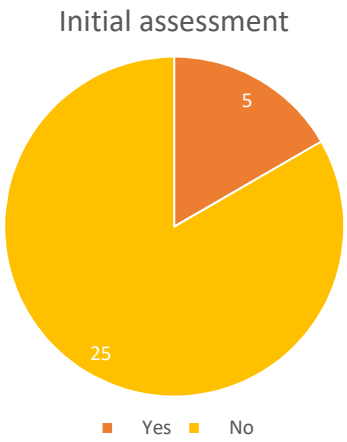

Asthma Symptom Control:
Nighttime Awakenings
Initial Assessment
28%
14%
24%
34%
0
1-2 times per month
Weekly
>1 time/week
Follow-up Assessment
77%
18%
5%
0
1-2 times per month
Weekly
>1 time/week

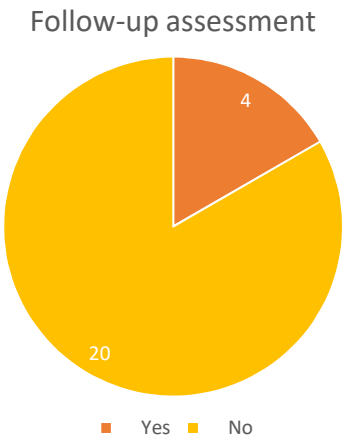

Asthma Symptom Control:
Immunization Status
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
81%
19%
76%
24%
Initial Assessment
Follow-up Assessment
Yes
No


Activities of Daily Living (ADL)
During the past 4 weeks, has the patient missed work, school, or planned activities because of asthma related issues?
Yes - missed work
Yes - missed school
Yes - missed planned activities
No
N/A
During the past 4 weeks, did you seek urgent care because of asthma related issues?
Yes
No


ADL: Asthma-Related Absences
Initial assessment
10%
3%
17%
70%
Yes: missed work
Yes: missed school
Yes: missed planned activities
No or N/A
Follow-up assessment
4%
96%
Yes: missed work
Yes: missed school
Yes: missed planned activities
No or N/A

ADL: Asthma-Related Urgent Care Visits





Other Useful Metrics

- Frequency of oral corticosteroid use
- Exacerbations requiring hospitalizations
- Spirometry results
- Pre-treatment vs. post-treatment labs
  - IgE
  - Absolute eosinophils

Key Takeaways

- Specialty pharmacy involvement can enhance or improve:
  - Quality of life
  - Adherence
  - Asthma symptom control
  - Activities of daily living
- Assessment of comorbidities is important to identify populations that are more likely to have poorer asthma outcomes
- Pre-treatment and post-treatment of objective data does not always correlate to positive asthma outcomes