

Guidelines for the Management of Asthma: 2007 Update

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Learning objectives:

At the conclusion of this program, participants will be able to:

1. State the goals of asthma therapy as they relate to control of asthma.
2. Explain environmental control activities patients can use to improve their asthma symptoms.
3. Understand the principles for managing asthma using a stepwise approach.
4. Identify preferred drug therapy recommendations based on the assigned asthma step.
5. Recognize ways pharmacists can assess and monitor asthma control for patients.

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INTRODUCTION

Asthma is characterized as a reversible, chronic inflammatory disorder of the airways involving mast cells, eosinophils, and neutrophils.^{1,2} This inflammation leads to limitations in airflow due to bronchoconstriction, airway hyper-responsiveness, and airway edema. As a result, patients with asthma initially present with recurrent episodes of wheezing, breathlessness, chest tightness, and cough. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. Overtime, remodeling of the airways may occur with changes in airway structure.² Without a proper diagnosis and adequate management,

uncontrolled asthma can lead to impaired quality of life, progressive decline in lung function, and high rates of morbidity and mortality.^{3,4}

As one of the most common chronic medical conditions affecting over 22 million Americans, asthma is responsible for about 14 million physician visits, 2 million emergency department visits, 500,000 hospitalizations, and 4,000 deaths each year.⁵ The Centers for Disease Control (CDC) estimates that more children than adults are diagnosed with asthma. In addition, minority groups disproportionately share the burden of asthma.⁵ Although the exact etiology of asthma and its underlying inflammation have not been established, genetic predisposition and environmental triggers have shown to play a role.²

DIAGNOSIS OF ASTHMA

Diagnosis of asthma follows 3 general principles:

- 1) Symptoms of recurrent episodes of airflow obstruction or airway hyper-responsiveness;
- 2) Airflow obstruction is at least partially reversible;
- 3) Alternative diagnoses are excluded.²

On initial presentation, a detailed patient history, presenting symptoms, possible triggers, and physical examination are helpful in establishing a diagnosis of asthma.² Most often, patients present with symptomatic complaints such as coughing, wheezing, dyspnea, chest tightness, and excessive mucous production. These symptoms are highly variable from person to person and from episode to episode.^{2,6} Although asthma symptoms can occur at anytime throughout the day, patients typically report symptoms at night which interrupts sleep. On physical exam, review of the upper respiratory tract, chest, and skin may provide additional useful information when evaluating a patient for asthma.²

When a diagnosis of asthma is suspected, spirometry testing can be performed to confirm the diagnosis. Spirometry testing can demonstrate obstruction by measuring the amount of air expelled after a deep breath and reversibility by showing improvement in lung function after use of a bronchodilator.^{2,7} Methacholine challenge tests may be performed if the diagnosis of asthma is still questionable after spirometry testing.⁸ Peak flow measurements should not be used for diagnosis and are currently reserved for monitoring asthma control.² Exclusion of other conditions that can lead to a similar presentation as asthma is also important for an accurate diagnosis. These include: upper airway disease, large airway obstruction, small airway obstruction, congestive heart failure (CHF), pulmonary embolism (PE), gastroesophageal reflux disease (GERD), mechanical obstruction of airways, pulmonary infiltration with eosinophilia, cough secondary to drugs, and vocal cord dysfunction.²

UPDATED ASTHMA GUIDELINES (*Based on EPR-3*)

In 1989, the National Asthma Education and Prevention Program (NAEPP) was created by the National Heart, Lung, and Blood Institute (NHLBI) to address the growing problem of asthma in the United States, enhance the quality of life for people with asthma, and decrease asthma-related morbidity and mortality. The goals of the NAEPP were to:

- Raise awareness of patients, health professionals, and the public that asthma is a serious disease;

- Ensure the recognition of the symptoms of asthma by patients, families, and the public and the appropriate diagnosis by health professionals;
- Ensure effective control of asthma by encouraging a partnership among patients, physicians, and other health professionals through modern treatment and education programs.^{3,9}

In an effort to achieve these goals, the “Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma” (EPR-1) were developed in 1991. Updates were published in 1997, 2002, and 2007 to inform all providers involved in asthma care with an interpretation of advances in asthma research to enable patients to better control their disease.^{2,9,10} According to the Expert Panel, optimal management of asthma incorporates 4 components of care: assessment and monitoring, education for a partnership in care, control of environmental factors and comorbid conditions that affect asthma, and medications.² In addition, the most recent update, EPR-3, introduced a number of new concepts including: evaluation of asthma severity and control in terms of impairment and risk, a stepwise approach to asthma management divided into 6 steps (previously 4 steps), and treatment recommendations separated into 3 age groups (previously 2 age groups).^{2,10}

Assessment and Monitoring

In order to ensure adequate control of asthma, ongoing assessment and monitoring must be performed to determine if all goals of therapy are being met. More specifically, EPR-3 emphasizes distinguishing between assessing asthma severity and monitoring asthma control.² Assessment of asthma severity should be performed at the initial patient visit when the patient is treatment-naïve. Asthma severity is used to guide clinical decision-making for choosing appropriate medication and other therapeutic interventions. Based on presenting symptoms, asthma severity is classified as intermittent, mild persistent, moderate persistent, and severe persistent (*See Figures 11, 14 of the EPR-3 Summary Report*). Once therapy is initiated, monitoring asthma control should be performed periodically to maintain or adjust therapy using the step up or step down approach. (*See Figures 12, 15 of the EPR-3 Summary Report*). Using this approach, the type, amount, and frequency of medication use is determined by the level of asthma severity or asthma control. In general, clinic visits are scheduled at 2 to 6 week intervals for patients starting therapy or who had a recent step up in therapy. Clinic visits are scheduled at 1 to 6 month intervals once asthma control is achieved to monitor if asthma control is maintained. If step down in therapy is anticipated, clinic visits at 3 month intervals is suggested. During clinic visits, assessment of asthma control, medication technique, the written asthma action plan, adherence, and addressing patient concerns are typically performed.²

When assessing and monitoring asthma severity and control, EPR-3 focuses on distinguishing between impairment and risk. Impairment is an assessment of the frequency and intensity of symptoms and its impact on a patient’s quality of life. Reduction in asthma impairment can be achieved by: prevention of symptoms, infrequent use of inhaled short-acting beta-agonists (SABA), maintenance of near normal pulmonary function, maintenance of normal activity levels, and meeting expectations of patients and family members regarding expectations and satisfaction with asthma care. In contrast, risk estimates the likelihood of asthma exacerbations, progressive loss of lung function, and/or risk of adverse effects from therapeutic interventions. Risk reduction can

be achieved by: prevention of recurrent exacerbations of asthma and minimization of the need for ED visits or hospitalizations, prevention of loss of lung function, and provision of optimal drug therapy with minimal or no adverse effects of therapy.²

Education for a Partnership in Care

Establishing a partnership between the patient and clinician is vital to effective asthma management. This partnership should commence at the time of diagnosis and continue throughout follow-up. It involves all healthcare professionals (ie. physicians, nurses, pharmacists, respiratory therapists, etc.) who interact with patients who have asthma and occurs at all points of care (ie. clinic, community pharmacy, hospital, emergency department, etc.). A successful partnership involves open communication to provide education regarding basic facts about asthma, the role of various medications used for symptomatic relief and prevention, and self-monitoring and self-management skills. Emphasis of self-care is facilitated by a written asthma action plan which should be provided to patients at each visit. A written asthma action plan includes instructions for daily management and actions to manage worsening asthma which are agreed upon by the patient and clinician (*See Figures 5, 6 of the EPR-3 Summary Report*). Although written action plans can be beneficial for any patient with asthma, they are especially recommended for those with moderate persistent or severe persistent asthma, a history of severe exacerbations, or poorly controlled asthma. When providing education to patients, it is extremely important to consider the literacy level, learning styles, and cultural background of patients.²

In the case of children, a partnership between the caregiver and clinician is essential to effective asthma management. Most children develop asthma symptoms at a young age when they are totally dependent on their caregivers. As children mature and become more capable of self-care, caregivers should still be involved with asthma care, but functioning more as coaches and supervisors.⁸

Aside from educating patients and their families, an effective partnership involves education of the clinician. When managing patients with asthma, it is essential for the healthcare provider to be up-to-date with current national asthma guidelines. Communication skills training is also essential for the clinician as effective asthma self-management education requires sensitivity to the patients' cultural beliefs and ethnocultural practices.^{2,8}

Control of Environmental Factors and Comorbid Conditions That Affect Asthma

The Expert Panel recommends a thorough evaluation of patients with asthma for possible triggers which may increase asthma symptoms and precipitate exacerbations. Identification of allergens and irritants can be conducted through a review of the patient's medical history to determine relationships between allergen exposure and worsening asthma and skin testing to identify possible allergens. Common triggers are characterized as: inhalant allergens, occupational exposures, irritants, comorbid conditions, and other factors.²

Inhalant Allergens

For both children and adults, inhaled allergens (indoor and outdoor) appear to be the most common asthma triggers. In sensitive individuals, inhaled allergen exposure leads to a cascade of inflammatory responses resulting in airway hyperresponsiveness,

airway obstruction, and exacerbation of asthma symptoms. Effective management involves specific recommendations for environmental control to reduce allergen exposures thereby minimizing inflammation, asthma symptoms, and the need for medications.²

Animal Dander

- If the sensitivity is due to an animal, the recommendation of choice is removal of the exposure from the household
- If this is not possible:
 - Keep the pet out of the patient's bedroom
 - Keep the door of the patient's bedroom closed
 - Remove upholstered furniture and carpets (or isolate the pet from these items)

Dust Mites

- Encase mattresses and pillows in allergen-permeable covers
- Wash linens weekly in hot water ($\geq 130^{\circ}\text{F}$)
- Reduce indoor humidity $\leq 60\%$
- Remove carpets from the bedroom
- Keep stuffed toys out of the bed (or wash weekly in hot water or in cold water with detergent and bleach)

Cockroaches

- Keep food out of the bedroom
- Keep food and garbage in closed containers
- Use poison baits, powders, gels, paste, or traps

Vacuum Cleaning

- Have a patient without asthma vacuum once to twice weekly, if possible
- If the patient with asthma is vacuuming, recommend the use of a dust mask, central cleaner with a collecting bag outside the house, vacuum cleaner with a HEPA filter or double-layered bag

Indoor Mold

- Fix leaking faucets, pipes, or other sources of water
- Clean moldy surfaces
- Dehumidify basements if possible

Pollen and Outdoor Molds

- During the patient's allergy season:
 - Keep windows closed
 - If possible, stay indoors
 - Initiation or increase of anti-inflammatory medications before the allergy season starts

Smoking, Strong Odors, Sprays

- If possible, avoid use wood-burning stove, kerosene heater, fireplace, unvented gas stove, or heater
- Stay away from strong odors and sprays
- Avoid tobacco smoke in the home, car, or around the patient with asthma

Occupational Irritants

For patients with new-onset asthma, questioning patients about possible occupational exposures is recommended. Occupational irritants are identified as a possible source of asthma exacerbation if asthma symptoms occur at work but improve when away from work for several days. Common jobs associated with occupational asthma are domestic cleaners, laboratory technicians, and house painters.²

Irritants

Several irritants such as tobacco smoke and air pollution have been identified which may cause worsening of asthma control. It is important to determine the smoking status of patients and family members and encourage smoking cessation, especially if there are young children in the household who have asthma. Environmental tobacco smoke is associated with increased asthma symptoms, decreased lung function, and greater use of health services among those who have asthma. Therefore, it is recommended that patients avoid situations where exposure to environmental tobacco smoke is expected to be high. For patients sensitive to air pollution, it is recommended that patients avoid, if possible, exertion or outdoor exercise when levels of air pollution are high.²

Comorbid Conditions

In addition to environmental factors, several comorbid conditions may adversely affect asthma management. Proper management of these secondary causes may lead to improvement in asthma symptoms and control. For patients complaining of frequent nighttime asthma symptoms, undiagnosed gastroesophageal reflux disease (GERD) should be considered in the differential. Management of GERD via nonpharmacologic and pharmacologic measures may lead to improvement of symptoms. Obesity has also been shown to impede asthma management. Weight loss should be encouraged as it can improve asthma control and overall well-being. Research has indicated that allergic rhinitis or sinusitis often leads to upper and lower airway involvement. As a result, management of these conditions will improve asthma control. Obstructive sleep apnea (OSA) should also be considered in patients with difficult to control asthma management. In addition, stress and depression should be considered in patients with hard to control asthma related to the possibility of non-adherence. In this case, self-management and coping skills may be beneficial.²

Other Factors

Identification of medication sensitivities is prudent in patients with asthma given its potential to cause severe and fatal exacerbations. Aspirin and other NSAIDs have been identified as common culprits leading to bronchoconstriction in susceptible patients. Patients should be advised of the seriousness of these reactions and recommended to use alternative agents for pain control such as acetaminophen, salicylates, and COX-2 inhibitors. Nonselective β -blockers have also been implicated to cause worsening asthma in some patients by antagonism of the β_2 -receptors in the lungs resulting in bronchoconstriction. Patients should be advised to avoid nonselective β -blockers, including ophthalmological preparations, although cardioselective β -blockers may be tolerated. Sulfites in foods, a preservative, have also been shown to cause severe asthma exacerbations. Sensitive patients should be advised to avoid processed potatoes, shrimp or dried fruit or drink beer or wine.²

Medications

As alluded to earlier, control of asthma in terms of impairment and risk is achieved using a stepwise approach based on different age categories. The stepwise approach incorporates all components of asthma care: assessment and monitoring, partnership in care, environmental control measures and management of comorbid conditions, and selection of medication therapy. With regards to pharmacologic management, initial treatment is dependent on the patient's degree of asthma severity (*See Figures 11, 13, 14, 16 of the EPR-3 Summary Report*). Evaluation of asthma control should be assessed and monitored at regular intervals due to the variability of asthma overtime. Therapy is increased (stepped up) to achieve more asthma control. Before stepping up therapy, it is recommended to review a patient's adherence to medications, inhaler technique, and environmental control measures. Therapy is decreased (stepped down) to avoid excessive use of unnecessary medications. Step down therapy should be initiated once asthma is well-controlled for at least 3 months to identify the minimum therapy required to maintain good control. Unique to the most recent set of national asthma guidelines, EPR-3, is that this stepwise approach has increased from 4 steps to 6 steps. With this change, recommendations at each step are more specific to further aid with treatment decisions.²

Given the high level of variability in asthma control over time, treatment decisions incorporating this heterogeneity should be considered. One of the biggest influences of asthma variability is related to the age of the patient. As a result, EPR-3 expanded to 3 age categories: 0 to 4 years, 5-11 years, ≥ 12 years.² According to members of the Expert Panel, these age categories were chosen for several reasons. Of importance is that fact that clinical trial data demonstrating safety and efficacy of medications is age-dependent with the majority of trials including patients ≥ 12 years of age. Therefore, it is unknown if these results are applicable to younger children and FDA approval of drugs is based on age. Another consideration is the issue related to achievement of adequate drug delivery for various age groups. For example, consideration must be given regarding the patient or caregiver's ability to use a nebulizer versus a metered dose inhaler versus a dry powder. In addition, assessment of lung function for severity and control are often difficult in young children making selection of appropriate drug therapy more challenging.^{2,10}

Medications used in the management of asthma belong to 2 general categories: quick-relief ("rescue") or long-term control ("preventative") medications. Selection of medications includes consideration of the mechanism of action, place in therapy, delivery devices, and safety. In general, all patients with asthma should be prescribed a short-acting beta₂ agonist for management of acute exacerbations. However, since asthma is a chronic inflammatory disorder, the mainstay of therapy for patients with any degree of persistent asthma is inhaled corticosteroids. Selection of alternative treatment options is based on consideration of treatment effectiveness, patient's history of previous response to therapy, willingness and ability to use medications, and costs.²

Quick-relief Medications (*See Figure 19 of the EPR-3 Summary Report*)

All patients with asthma should be provided with quick-relief medications in the event of an asthma exacerbation. Short-acting beta₂-agonists (SABAs), more commonly referred to as rescue medications, are considered the treatment of choice for management of acute symptoms and prevention of exercise-induced asthma. SABAs are bronchodilators that work specifically in the airways to relax smooth muscles. Albuterol

(Proventil[®], Ventolin[®], Proair[®]) and levalbuterol (Xopenex[®]) are the mostly commonly used SABAs. Patients with asthma requiring the use of SABAs ≥ 2 days per week for symptomatic relief are considered to be inadequately controlled (persistent asthma) requiring the use of long-term control medications. Although SABAs may provide quick symptomatic relief, overuse can lead to increase airway hyperresponsiveness and worsen asthma control.¹¹ Furthermore, patients should be counseled that regular and scheduled use of SABAs can lead to possible increased risks for hypokalemia, tachycardia, hyperglycemia.²

Although more commonly used in the management of chronic obstructive pulmonary disease (COPD), anticholinergic medications may provide additive benefit to SABAs for moderate or severe asthma exacerbations. Anticholinergic medications exert their beneficial effects in asthma therapy by inhibiting muscarinic cholinergic receptors and reducing intrinsic vagal tone of the airway. Ipratropium (Atrovent[®]) is the most commonly used anticholinergic inhaler and is available as a single inhaler or in combination with albuterol (Combivent[®]). Although studies have not directly compared the efficacy of anticholinergic inhalers to SABAs, ipratropium may be considered as an alternative bronchodilator in patients not able to tolerate SABAs.²

Systemic corticosteroids may be used in the acute setting. Although they are not considered short-acting, they are more commonly used in combination with SABAs for moderate and severe exacerbations to speed recovery and to prevent recurrence of exacerbations.²

Long-term Control Medications (See Figures 17, 18 in the EPR-3 Summary Report)

Long-term control medications are intended for daily use to prevent asthma exacerbations and loss of asthma control. Since asthma is a chronic inflammatory disorder, patients with all degrees of persistent asthma (mild, moderate, severe) are most effectively managed using long-term control medications directed at suppressing inflammation. Inhaled corticosteroids (ICS) are the drugs of choice for asthma maintenance therapy which reduce the underlying inflammation seen in asthma.² Commonly used ICS include: triamcinolone (Azmecort[®]), fluticasone (Flovent[®]), budesonide (Qvar[®], Pulmicort[®]), flunisolide (Aerobid[®]) and mometasone (Asmanex[®]). Low-doses of ICS should be chosen for initial therapy and therapy should be stepped up with higher doses of ICS for better asthma control as needed. ICS are safe, well-tolerated, and effective at recommended dosages in both children and adults. Use of long-term, high dose ICS have shown to have less adverse effects compared to systemic corticosteroids. However, it is recommended that children and adults who use long-term ICS have adequate intake of calcium and vitamin D due to possible adverse effects of decrease in bone mineral density with long-term, high dose ICS use. Furthermore, patients should be advised to rinse their mouth after ICS use to reduce local oral side effects.²

In addition to increasing the dose of the ICS, long-acting beta₂-agonists (LABAs) may be used adjunctively to achieve further control in moderate persistent or severe persistent asthma. The LABAs, salmeterol (Serevent[®]) and formoterol (Foradil[®]), are inhaled bronchodilators that have a duration of at least 12 hours after a single dose. LABAs are not to be used as monotherapy and are most effective when combined with an inhaled corticosteroid.² Recent studies have reported an increase in severe and life-

threatening asthma exacerbations and asthma-related deaths in patients receiving LABAs.^{2,12,13} In addition to being used as long-term controller medications, LABAs may be used before exercise for patients with exercise-induced asthma.²

Alternative agents used for long-term control of asthma include cromolyn sodium and nedocromil, immunomodulators, leukotriene modifiers, and methylxanthines. Cromolyn sodium (Intal[®]) and nedocromil (Tilade[®]) stabilize mast cells and interfere with chloride function. They can be used for patients with exercise-induced asthma or unavoidable exposure to known allergens. Omalizumab (Xolair[®]) is the only immunomodulator approved for adjunctive use for patients at least 12 years of age who have sensitivity to dust mites, cockroaches, cats, or dogs and who have severe persistent asthma. It is a monoclonal antibody that prevents binding of IgE to the high-affinity receptors on basophils and mast cells. The leukotriene modifiers montelukast (Singulair[®]), zafirlukast (Accolate[®]), and zileuton (Zyflo[®]) are also reserved for adjunctive use in asthma. Their beneficial effects in asthma are related to their ability to interfere with pathways that release mast cells, eosinophils, and basophils. Methylxanthines are systemic bronchodilators which are not widely used in the management of asthma. Examples include theophylline (Uniphyl[®], Theo-24[®]) and aminophylline which require monitoring of serum concentration given their narrow therapeutic index.²

Complimentary and Alternative Medications

It is important to keep in mind that some patients diagnosed with asthma may resort to complimentary and alternative therapies for asthma management. Such therapies include chiropractic therapy, homeopathy and herbal medicine, breathing or relaxation techniques, and acupuncture. Patients should be informed that these are not approved by the FDA and have insufficient evidence to support their use.²

Delivery Devices (See Figure 10 of the EPR-3 Summary Report)

Medications used for the management of asthma can be administered by either the inhaled or systemic routes. In most instances, the inhaled route is favored as it allows delivery of the medication directly to the lungs with minimal systemic adverse effects. Many inhalers available for asthma management are metered-dose inhalers (MDIs). Traditionally, albuterol MDIs have utilized chlorofluorohydrocarbons (CFCs) which cause deleterious effects to the ozone.² As a result, the FDA released a statement announcing that albuterol MDIs containing CFCs will no longer be produced, marketed or sold in the US after December 31, 2008. Instead, albuterol MDIs containing hydrofluoroalkane (HFA) will be favored.^{2,14} Breath-activated dry powder inhalers (DPIs) such as formoterol (Foradil[®]) and tiotropium (Spiriva[®]) are also considered environmentally friendly inhalers.²

For patients unable to master the proper MDI inhaler technique, spacers and valved holding chambers (VHCs) may be utilized. Spacers may be manufactured or homemade such as plastic bottles, corrugated ventilation tubing, toilet tissue cores, etc. Regardless, these devices are placed on the mouthpiece of the MDI to extend from the mouth of the patient and allow for more adequate delivery of medication into the lungs. VHCs are manufactured devices have one-way valves that do not allow patients to exhale into the device. These are especially useful for young children who can breathe normally and have someone else actuate the inhaler without loss of medication.²

Nebulizers are used for patients who cannot use MDIs, even with the assistance of spacers or VHCs. These devices are less dependent on a patient's coordination and cooperation and may be ideal for very young or old patients. However, devices can be expensive, time consuming, and bulky.²

PHARMACIST'S ROLE

The Expert Panel has identified several areas in which healthcare professionals can educate patients regarding basic facts about asthma, avoidance of environmental triggers, the role of medications, and patient self-management skills.² As one of the most easily accessible healthcare professions, pharmacists are certainly in the position to provide asthma-related care. Pharmacists have the knowledge and skills to identify and resolve medication-related problems, patients typically use the same pharmacy repeatedly, pharmacists are usually the last healthcare professional a patient comes in contact with before taking their medications, and pharmacists are trusted by patients making them the ideal healthcare professionals to provide asthma care.¹⁵

Whether in the community, hospital, or clinical setting, pharmacists can have a major impact in asthma management. Aside from providing asthma education, pharmacists can counsel patients regarding asthma triggers and recommendations to reduce exposure. Educating patients about the differences between quick-relief medications and long-term control medications is a valuable service pharmacists can provide. Furthermore, patients are frequently found to be under using long-term control medications due to perceived ineffectiveness while overusing quick-relief medications for symptomatic relief.¹¹ Since pharmacists are often the last healthcare professional seen by patients before using their inhaler, pharmacists are in an ideal position to teach and assess inhaler technique which has been estimated to take about 2.5 minutes per patient. Education regarding proper inhaler technique is important as high rates of incorrect inhaler technique often leads to poor asthma control and increased utilization of healthcare resources.¹⁶

In some situations, pharmacists are being called upon to collaborate with other healthcare professionals to manage patients with asthma.¹⁷ For example; some pharmacists may be responsible for directly assessing and monitoring asthma control.¹⁸ Combined with their knowledge of available asthma-related medications, various formulations, and delivery devices, pharmacists are able to make reasonable recommendations to assist in optimizing drug therapy and improving a patient's quality of life.

CONCLUSION

Asthma is a highly heterogeneous chronic condition which affects millions of Americans of all ages. Advancements in research regarding the pathophysiology, preventative measures, and treatment options emphasizes the growing need to keep current with national guidelines. As the profession of pharmacy continues to grow, so will its role in chronic disease state management. Given the high prevalence of asthma and the accessibility of pharmacists, it is imperative that pharmacists become more involved in asthma care to decrease morbidity and mortality and improve quality of life for patients.

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