Physician Implementation of Asthma Management Guidelines and Recommendations: 2 Case Studies

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Despite the development and availability of new treatments and prescription medications, asthma remains a widespread chronic health problem in the United States. Achieving asthma control in patients is a resource-intensive enterprise that requires close assessment and personalized management. Asthma is simply not a disease that can be remedied with prescription medications alone. In 2007, the National Asthma Education and Prevention Program released their Guidelines for the Diagnosis and Management of Asthma. The guidelines provide assistance and direction to health care professionals in the assessment and treatment of patients with asthma. Two cases are presented to illustrate the treatment process in light of the Guidelines and the outcomes of these patients, who have varying degrees of support, education, and assessment of adherence to an asthma treatment plan.

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A total of 18.7 million adults (8.0%) in the United States currently have asthma, and 14.2 million patient visits to physicians’ offices result in a primary diagnosis of asthma. Moreover, 1.3 million visits to hospital outpatient departments and 1.8 million visits to emergency departments occur as a result of complications caused by asthma. In 439,000 hospitalizations, asthma is the first-listed discharge diagnosis (average length of stay, 3.6 days), and 3404 deaths are caused by asthma annually (1.1 per 100,000). The vast majority of these deaths are preventable.

Asthma is a disease not easily controlled by medication alone. It has been determined that to achieve the highest degree of control possible, physicians should actively engage with their asthmatic patients, conducting appropriate testing for accurate diagnosis, teaching and observing therapy techniques, encouraging adherence, and remaining in close contact throughout treatment.

The purpose of this activity is to highlight important diagnostic considerations and management strategies and to illustrate these processes as they are applied to 2 patients who presented with nearly identical asthma symptoms and medical histories. The primary difference in the patients’ experiences correlates with the level of physician adherence to the Guidelines for the Diagnosis and Management of Asthma from the National Asthma Education and Prevention Program (NAEPP). The 2 cases reported herein demonstrate the value of incorporating these guidelines into the asthma management paradigm.

Overview of Asthma Diagnosis and Management

The recommended methods to establish a diagnosis of asthma include a detailed medical history, physical examination, and spirometry. Spirometry is an important objective method to establish the diagnosis of asthma; patient history and physical examination are not reliable methods to assess lung function or to exclude other diagnoses.

For the diagnosis of asthma to be established, the following presenting features are required:

- recurrent episodes of airflow obstruction or airway hyperresponsiveness
- wheezing, cough, shortness of breath, and chest tightness
- onset or worsening of symptoms in the presence of the following triggers: respiratory irritants, exercise, respiratory tract infection, allergens or irritants, changes in the weather, stress or strong emotional expression, and menstruation, with exclusion of alternative diagnoses
- airflow obstruction that is at least partially reversible (reversibility should be determined by an increase in forced expiratory volume in 1 second [FEV₁] of greater than 200 mL and 12% or more from baseline measured after inhalation of a short-acting β₂-agonist)

In some patients who are older than 40 years, it can be difficult to differentiate asthma from other respiratory disorders, such as chronic obstructive pulmonary disease (COPD). Typical features of COPD include midlife onset, symptoms that progress slowly, and a long history of smoking. Exceptions occur, and patients with α₁-antitrypsin deficiency can have obstructive lung disease before the age of 40 years even without smoking. In certain cases, patients with chronic asthma cannot be differentiated from those with COPD using currently available imaging and lung function testing. The patients should therefore be treated for both conditions; the management of asthma and COPD should be similar to that of asthma alone.

Studies that may be useful when considering asthma and related diagnoses include the following:

- **Spirometry.** An increase of FEV₁ back to normal after inhalation of a short-acting β₂-agonist and a course of prednisone or inhaled corticosteroids may differentiate patients who have asthma from those who have COPD.
- **Bronchoprovocation with methacholine, histamine, cold air, or exercise challenge.** A positive test result is indicative of airway hyperresponsiveness and asthma; however, methacholine often causes false-positive test results because it is nonspecific.
- **Chest radiography.** Other differential diagnoses, such as a paralyzed diaphragm, should be excluded.
- **Laboratory analyses.** Biomarkers of inflammation include total and differential white blood cell count and mediator assays of sputum.
blood, urine, and exhaled air; however, at this time, total blood immunoglobulin E (IgE), blood eosinophil count, and exhaled nitric oxide are the recommended clinical tests; these levels are usually high in patients with asthma.

**Skin test for positive allergens.**
Most patients with asthma are expected to have positive results.8

When asthma assessment and management guidelines2 are implemented, many patients with asthma demonstrate positive clinical outcomes, including improved control of asthma and health status, better quality of life, reduced limitation of activities, and fewer urgent-care visits and hospitalizations.

In 2007, the NAEPP, coordinated by the National Heart, Lung, and Blood Institute, released its most recent report, titled Expert Panel Report-3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma.7 The guidelines provide recommendations for the individualized treatment of patients with asthma and guidance for maintaining treatment based on the extent of asthma control. The National Asthma Control Initiative, also by the National Heart, Lung, and Blood Institute, focuses on 6 priority messages. Selected by the Guidelines Implementation Panel, these messages reinforce the above-mentioned clinical practice recommendations, which are vital for asthma control and high-quality, patient-centered care. These priority messages are as follows:6: assess asthma severity at the initial visit to determine initial treatment; use inhaled corticosteroids to control asthma; control environmental exposures that worsen asthma; use written asthma action plans to guide patient self-management; schedule follow-up visits at periodic intervals; and assess and monitor asthma control and adjust treatment if needed.

The Expert Panel applied a system to describe the level of evidence for each of their recommendations as follows: Evidence Category A is described as randomized controlled trials, rich body of data; B, randomized controlled trials, limited body of data; C, nonrandomized trials and observational studies; and D, panel consensus judgment.7

### Guidelines for the Diagnosis and Management of Asthma: Six Key Messages for 2 Patients

Two male patients with a history of asthma and a similar presentation received care in 2 different clinics. Henry, a 32-year-old paving contractor, and Lou, a 30-year-old construction worker, have asthma characterized by dyspnea, coughing, wheezing, and chest tightness that occasionally limit their ability to perform work duties that require intense physical labor. Their symptoms have become more frequent during the past year; each patient experiences symptoms more than 2 days per week (but not daily), and symptoms wake them 3 times per month. Each patient has had minor limitations in activity.

Henry and Lou smoke cigarettes, with a 1.5 pack-per-day habit and a history of unsuccessful attempts at nicotine replacement therapy for smoking cessation. They are currently taking a short-acting β-agonist (SABA), as needed. In the past year, 2 exacerbations have required oral systemic corticosteroid treatment. Henry’s physical examination results showed congested nasal mucosa and normal heart and lungs. His physician also ordered pulmonary function tests (spirometry). His prebronchodiator (short-acting) test showed an FEV₁ level of 4.07 L, which is 87% of the predicted value, and an FEV₁/FVC (forced vital capacity) of 81%, which is normal for his age. The postbronchodiator test showed an FEV₁ of 4.60 L, which represents a 13% (530 mL) improvement vs the prebronchodiator FEV₁. The predicted FEV₁ value for Henry (4.68 L) was based on his age and height (183 cm). Lou’s physical examination results showed congested nasal mucosa and normal heart and lungs, like Henry. However, his physician did not order spirometric testing. On allergen assessment, both patients were positive for dust mite hypersensitivity.

### Asthma Severity: Determining Initial Treatment

As the National Asthma Control Initiative states:

All patients should have an initial severity assessment based on measures of current impairment and future risk in order to determine type and level of initial therapy needed.11(p14)

Table 17 shows the recommended methods for classifying asthma severity and initiating treatment in adults.
His physician determined the level of Henry’s asthma severity to be mild persistent, per the NAEPP asthma guidelines.7 This assessment was based on Henry’s current impairment: (1) symptoms occurring more than twice per week (but not daily), (2) 3 to 4 nighttime awakenings per month, and (3) minor limitation in normal activity. The diagnosis was also made based on (4) Henry’s spirometry results (FEV₁ >80% predicted; FEV₁/FVC normal), with reversibility in FEV₁ demonstrated after the administration of a short-acting bronchodilator (>12% improvement in FEV₁, and a >200-mL increase). Relative to future risk7 and on the basis of his recent history, the physician determined that Henry was at risk for 2 or more exacerbations per year, which would require oral systemic corticosteroids.

Current impairment was assessed by determining the frequency and intensity of symptoms, the functional limitations experienced recently, and his spirometry results. Future risk was assessed by considering the frequency (within the past year) and severity of his asthma exacerbations that required oral systemic corticosteroid therapy.
Lou
In contrast, Lou’s physician did not assess the severity of his asthma—neither his current impairment nor his level of future risk.

ICS: Effective for the Long-term
According to the National Asthma Control Initiative:

Inhaled corticosteroids are the most effective medications for long-term management of persistent asthma and should be utilized by patients and clinicians as is recommended in the guidelines for treatment of asthma.12

Asthma is a chronic inflammatory condition; thus, persistent asthma is most effectively controlled with daily asthma control medication that minimizes inflammation.12 Inhaled corticosteroids are anti-inflammatory medications that work by reducing airway hyperresponsiveness, inhibiting inflammatory cell migration and activation, and blocking late-phase reaction to allergens.12 As the National Asthma Control Initiative states: "The benefits of inhaled corticosteroids outweigh the possible adverse effects." These treatments are generally well tolerated and safe when used at recommended doses.12

Figure 1 shows the available methods for asthma management.7

Henry
After discussing his treatment options with his physician, Henry expressed reluctance toward the long-term use of ICSs, citing concerns about thrush and eye problems. His physician explained the facts about low-dose ICSs vs oral corticosteroids, and Henry agreed to try a low-dose ICS to be used twice per day, with continuation of a SABA as needed for symptoms per the NAEPP asthma guidelines (step 2 therapy; Figure 2).7 The physician also prescribed a spacer to be used with the inhalers to optimize inhaler safety and efficacy. Spacers enhance delivery of medication to the lungs by decreasing oropharyngeal deposition of ICSs, thus decreasing risk of local adverse events (such as thrush7) and increasing deposition of the ICS into the lungs.

Per the NAEPP asthma guidelines, the physician also taught Henry the appropriate inhaler/spacer technique using the teach-back method and counseled him on rinsing his mouth after inhaler use.7 Henry’s physician also stressed adherence and discussed tobacco cessation and dust mite avoidance. If the physician had less time available during the visit, he would have had an allied health professional (AHP) educate Henry on asthma action plan adherence, mite avoidance, and inhaler technique.

Lou
After discussing treatment options with his physician, Lou expressed hesitancy about the long-term use of ICSs, citing concerns about thrush and his belief that ICSs increase blood glucose level (Lou’s parents have type 2 diabetes mellitus). His physician prescribed another course of oral corticosteroids and advised Lou to continue using the SABA as needed. Lou’s physician did not counsel Lou on his technique, adherence, mite avoidance, or tobacco cessation.

Allergen and Irritant Exposure Control: Managing the Environment

Clinicians should review each patient’s exposure to allergens and irritants and provide a multipronged strategy to reduce exposure to those allergens and irritants to which a patient is sensitive and exposed, that is, that make a patient’s asthma worse.13

Substantially decreasing exposure to allergens and irritants, such as first- and secondhand cigarette smoke, may significantly reduce inflammation, symptoms, and the need for medications.13

Henry
Based on Henry’s history, his physician determined that the asthma worsened when Henry was exposed to tobacco through smoking or inhaling secondhand smoke. Furthermore, Henry reported that his asthma improved during previous short-term periods of smoking cessation and when he avoided passive smoke exposure. Henry’s physician discussed the importance of smoking cessation and avoiding passive smoke to optimize asthma control, and he asked the AHP in the clinic to discuss with Henry, in layperson language, various smoking-cessation methods.
**Long-Term Control Medications**

**Corticosteroids:** Block late-phase reaction to allergen, reduce airway hyperresponsiveness, and inhibit inflammatory cell migration and activation. They are the most potent and effective anti-inflammatory medications currently available (Evidence A). ICSs are used in the long-term control of asthma. Short courses of oral systemic corticosteroids are often used to gain prompt control of the disease when initiating long-term therapy; long-term oral systemic corticosteroids are used for severe persistent asthma.

**Cromolyn sodium and nedocromil:** Stabilize mast cells and interfere with chloride channel function. They are used as alternative, but not preferred, medication for the management of mild persistent asthma (Evidence A). They can also be used as preventive treatment prior to exercise or unavoidable exposure to known allergens.

**Immunomodulators:** Omalizumab (anti-IgE) is a monoclonal antibody that prevents binding of IgE to the high-affinity receptors on basophils and mast cells. Omalizumab is used as adjunctive therapy for patients aged ≥12 y who have allergies and severe persistent asthma (Evidence B). Clinicians who administer omalizumab should be prepared and equipped to identify and treat anaphylaxis that may occur.

**LABAs:** Salmeterol and formoterol are bronchodilators that have a duration of bronchodilation of at least 12 h after a single dose.

LABAs are not to be used as monotherapy for long-term control of asthma (Evidence A).

LABAs are used in combination with ICSs for long-term control and prevention of symptoms in moderate or severe persistent asthma (step 3 care or higher in children aged ≥5 y and adults) (Evidence A for ages ≥12 y, Evidence B for ages 5-11 y).

Of the adjunctive therapies available, LABA is the preferred therapy to combine with ICS in youths aged ≥12 y and adults (Evidence A).

In the opinion of the Expert Panel, the beneficial effects of LABA in combination therapy for the great majority of patients who require more therapy than low-dose ICS alone to control asthma (ie, require step 3 care or higher) should be weighed against the increased risk of severe exacerbations, although uncommon, associated with the daily use of LABAs.

For patients aged ≥5 y who have moderate persistent asthma or asthma inadequately controlled on low-dose ICS, the option to increase the ICS dose should be given equal weight to the option of adding LABA.

For patients aged ≥5 y who have severe persistent asthma or asthma inadequately controlled on step 3 care, the combination of LABA and ICS is the preferred therapy.

LABA may be used before exercise to prevent EIB (Evidence A), but duration of action does not exceed 5 h with chronic regular use. Frequent and chronic use of LABA for EIB is discouraged, because this use may disguise poorly controlled persistent asthma (Evidence D).

In the opinion of the Expert Panel, the use of LABA for the management of acute symptoms or exacerbations is not currently recommended (Evidence D).

**Leukotriene modifiers:** Include LTRAs and a 5-lipoxygenase inhibitor. Two LTRAs are available: montelukast (for patients aged >1 y) and zafirlukast (for patients aged ≥7 y). The 5-lipoxygenase pathway inhibitor zileuton is available for patients aged ≥12 y; liver function monitoring is essential. LTRAs are alternative, but not preferred, therapy for the management of mild persistent asthma (step 2 care) (Evidence A). LTRAs can also be used as adjunctive therapy with ICSs, but for youths aged ≥12 y and adults they are not the preferred adjunctive therapy compared with the addition of LABAs (Evidence A). Zileuton can be used as alternative but not preferred adjunctive therapy in adults (Evidence D).

**Methyloxanthenes:** Sustained-release theophylline is a mild to moderate bronchodilator used as alternative, not preferred, adjunctive therapy with ICS (Evidence A). Theophylline may have mild anti-inflammatory effects. Monitoring of serum theophylline concentration is essential.

**Quick-Relief Medications**

**Anticholinergics:** Inhibit muscarinic cholinergic receptors and reduce intrinsic vagal tone of the airway. Ipratropium bromide provides additive benefit to SABA in moderate-to-severe asthma exacerbations. May be used as an alternative bronchodilator for patients who do not tolerate SABA (Evidence D).

**SABAs:** Albuterol, levalbuterol, and pirbuterol are bronchodilators that relax smooth muscle. Therapy of choice for relief of acute symptoms and prevention of EIB (Evidence A).

**Systemic corticosteroids:** Although not short acting, oral systemic corticosteroids are used for moderate and severe exacerbations as adjunct to SABAs to speed recovery and prevent recurrence of exacerbations (Evidence A).

**Figure 1.**
Long-term control and quick-relief medications, listed in alphabetical order. Medications for asthma are categorized into 2 general classes: (1) long-term control medications used to achieve and maintain control of persistent asthma and (2) quick-relief medications used to manage acute symptoms and exacerbations. Adapted from the National Asthma Education and Prevention Program. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma 2007.7

**Abbreviations:** EIB, exercise-induced bronchospasm; ICS, inhaled corticosteroid; Ig, immunoglobulin; LABA, long-acting β-agonist; LTRA, leukotriene receptor agonist; SABA, short-acting β-agonist.
Intermittent Asthma

Consult with asthma specialist if step 4 care or higher is required. Consider consultation at step 3.

Step 1
Preferred: SABA PRN
Alternative: cromolyn, LTRA, nedocromil, or theophylline

Step 2
Preferred: low-dose ICS + LABA
Alternative: low-dose ICS + either LTRA, theophylline, or zileuton

Step 3
Preferred: medium-dose ICS + LABA
Alternative: medium-dose ICS + either LTRA, theophylline, or zileuton

Step 4
Preferred: high-dose ICS + LABA
AND
Consider omalizumab for patients who have allergies

Step 5
Preferred: high-dose ICS + LABA + oral corticosteroid
AND
Consider omalizumab for patients who have allergies

Step 6
Preferred: high-dose ICS + LABA + oral corticosteroid + oral systemic corticosteroids
AND
Consider omalizumab for patients who have allergies

Step up if needed
(first, check adherence, environmental control, and comorbid conditions)

ASSESS CONTROL
Step down if possible
(and asthma is well controlled at least 3 months)

Quick-Relief Medication for All Patients
SABA as needed for symptoms. Intensity of treatment depends on severity of symptoms; up to 3 treatments at 20-minute intervals as needed. Short course of oral systemic corticosteroids may be needed.
Use of SABA >2 d/wk for symptom relief (not prevention of EIB) generally indicates inadequate control and the need to step up treatment.

Figure 2.
Stepwise approach for managing asthma in patients aged ≥12 years. The stepwise approach is meant to assist, not replace, the clinical decision making required to meet individual patient needs. If alternative treatment is used and response is inadequate, discontinue it and use the preferred treatment before stepping up. Step 1, 2, and 3 preferred therapies are based on Evidence A; step 3 alternative therapy is based on Evidence A for LTRA, Evidence B for theophylline, and Evidence D for zileuton. Step 4 preferred therapy is based on Evidence B, and alternative therapy is based on Evidence B for LTRA and theophylline and Evidence D zileuton. Step 5 preferred therapy is based on Evidence B. Step 6 preferred therapy is based on Expert Panel Report 2 (1997) and Evidence B for omalizumab. Immunotherapy for steps 2-4 is based on Evidence B for house-dust mites, animal dander, and pollens; evidence is weak or lacking for molds and cockroaches. Evidence is strongest for immunotherapy with single allergens. The role of allergy in asthma is greater in children than in adults.

Footnotes:
*Theophylline requires monitoring of serum concentration levels.
Zileuton is a less desirable alternative because of limited studies as adjunctive therapy and the need to monitor liver function.
Clinicians who administer immunotherapy or omalizumab should be prepared and equipped to identify and manage anaphylaxis that may occur. In step 6, before oral corticosteroids are introduced, a trial of high-dose ICS + LABA + either LTRA, theophylline, or zileuton may be considered, although this approach has not been studied in clinical trials.

Abbreviations: EIB, exercise-induced bronchospasm; ICS, inhaled corticosteroid; LABA, long-acting β-agonist; LTRA, leukotriene receptor agonist; SABA, short-acting β-agonist.
**Lou**

The physician neither mentioned the importance of smoking cessation to Lou, nor did he educate his patient on smoking-cessation methods.

**Asthma Action Plan: Self-Management**

The National Asthma Control Initiative states that “All people with asthma should receive a written asthma action plan to guide their self-management efforts.”

A written asthma action plan should be tailored to the needs of the patient and provide instructions and information on how to self-manage asthma daily, including taking medications appropriately, identifying and avoiding exposure to allergens and irritants that can cause asthma symptoms, and recognizing and managing worsening asthma, including when, how, and whom to contact in an emergency. The action plan should also educate patients on how to adjust their therapy based on symptoms or peak flow. A sample asthma action plan is shown in [Figure 3].

**Henry**

The AHP developed a tailored, written asthma action plan that was easy to follow and presented in layperson’s language for optimal usability and reviewed it with Henry. The action plan included elements recommended by the asthma guidelines, including information and instructions on how to self-manage his asthma daily, such as when to use his inhalers and how much to use, and reminders about avoiding exposure to tobacco smoke (active or passive). The asthma action plan also included instructions to help Henry use symptoms to assess his asthma control, to know what to do in an emergency situation, to know when and how to step up therapy, and to know when to start taking oral corticosteroids.

**Lou**

The physician sent an electronic prescription for the oral corticosteroids to Lou’s pharmacy. He did not provide Lou with a written asthma action plan.

**Follow-up Visits: Monitoring and Maintaining Asthma Control**

According to the National Asthma Control Initiative, “Patients who have asthma should be scheduled for planned follow-up visits at periodic intervals in order to assess their asthma control and modify treatment if needed,” and it further advises:

At planned follow-up visits, asthma patients should review their level of asthma control with their healthcare provider based on multiple measures of current impairment and future risk in order to guide physician decisions to either maintain or adjust therapy.

Asthma symptoms and response to asthma therapy can vary; thus, periodic monitoring of asthma control through clinical visits is essential to maintain asthma control with the optimal amount of medication. The frequency of monitoring should be determined by the physician’s judgment and will vary depending on several factors, including the level of asthma control.

In general, patient visits should be scheduled at 2- to 6-week intervals while initiating therapy or stepping up therapy to achieve control; 1- to 6-month intervals after asthma control is achieved to monitor whether asthma control is maintained; and at 3-month intervals if a step-down in therapy is anticipated. Table 2 shows the recommended methods for assessing asthma control and adjusting therapy in adults. At follow-up visits, the physician should teach and reinforce self-monitoring techniques (eg, symptom and peak flow result assessment) to enable patients to assess their level of asthma control and to recognize signs of worsening asthma.

The level of asthma control achieved in response to treatment dictates whether a treatment regimen can be maintained, stepped up (increasing dose, frequency, or number of medications, or a combination), or stepped down (decreasing dose, frequency, or number of medications, or a combination).

**Henry**

Henry’s physician had him schedule a follow-up appointment within 2 to 6 weeks after the initial visit per the NAEP asthma guidelines. At the 2-week follow-up visit, Henry reported that he had 1 mild occurrence of wheezing while performing intense labor at work, and he controlled the symptom with the assistance of his asthma action plan and, as instructed, used his SABA. He was able to fully participate in work activities, began a smoking cessation program (he had not smoked for the past week), and had ensured a mite-free home environment.
Figure 3.
Sample asthma action plan. Reprinted with permission from the Regional Asthma Management and Prevention website. Available at http://www.rampasthma.org/info-resources/asthma-action-plans/. 
As requested by his physician, Henry brought his ICS canister to the appointment, and the physician confirmed his inhaler adherence by verifying that half of the 30-day supply was gone. Using the teach-back method to reinforce proper use of his inhaler and spacer, Henry once again demonstrated the technique per the NAEPP asthma guidelines.7

The physician used this recent history to assess Henry’s asthma control (both current impairment and future risk) and decided to maintain the current therapy (step 2). He had Henry schedule follow-up appointments at 4 weeks, 3 months, and 6 months, per the NAEPP guidelines.7

3-WEEK FOLLOW-UP
Henry continued to follow his asthma action plan. Having the plan at hand allowed him to return to his normal activities, including performing his regular duties at work.

3- AND 6-MONTH FOLLOW-UP
Henry reported continued asthma control and medication adherence and stated that he had not smoked since his quit date. He completed the 5-question, validated Asthma Control Test (QualityMetric, Inc),15,16 and scored 25 out of 25, indicating that his asthma was controlled.

The physician assessed Henry’s asthma (impairment and risk), concluding that his patient’s asthma had been well controlled for 6 months. Therapy could be stepped down to step 1, and Henry could discontinue ICS use, per the NAEPP asthma guidelines.7 The physician reviewed with Henry his action plan and inhaler/spacer technique and had him schedule a follow-up appointment in 3 months, per the guidelines.7 The education included a discussion on when ICS should be re-started if necessary.

Lou

3-WEEK FOLLOW-UP
After a visit to the emergency department for an acute exacerbation of asthma symptoms, Lou returned to his physician’s office. He reported that shortly after the oral corticosteroid regimen, his daytime and nighttime symptoms returned, and his activities, including his work duties, had become increasingly limited. His physician advised him to call the office if the symptoms persisted or to make another appointment. He did not recommend any follow-up visits, but he did refer Lou to an asthma specialist. Lou was subsequently lost to follow-up.

New Treatments on the Horizon
In addition to the medications previously discussed, numerous agents are currently being investigated for the management of asthma. Ultra-long-acting inhaled β2-agonists (eg, olodaterol, indacaterol)19,20 provide 24-hour bronchodilation that allow for once-daily dosing19,20 and are being investigated in combination with ICSs.19,20 Vilanterol, also a once-per-day LABA, in combination with fluticasone furoate was recently approved for a once-per-day inhalent.19,20 Long-acting inhaled anticholinergic bronchodilators (eg, tiotropium, aclidinium),21-23 which have been approved for use in patients with COPD,21,22 provide sustained bronchodilation, improve pulmonary function, decrease asthma exacerbations, and reduce corticosteroid requirements in patients with poorly controlled asthma. Published reports have demonstrated their effectiveness in patients with asthma as an additional agent to ICS or in addition to the combination of ICS and long-acting β2-agonists; however, they are not yet approved by the US Food and Drug Administration for use in patients with asthma.21-23

Monoclonal antibodies (reslizumab [anti-interleukin 5 (IL-5)], mepolizumab [anti-IL-5], lebrikizumab [anti-IL-13], Medi-528 [anti-IL-9], Medi-563 [anti-IL-5 receptor], dalclizumab [anti-CD25], lumiliximab [anti-CD23], AMG-317 [anti-IL-4 receptor], anti-IL-4, and tralokinumab [anti-IL-13]) are parenterally administered agents being researched,25-27 and they mainly provide reduction in exacerbations in patients with poorly controlled asthma despite high-dose ICS therapy.26-27 The benefit of these agents is limited to a small number of patients with similar phenotypes, but the above monoclonal antibodies are not yet approved for therapy.

The only approved monoclonal antibody is omalizumab. Omalizumab is anti-IgE and is indicated, according to the guidelines, for severe refractory asthma not controlled with high doses of inhaled corticosteroids. Omalizumab has been demonstrated to reduce asthma exacerbations and improve asthma control.28

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Table 2. Assessing Asthma Control and Adjusting Therapy in Patients Aged ≥12 y

<table>
<thead>
<tr>
<th>Components of Control</th>
<th>Classification of Asthma Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well Controlled</td>
</tr>
<tr>
<td>Impairment*</td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>≤2 d/wk</td>
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<tr>
<td>Nighttime awakenings</td>
<td>≤2/mo</td>
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<td>Interference with normal activity</td>
<td>None</td>
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<tr>
<td>SABA use for symptom control (not prevention of EIB)</td>
<td>≤2 d/wk</td>
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<td>FEV1 or peak flow</td>
<td>&gt;80% predicted/ personal best</td>
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<tr>
<td>Validated questionnairesb</td>
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<tr>
<td>ACQ</td>
<td>≤0.75</td>
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<tr>
<td>ACT</td>
<td>≥20</td>
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<tr>
<td>Risk</td>
<td></td>
</tr>
<tr>
<td>Exacerbations (requiring oral systemic corticosteroids)</td>
<td>0-1/y</td>
</tr>
<tr>
<td>Progressive loss of lung function</td>
<td>Medication side effects can vary in intensity from none to very troublesome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk.</td>
</tr>
<tr>
<td>Treatment-related adverse effects</td>
<td>Evaluation requires long-term follow-up care</td>
</tr>
<tr>
<td>Recommended Action for Treatmente</td>
<td>Maintain current step. Regular follow-up every 1-6 mo to maintain control. Consider step down if well controlled for ≥3 mo.</td>
</tr>
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* Assess impairment domain by patient’s recall of previous 2-4 wk and by spirometry or peak flow measures. Symptom assessment for longer periods should reflect a global assessment, such as inquiring whether the patient’s asthma is better or worse since the last visit.

b Minimal important difference for these questionnaires is as follows: 1.0 for the ATAQ (Asthma Therapy Assessment Questionnaire); 0.5 for the ACQ (Asthma Control Questionnaire); not determined for the ACT (Asthma Control Test).

c At present, there are inadequate data to correspond frequencies of exacerbations with different levels of asthma control. In general, more frequent and intense exacerbations (eg, requiring urgent, unscheduled care; hospitalization; intensive care unit admission) indicate poorer disease control. For treatment purposes, patients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have not-well-controlled asthma, even in the absence of impairment levels consistent with not-well-controlled asthma.

d See Figure 2 for steps. The stepwise approach is meant to assist, not replace, the clinical decision making required to meet individual patient needs. Level of control is based on the most severe impairment or risk.

e Before step up in therapy, review adherence to medication, inhaler technique, environmental control, and comorbid conditions. If an alternative treatment option was used in a step, discontinue and use the preferred treatment for that step.

Abbreviations: EIB, exercise-induced bronchospasm; FEV1, forced expiratory volume in 1 second; NA, not applicable; SABA, short-acting β-agonist.

Conclusion

In patients with suspected asthma, spirometric testing is important in establishing the diagnosis. The proper assessment and management of asthma is essential to patients' quality of life and well-being. Most patients can control their asthma with appropriate care. Follow-up appointments should be scheduled within 2 to 6 weeks after treatment initiation, with subsequent follow-up appointments at 3-month intervals once asthma control is achieved. At each follow-up visit, physicians should review the patients' level of asthma control (based on current impairment and future risk), success and adherence with inhaler/spacer techniques, and use of the asthma action plan. The science behind ideal management strategies for asthma control is robust and has been translated into evidence-based asthma guidelines, which, if implemented, can improve patient care. The use of the 6 priority messages selected by the Guidelines Implementation Panel can help physicians efficiently optimize patient outcomes.

References


