



ASTHMA UPDATE

A focus on new
management
recommendations
for children
and adults

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Asthma is the most common chronic respiratory disorder in Canada. In 2009, 2.3 million Canadians, aged 12 years and older, had asthma.⁽¹⁾ Pharmacists working in the community setting have the potential to make a significant impact on the clinical outcomes of patients with asthma.⁽²⁾ It is important that pharmacists keep up-to-date with current management strategies, since they could be a significant resource to help narrow the identified care gaps in asthma management.⁽³⁾

In response to recent significant scientific evidence, the Canadian Thoracic Society (CTS) initiated the formal lengthy process of updating the 2003 Canadian Asthma Consensus Guidelines. To assist practitioners until the new guidelines are available, the CTS recently published a comprehensive management continuum diagram encompassing asthma management for children six years and older and adults (see Figure 1 of the article available at [www.respiratoryguidelines.ca/sites/all/files/cts_asthma_consensus_](http://www.respiratoryguidelines.ca/sites/all/files/cts_asthma_consensus_summary_2010.pdf)

[summary_2010.pdf](http://www.respiratoryguidelines.ca/sites/all/files/cts_asthma_consensus_summary_2010.pdf)).⁽⁴⁾ In addition, pending the development of Canadian guidelines for asthma in children five years of age and younger, the CTS endorsed application of the Global Initiative for Asthma (GINA) guidelines for the diagnosis and management of asthma in this age group.⁽⁵⁾ This article highlights the main changes in the 2010 CTS asthma management recommendations for children six years and older and adults. It puts into perspective recently published literature, including the GINA guidelines for the management of acute exacerbations of asthma in the community setting. It also addresses the role pharmacists should play in the management of asthma and suggests specific actions that pharmacists could take in day-to-day practice.

Pathophysiology

Asthma is an inflammatory disorder of the airways characterized by paroxysmal or persistent symptoms, such as dyspnea, chest tightness, wheezing, sputum production and cough, which are associated

with variable airflow limitation and a variable degree or hyperresponsiveness of airways to endogenous or exogenous stimuli.⁽⁶⁾ The fact that asthma is a chronic inflammatory disorder of the airways has implications for the diagnosis, management and potential prevention of the disease. Airway inflammation contributes to airway hyperresponsiveness, airflow limitation, respiratory symptoms and disease chronicity. In some patients, persistent changes in airway structure occur, including sub-basement fibrosis, mucus hypersecretion, injury to epithelial cells, smooth muscle hypertrophy and angiogenesis. Gene-by-environment interactions are important to the expression of asthma. Atopy, the genetic predisposition for the development of an immunoglobulin E (IgE)-mediated response to common aeroallergens, is the strongest identifiable predisposing factor for the development of asthma. Viral respiratory infections are one of the most important causes of asthma exacerbations and may also contribute to the development of asthma.⁽⁷⁾

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Approach to Management

Five main principles of asthma management are common for all patients⁽⁸⁾

1. Confirm diagnosis with history and objective lung function measurements
2. Self-management education including:
 - a. Environmental trigger avoidance
 - b. Inhaler technique
 - c. Adherence
 - d. Written action plan
3. Reliever therapy (fast-acting bronchodilator for PRN use)
4. Daily controller therapy
5. Regular reassessment of asthma control, including spirometry or peak expiratory flow (PEF)

Diagnosis

Features suggestive of asthma include the following:⁽⁸⁾

- Frequent episodes of breathlessness, chest tightness, wheezing or cough
- Symptoms worse at night and in the early morning
- Symptoms develop with a viral respiratory tract infection, after exercise or exposure to aero-allergens or irritants
- Symptoms develop in young children after playing or laughing

table 1

Diagnosis of asthma: pulmonary function criteria⁽⁴⁾

PULMONARY FUNCTION MEASUREMENT	CHILDREN (6 YEARS OF AGE AND OLDER)	ADULTS
Preferred: Spirometry showing reversible airway obstruction Reduced FEV ₁ /FVC AND Increase in FEV ₁ after a bronchodilator or after course of controller therapy	Less than lower limit of normal based on age, sex, height and ethnicity (< 0.8–0.9)* AND ≥ 12%	Less than lower limit of normal based on age, sex, height and ethnicity (< 0.75–8.0) AND ≥ 12% (and a minimum ≥ 200 mL)
Alternative: Peak expiratory flow variability Increase after a bronchodilator or after course of controller therapy OR Diurnal variation†	≥ 20% OR Not recommended	60 L/min (minimum ≥ 20%) OR > 8% based on twice daily readings; > 20% based on multiple daily readings
Alternative: Positive challenge test Methacholine challenge OR Exercise challenge	PC ₂₀ < 4 mg/mL (4 mg/mL–16 mg/mL is borderline; >16 mg/mL is negative) OR ≥ 10–15% decrease in FEV ₁ post-exercise	

*Approximate lower limits of normal ratios for children and adults; †Difference between minimum morning pre-bronchodilator value in one week and maximum nighttime value as % of recent maximum; FEV₁ = forced expiratory volume in one second; FVC = forced vital capacity; PC₂₀ = provocative concentration of methacholine producing a 20% fall in FEV₁.

• Symptoms improve with bronchodilators or corticosteroids.

Clinical suspicion of asthma should be confirmed by objective measures of pulmonary functions showing reversible airway obstruction (after a bronchodilator), variable airflow limitation over time or airway hyper-responsiveness in all patients able to undergo lung function testing reproducibly.⁽⁴⁾ In the new CTS guidelines, the diagnostic criteria for asthma are unchanged compared to the previous version of the guidelines, but greater emphasis is placed on the need to confirm the diagnosis of asthma with objective assessment of lung function using the methods outlined in Table 1. Up to one-third of adults with physician-diagnosed asthma do not have asthma when objectively assessed.^(9–11) Many patients with controlled asthma will not exhibit airflow obstruction or a > 12% post-bronchodilator reversibility at each spirometry assessment. To increase sensitivity, spirometry should be repeated particularly during periods when a patient is experiencing symptoms. A trial of therapy is acceptable to confirm a clinical diagnosis, particularly in young children and when methacholine testing is not feasible.⁽⁴⁾

Asthma Control

The primary goal of asthma management is to control the disease and, by doing so, prevent or minimize the risk of short- and long-term complications, morbidity and mortality.⁽⁴⁾

The current CTS criteria to assess asthma control (Table 2) generally remain the same as in the 2003 guidelines, with two exceptions. First, the regular need for a reliever to prevent or treat exercise-induced symptoms indicates suboptimal control and should be included in the weekly reliever dosage limit. Such individuals may need escalation of controller therapy. Second, an acute care visit (e.g., walk-in clinic, emergency department or hospitalization) is considered a management failure and should prompt the review of maintenance therapy and factors contributing to poor control.⁽⁴⁾

GINA and the Asthma Society of Canada, on the other hand, strive for complete control of asthma symptoms, including no symptoms, no night-time awakenings, no time lost from school, work or play, no exercise limitations, no emergency room visits, no time spent in hospital because of asthma, and no side effects from asthma medications.^(12,13)

TO ASSESS ASTHMA CONTROL

ACTION BY PHARMACIST:

1. Assess the criteria of good asthma control as per Table 2. In order to have good asthma control, all criteria must be met.
2. Review the date of last refill of inhalers. At 200 doses per inhaler, a salbutamol inhaler should last at least a year (52 weeks x 3 doses/week = 156 doses) in a patient with well-controlled asthma.
3. Assess technique of inhaler administration.
4. Assess adherence.

NEW DEVICES

Two new devices are now available to assist patients in monitoring asthma control. Microlife has developed a Digital Asthma Monitor (www.microlife.com, \$78, Figure 1). The device is designed for use by adults and children with asthma and other chronic lung diseases. It allows patients to monitor

feature

figure 1
Digital
Asthma
Monitor



figure 2
Pulmo
Scale



PEF and forced expiratory volume in one second (FEV₁). The measurements can be easily downloaded to a computer.

Another new device called Pulmo Scale (Eristan Medical Systems, www.PulmoScale.com, \$59, Figure 2) is designed to count (by weight) the remaining doses in any metered dose inhaler. This device can be used by individual patients or it could be used by pharmacists to screen patients' inhalers in the pharmacy to help assess adherence.

CURRENT STATE OF CONTROL

Recent survey results indicate that the control of symptoms of asthma in Canadians is poor and patients also consider themselves well-controlled despite severe episodes. A 2010 survey (the Asthma Insight and Management in Europe and Canada

[EUCAN AIM] survey, sponsored by Merck) was conducted in 401 randomly selected Canadians adults and parents of adolescents aged 12–17 years.⁽¹⁴⁾ The majority (77%) considered their asthma well-controlled at the time of the survey. However, in the year prior to the survey, half (52%) of patients reported that they were hospitalized, visited an emergency room or received other emergency medical care for their asthma symptoms, with five per cent requiring hospitalization overnight. This illustrates that many Canadians living with asthma currently have low expectations for achieving control of their disease, which impacts important aspects of their daily lives. During the past year, 21% of survey respondents had missed work or school due to their asthma.

The results of this survey are consistent with The Reality of Asthma Control (TRAC) study published in 2007, which found that almost all (97%) of the 893 patients studied believed that they had controlled asthma; however, only 47% had controlled disease according to symptom-based criteria.⁽¹⁵⁾ Only three per cent of patients thought that their asthma was uncontrolled, while family physicians and specialists determined asthma to be uncontrolled in 12% and 10% of patients, respectively. Almost three-quarters of patients expressed concerns about taking inhaled corticosteroids (ICS). One-third of patients thought they had not been taught to recognize the early signs of asthma worsening and one-quarter claimed they had received no instruction on what to do when asthma symptoms became worse.⁽¹⁶⁾ Up to one-third of patients had never heard of the distinction between reliever and controller medications, were confused about the differences between the two, or did not know whether to use them regularly or as needed.

In a recent study, a large percentage of children with persistent asthma were prescribed intermittent rather than daily ICS and adherence to ICS in children was suboptimal (62.4%, using the proportion of prescribed days covered, and 18.5%, using the proportion of days covered), even if many continued to experience poor asthma control.⁽¹⁷⁾

table 2

Signs of good asthma control⁽⁴⁾

CHARACTERISTIC	FREQUENCY OR VALUE
Daytime symptoms	< 4 days/week
Night-time symptoms	< 1 night/week
Physical activity	Normal
Exacerbations	Mild, infrequent
Absence from work or school due to asthma	None
Need for a fast-acting beta ₂ -agonist	< 4 doses/week
FEV ₁ or PEF	> 90% personal best
PEF diurnal variation*	< 10–15%

*Diurnal variation is calculated as the highest peak expiratory flow (PEF) minus the lowest PEF divided by the highest PEF multiplied by 100 for morning and night (determined over a two-week period); FEV₁ = forced expiratory volume in one second.

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Essentials of Pharmacovigilance and Risk Management: Industry and Pharmacists Advancing Patient Safety

By Nancy Hanna, B.Comm, B.Pharm

Upon successfully completing this lesson, the pharmacist will be able to:

1. Discuss the limitations of clinical trial safety data and the importance of adverse reaction reporting
2. Describe the general concept of pharmacovigilance activities within the pharmaceutical industry, and the regulated environment surrounding such activities
3. Understand the process or related to reporting an adverse reaction
4. Describe the concept of benefit-risk assessment and risk management planning
5. Recognize the fundamental role of the pharmacist in pharmacovigilance and risk management

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TO IMPROVE ASTHMA CONTROL

ACTION BY PHARMACIST:

1. When counselling patients about inhalers, use the terms “reliever” and “controller” and reinforce their proper use over several visits.
2. Patients are frequently concerned about inhaled corticosteroids. Assess whether this is an issue for them.
3. Ask patients if they know how to recognize early symptoms indicating that their asthma is not controlled and what they are planning to do if this situation occurs.

ENVIRONMENTAL CONTROL

Controlling environmental factors (Table 3) still plays an important role in the management of asthma.⁽¹⁸⁾ The Asthma Society of Canada has compiled a list of triggers according to the season of the year and strategies to control them.⁽¹⁹⁾ The clinical benefits of single interventions to reduce indoor allergens are controversial.⁽⁴⁾ Evidence is strongest for multifaceted interventions, but further research is warranted to assess their cost-benefit ratio. Of note, studies of bathing pets and using high-efficiency particulate air filters have not demonstrated substantial benefits.⁽⁴⁾

In the 2010 Asthma Management Continuum consensus summary, more emphasis is placed on work-related issues. Approximately 25% of adult asthma cases are estimated to be work-related and 10–15% of adult asthma may be caused by occupational agents.⁽²⁰⁻²²⁾ The red flags in Table 4 may be clues that symptoms are caused by something at work.⁽²³⁾

ASSESSMENT OF TRIGGERS

ACTION BY PHARMACIST:

1. Assess asthma triggers, including red flags (Table 4) for people who work.
2. At each clinical visit, if appropriate, parents should be encouraged to cease smoking in the home and other enclosed spaces (e.g., automobiles).

Self-management education, and written action plan

Guided self-management education and

written action plans have been shown to reduce hospitalizations, emergency visits, urgent physician visits, missed days at work or school and days of restricted activity, and also improve pulmonary function in children and adults.⁽²⁴⁻²⁶⁾ Written action plans are a key component of care for all patients with asthma. In contrast to verbal action plans, which have not been shown to be of benefit, written action plans are highly effective therapeutic tools, particularly when combined with asthma education, self-monitoring and regular review of the action plan.⁽²⁷⁾ Pharmacists are particularly skilled to play a role in the education and development of written action plans in collaboration with physicians.⁽²⁸⁻³¹⁾ Many examples of paper-based and electronic asthma action plans are available for children and adults.⁽³²⁻⁴¹⁾

WRITTEN ACTION PLAN

ACTION BY PHARMACIST:

Ask patients if they have a written Asthma Action Plan. At a minimum, this will plant the seed for the need to have one. It is also a good opportunity to get involved in asthma care.

Pharmacotherapy

The main highlights of the 2010 Asthma Management Continuum consensus summary for the pharmacological management of asthma are as follows:⁽⁴⁾

- 1) ICS should be introduced early, as the initial maintenance treatment for asthma, even in individuals who report asthma symptoms fewer than three times per week.
- 2) Leukotriene receptor antagonists (LTRAs) are second-line monotherapy for mild asthma.
- 3) Children Most children will achieve control on a low-dose ICS. Higher doses of ICS may be associated with significant adverse effects in children and should only be used by asthma specialists. Most children six years and older should be able to use a holding chamber with a mouthpiece or a dry powder inhaler. If a low-dose ICS is not adequate to maintain control:

- In children six to 11 years: Increase the ICS to moderate dose before adding an addi-

tional agent such as a long-acting β_2 -agonist (LABA) or LTRA. Use of a LABA (only in combination with an ICS, ideally in the same inhaler device) should only be considered as add-on therapy for individual children whose asthma remains uncontrolled despite medium-dose ICS. Single inhaler budesonide-formoterol (or mometasone-formoterol, which was recently approved in Canada) combination therapy is not approved in children < 12 years old. Clinical data are insufficient to recommend use of the salmeterol-fluticasone combination dry powder inhaler in children younger than four years of age or the salmeterol-fluticasone inhalation aerosol in children younger than 12 years of age.⁽⁴²⁾

- In patients 12 years and older: use of a LABA may be considered as add-on therapy for individuals whose asthma remains uncontrolled despite a low-dose ICS. A LABA should be considered first as add-on therapy only in combination with an ICS, ideally in the same inhaler device. Third-line therapeutic options are increasing to a moderate dose of ICS or addition of a LTRA.

- 4) Theophylline may be considered as a fourth-line agent in adults.
- 5) Severely uncontrolled asthma may require additional treatment with oral prednisone.
- 6) Omalizumab, an anti-immunoglobulin E (IgE) monoclonal antibody, may be considered in individuals 12 years of age and older with poorly controlled atopic asthma despite high doses of ICS and appropriate add-on therapy, with or without prednisone. Because of its significant cost, omalizumab should only be considered for patients with difficult-to-control asthma (confirmed with objective measures), who have documented allergies to a perennial aeroallergen, a serum IgE level of 30–700 IU/mL and whose asthma symptoms remain uncontrolled despite adherence to high-dose ICS plus at least one additional controller therapy. It is administered subcutaneously once or twice per month, depending on the patient's body weight and serum IgE level.
- 7) Asthma symptom control and lung function tests, inhaler technique, adherence to asthma treatment, exposure to asthma triggers in the environment (allergens,



table 3 Triggers of asthma⁽¹⁸⁾

<p>Inflammatory (allergic) triggers</p> <ul style="list-style-type: none"> • Dust mites • Animals • Cockroaches • Moulds • Pollens • Viral infections • Certain air pollutants 	<p>Symptom (nonallergic) triggers</p> <ul style="list-style-type: none"> • Smoke • Exercise • Cold air • Chemical fumes and other strong-smelling substances (e.g., perfumes) • Certain food additives (e.g., sulfites) • Certain air pollutants • Intense emotions
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irritants, occupational sensitizers) or medications that could worsen asthma (NSAIDs, β -blockers) and the presence of comorbidities (sinus symptoms, GERD) should be reassessed at each visit and before altering maintenance therapy. Demonstration videos of the different inhalation devices are available from the Lung Association (www.olapep.ca/online-learning/inhalation-devices-cd).⁽⁴³⁾

- 8) After achieving proper asthma control for at least a few weeks to months, the medication(s) should be reduced to the minimum dose(s) necessary to achieve adequate control.

EFFICACY OF ICS IN SMOKERS

The efficacy of ICS is reduced in patients who smoke. Patient with mild persistent asthma are insensitive to low-dose ICS.⁽⁴⁴⁾ This difference in response compared to non-smokers is not as pronounced at high doses of ICS. A patient with asthma who smokes may particularly benefit from a LTRA.⁽⁴⁵⁾ In asthma patients who smoke, the clinician conscientiously following the guidelines might find no response to low-dose ICS, increase the dose as instructed and continue to get no response. The consequence of failing to account for the smoking status of asthma patients will result in over-treatment with ICS.

Monitoring and education in children

Education must be given to the parent-child for young children, with shifting of the educational efforts to the child as he/she approaches adolescence. Carefully monitor growth (height and weight) of children at each visit. A fall off the growth curve should prompt referral to a specialist. The World Health Organization growth charts were updated in 2007 and paper-based or electronic versions are available.⁽⁴⁶⁻⁴⁸⁾ A guide on how to use these growth charts is also available.⁽⁴⁹⁾

Recent developments

The following issues have arisen in the literature after publication of the CTS 2010 consensus summary.

STEP-UP THERAPY IN CHILDREN

In the Best Add-on Therapy Giving Effective Responses (BADGER) trial, LABA step-up therapy in children (6 to 17 years of age) was significantly more likely to provide the best response compared to either ICS or LTRA step-up. However, many children had a best response to ICS or LTRA step-up therapy, which highlights the need to regularly monitor and personalize each child's asthma therapy.⁽⁵⁰⁾

USE OF LABAs

In response to safety concerns related to an observed increased risk of severe asthma exacerbations requiring hospitalizations in children and adults, and increased death, the CTS Asthma committee published a commentary on long-acting β_2 -agonist use for asthma in Canada.⁽⁵¹⁻⁵³⁾ The recommendations are summarized below:

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Strategies for Managing
 Nighttime Heartburn Symptoms:
 Introduction of a New Proton
 Pump Inhibitor Option

By Michael Boivin, BSc Pharm

Upon successfully completing this lesson, the pharmacist will be able to:

1. Educate a patient about the pathophysiology of GERD.
2. Counsel patients on important risk factors of PPI therapy necessary for optimal outcomes.
3. Discuss circumstances that cause many patients to experience breakthrough symptoms while taking PPIs.
4. Screen, as now and appropriately based on patients that experience GERD symptoms while taking PPI therapy.
5. Counsel patients on a new PPI option for the treatment of GERD.

Supported by an educational grant from

- LABAs should never be used alone (as monotherapy) for asthma in any age group
- LABAs should only be used as add-on therapy to an anti-inflammatory controller (such as an ICS, ideally in the same inhaler device) in any age group
- All patients and caregivers should receive self-management education, including the role and proper use of medications, and a written action plan; and
- All patients with asthma should receive regular medical review. Asthma controller therapy should be adjusted to the least amount required to maintain control under the supervision of a health-care provider.

SINGLE INHALER MAINTENANCE/ RELIEVER THERAPY

Controversy exists around the use of a single ICS/LABA inhaler for maintenance and reliever therapy (SMART: Single maintenance and reliever therapy). A recent critical appraisal did not find better treatment outcomes with that approach compared to conventional physician-monitored and individualized adjustment of separate ICS and LABA inhalers.⁽⁵⁴⁾ Two 2009 Cochrane reviews concluded that single ICS/LABA inhaler therapy can reduce the risk of asthma exacerbations requiring oral corticosteroids in patients with severe asthma compared to fixed-dose maintenance ICS, but did not significantly reduce exacerbations compared to current best practice.^(55,56)

TIOTROPIUM

Interestingly, in a recent study of 210 patients, tiotropium when added to an inhaled glucocorticoid, improved symptoms and lung function in patients with inadequately controlled asthma. Its effects

appeared to be non-inferior to those with the addition of salmeterol.⁽⁵⁷⁾

OVERTREATMENT

Many patients with asthma may be over-treated due to various reasons. Unlike hypertension and diabetes, overtreatment of asthma is not linked to overt adverse effects and, therefore, may not be readily detected. Long-term risks of maintaining high-dose ICS treatment include osteoporosis and cataracts, which develop slowly and are commonly seen in the population. Long-term high-dose treatment is also more costly. Unfortunately, clinicians are likely to perceive the risk of maintaining high-dose treatment to be less than the risk associated with reducing the dose and potentially losing asthma control and patient confidence.⁽⁵⁸⁾ Overtreatment applies not only to ICS, but also to combination inhalers (LABA + ICS).⁽⁵⁹⁾

MANAGEMENT OF EXACERBATIONS

Exacerbations of asthma are episodes of a progressive increase in shortness of breath, cough, wheezing or chest tightness, or some combination of these symptoms. They are characterized by decreases in expiratory airflow that can be quantified and monitored by measurements of lung function (PEF or FEV₁). PEF and FEV₁ are more reliable indicators of airflow limitation, but an increase in the severity of symptoms may be more sensitive to the onset of an exacerbation as it usually precedes the deterioration in airflow. However, a minority of patients perceives symptoms poorly and may have a significant deterioration in pulmonary function without a change in symptoms.⁽⁶⁰⁾

The key to successful management of an asthma exacerbation is early recognition with prompt initiation of medical therapy.⁽⁶⁰⁾ The upcoming full revision of the CTS asthma guidelines (expected in the fall of 2011) will update the management of exacerbations. In the interim, GINA provides guidance on this issue.⁽⁶¹⁾

PATIENTS AT HIGH RISK OF DEATH

Patients at high risk of asthma-related death require close attention and should be encouraged to seek urgent care early in the course of their exacerbation.

These include patients with the following risk factors:⁽⁶¹⁾

- History of near fatal asthma requiring intubation or mechanical ventilation
- Hospitalization or emergency visit within the past year
- Currently using or recently stopped using an oral corticosteroid
- Not currently using an ICS
- Overdependent on rapid-acting inhaled β_2 -agonists, especially those who use more than one canister of salbutamol (or equivalent) monthly
- History of psychiatric disease or psychosocial problems, including the use of sedatives
- History of non-compliance with an asthma medication plan.

ACUTE ASTHMA EXACERBATIONS

ACTION BY PHARMACIST:

Patients should immediately be referred for medical care if:

- The attack is severe:
 - ★ The patient is breathless at rest, is hunched forward, talks in words rather than sentences, is agitated, drowsy or confused, has bradycardia, or has a respiratory rate > 30/minute
 - ★ Wheeze is loud or absent
 - ★ Pulse is > 120/min
 - ★ PEF is < 60% of predicted or personal best, even after initial treatment
- The patient is exhausted
- The response to the initial treatment in the patient's Asthma Action Plan is not prompt and sustained for at least 3 hours
- There is no improvement within 2–6 hours after oral corticosteroid treatment is started
- There is further deterioration

Do not recommend mucolytics as they may worsen the cough.

Mild attacks, defined by a reduction in peak flow of < 20%, nocturnal awakening and increased use of rapid-acting β_2 -agonists, can usually be treated at home if the patient is prepared and has a personal asthma management plan that includes action steps. Moderate attacks may require—and severe attacks usually require—care in a clinic or hospital.⁽⁶¹⁾

(cont'd on page 64)

table 4

Red flags of asthma at work⁽²³⁾

Symptoms get worse at work or after work hours during the week

Symptoms go away when away from work for several days or while on holidays

Symptoms keep the patient up at night

Symptoms start after working with a new substance (e.g., a new kind of paint or flour)

Co-workers have similar symptoms

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