## Medicine Today THE PEER REVIEWED JOURNAL OF CLINICAL PRACTICE

Asthma
The guidelines
in practice

Foreword: Introduction to the *Australian Asthma Handbook* 

Long-term management of asthma: the new Australian guidelines

Spirometry: its role in diagnosing and managing asthma

Maintenance and reliever therapy in asthma: budesonide/eformoterol combination

Asthma action plans: two examples



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### MedicineToday







### Foreword: An introduction to the Australian Asthma Handbook

HELEN REDDEL

### PEER REVIEWED FEATURE ARTICLES

### Long-term management of asthma: the new Australian guidelines

KERRY HANCOCK

The key primary care management messages of the Australian Asthma Handbook emphasise accurate diagnosis of asthma and management based on assessment of asthma symptom control and risk factors, adjustment of therapy to achieve good control, and review of the response and monitoring to maintain control.

### Spirometry: its role in diagnosing and managing asthma

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### Maintenance and reliever therapy in asthma: budesonide/eformoterol combination 25

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The articles in this supplement have been specially commissioned for this publication. Each has been subjected to Medicine Today's usual rigorous peer review process. This supplement has been sponsored by an unrestricted educational grant from AstraZeneca. The opinions expressed in the articles are those of the author and not necessarily those of AstraZeneca. Some products and/or indications mentioned may not be approved for use in Australia. Please review Product Information, available from the manufacturer, before prescribing any agent mentioned in these articles.

### An introduction to the Australian Asthma Handbook

HELEN REDDEL MB BS, PhD, FRACP

The latest update to Australia's asthma guidelines, the Australian Asthma Handbook, aims to fill important gaps in quality care of asthma. This Medicine Today supplement explores some key changes in the handbook.

> ustralia has had a leading role in the development of clinical practice guidelines for the management of asthma, starting with the 1989 Asthma Management Plan. <sup>1</sup> This pivotal document was prompted by an epidemic of asthma-related deaths in Australia and New Zealand in the 1980s, together with emerging concepts of evidence-based medicine; it outlined a six-step plan for asthma management, with the aim of reducing mortality and morbidity. Australian asthma guidelines have been revised and updated several times since then as the Asthma Management Handbook, most recently in 2006.<sup>2</sup>

> Although asthma-related mortality in Australia has fallen by 70% since 1989, preventable morbidity remains high, and substantial gaps in quality asthma care can be identified.<sup>3</sup> For example, there are problems with both over- and under-diagnosis of asthma, and with inappropriate prescribing of high-potency asthma medications and underuse of written asthma action plans.4,5

> These issues were a high priority in the development of the new Australian asthma guidelines, entitled the Australian Asthma Handbook and published in March 2014.6 The new guidelines address several important gaps in the quality care of asthma and quality use of medicines in both



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adults and children. Key changes include:

- a focus on confirming the diagnosis of asthma, including in patients already on treatment
- assessment of asthma control in two domains, symptom control and future risk, with changes to the role of spirometry in monitoring asthma
- expansion of the indications for regular preventer treatment in adults and adolescents, primarily with low-dose inhaled corticosteroids
- an emphasis on optimising the use of existing medications through checking and correcting inhaler technique and adherence, before considering a step-up in treatment
- clarification of the role of combination therapy in conventional maintenance treatment and maintenance and reliever therapy
- specific advice about clinical challenges, such as how to ask a patient about their adherence, how to write an asthma action plan and how to step down asthma treatment
- prioritisation of assessment and treatment in management of acute asthma
- new recommendations, based on systematic reviews, about asthma in pregnancy, reflux, allergen avoidance, healthy eating, weight loss and physical activity in asthma.

Importantly, during planning for the new guidelines, careful attention was paid to feedback from over 1000 users of the previous guidelines and to strong evidence for how clinical practice guidelines should be presented and disseminated to facilitate their implementation. Rather than being presented as a 'textbook', as in the past, the Australian Asthma Handbook was developed as a unique online resource, with recommendations presented in a highly accessible format, with a hierarchical display of information and an efficient search function, so that users can access as much or as little detail as they need. Advice is provided about how recommendations can be implemented in clinical practice, rather than only what scientific evidence shows should be done. A print resource is provided in the form of a Quick Reference Guide containing the main figures and tables, but the 'guidelines' are the online resource itself.

Development and publication of guidelines, of course, are only the first steps in improving health outcomes. Most asthma care in Australia occurs in primary care, where pressure of time and resources limits what can be covered in a single consultation, and where patients often present when they are acutely unwell and then fail to return for follow-up or routine review. In order to effectively achieve change in asthma outcomes, the new

guidelines must be implemented by general practitioners, specialists, nurses, pharmacists, educators – everyone involved in asthma care. This is being facilitated by dissemination of the guidelines and related resources by the National Asthma Council, the consumer organisation Asthma Australia and NPS MedicineWise, as well as by government and industry. Communication of key messages across multiple platforms and removal of system barriers to change are essential for implementing effective strategies to reduce asthma morbidity and the burden of asthma to patients, their families and the community.

This Medicine Today Supplement summarises some of the key changes and important messages in the Australian Asthma Handbook and shows how they can be implemented in primary care.

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## Long-term management of asthma The new Australian guidelines

### **Key points**

- Ensure that the diagnosis of asthma is correct. Variability in lung function confirms the diagnosis and is best determined by spirometry.
- Assess symptom control, identify risk factors for poor outcomes and check inhaler technique and adherence at every presentation.
- All patients with asthma except those with symptoms less than twice per week and no flare in past 12 months should be taking regular inhaled corticosteroid (ICS).
- Most patients achieve good control with low-dose ICS.
   Trial this before a regimen containing a long-acting beta-agonist (LABA). Do not prescribe LABA without ICS for patients with asthma.
- Patients instructed to monitor symptoms, follow an asthma action plan and undergo regular medical review have fewer adverse asthma outcomes.
- Patients with asthma should be reviewed at least annually, and more regularly after a flare-up.

KERRY HANCOCK BM BS(Flin), DipObsRACOG

Asthma management in general practice remains challenging but is it that difficult? The key primary care management messages of the recently published National Asthma Council Australia asthma guidelines, the *Australian Asthma Handbook*, are summarised here.

n the 'perfect asthma world', as GPs we will have identified all of our patients in our practice with asthma, having confirmed and documented how the diagnosis was made in the patient's notes for the benefit of subsequent treating practitioners, thereby creating an asthma register. In all patients, we will have identified their risk factors for adverse outcomes (and will continue to do this at each and every visit) and implemented best practice ongoing management including addressing lifestyle factors and comorbidities, prescribing the right medicines in the right way, ensuring our patients know how to take their medicines correctly and continue to take them as prescribed, and back-titrating medications when good control is achieved. None of our patients

now smoke, nor are obese, and all their comorbidities are well managed. They all have written asthma action plans that they know how to use (and know where they are), and they all obediently attend, with or without reminders, for their asthma review visits without asking us to deal with any other issue at the time. We will also have uploaded all this information to each patient's personally controlled electronic health record just in case they decide to exercise their right to see another GP or need to attend the local hospital emergency department (not, of course, for their asthma because that is so well managed).

There are, however, many barriers to achieving that ideal asthma practice utopia, including the health system in which we operate, our

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own practice systems and individual GP and patient factors impeding on our capacity to attain the 'perfect asthma world'. But we do need to try, which means being aware of best practice guidelines developed by auspicious bodies such as the National Asthma Council, enlisting the assistance of other health professionals, practice staff and consumer-based organisations such as the Asthma Foundations to share this load and, most importantly, engaging our patients in this process.

This article summarises the key messages for the management of asthma in primary care contained in the current evidence-based Australian guidelines for managing asthma, the National Asthma Council Australia's Australian Asthma Handbook, which replaces the 2006 Asthma Management Handbook.¹ The new handbook is an online resource (http://www.asthmahandbook.org.au) with an accompanying printed quick reference guide, and much of the material in this article has been reproduced with permission from it.

### THE AUSTRALIAN ASTHMA HANDBOOK

The Australian guidelines for asthma management, the *Australian Asthma Handbook*, were recently updated with recommendations based on the best available evidence, and provide a benchmark for the standard of care for people with asthma. The new handbook, which was published in March 2014, has more detailed information than its predecessor, the 2006 *Asthma Management Handbook*, about:

- how to make an accurate diagnosis of asthma even if the patient is already on preventer therapy
- an emphasis on assessing asthma control and assessing risk factors for adverse outcomes
- more detailed recommendations on when and how to commence preventer therapy, with an emphasis on using preventer therapy, in particular low-dose inhaled corticosteroids (ICS), even for patients who previously would have been considered to have 'very mild asthma'
- how to advise patients to increase therapy to manage worsening symptoms using the various preventer therapy regimens currently available.



The guidelines also have more detailed advice on:

- how to step up therapy when control is not achieved and step down when control has been achieved
- algorithms for managing acute and/or life-threatening asthma
- more information about the role of healthy eating and physical activity in asthma management.

A more detailed comparison between the 2006 *Asthma Management Handbook* and the 2014 *Australian Asthma Handbook* is given on the website of the new guidelines at http://www.asthmahandbook.org.au/about/highlights.

### ASTHMA IN GENERAL PRACTICE

Australia has a high prevalence of asthma in the adult population (around 10 to 12%) and asthma remains one of the most frequently managed chronic problems in general practice. Australian respiratory experts and organisations such as the National Asthma Council have provided excellent leadership in best practice asthma management, and guidelines have been readily available since 1990. These have contributed to changes in practice that, with other factors, have led to significant reductions in mortality due to asthma (from about 1000 deaths per year in the

### 1. REVIEW AFTER AN ASTHMA FLARE-UP: MY EXPERIENCE AS A GP

Engaging with an unwell patient during a flare-up of their asthma can be difficult and they often do not appreciate the reasons for further GP visits when they are well again. However, I have found more success in arranging to see patients very soon after the flare-up, for example within a few days to a week depending on the clinical need. I try to make the first post flare-up review appointment a comprehensive visit. At that visit, when hopefully they are improving and appreciate that you actually do know how to manage asthma, I explain to them the need for ongoing regular review - that is, I want to be able to monitor their asthma and their medication use, assist them to be symptom-free, ensure that their lung function improves (by measuring it, just as they would expect that I would measure their blood pressure or cholesterol), develop strategies with them to prevent further flare-ups (thereby avoiding more time off work and more expense for them) and explain to them that I aim to do this with the most effective and safest level of medicine use. But to do that I need to see them at regular intervals, and not just see them when they are unwell with a flare-up.

If possible, I also aim to schedule an appointment for the patient with the practice nurse for spirometry, a check (and correction) of inhaler technique, a check of smoking status and the provision of some basic asthma education, emphasising the importance of adherence to medication and the regular asthma review. If there is no nurse available then I undertake all those tasks myself, although I might arrange for spirometry to be done elsewhere. Having these points addressed by the nurse gives me more time in my consultation to consider any other concerns the patient has and to review their medication regimen and asthma action plan (or write a temporary one for use until they are stable). I then negotiate a time for the next review visit, usually scheduled for about two months later, having outlined the purpose of that visit to them so they really understand why I am asking them to see me again.

My usual practice is to also place a reminder in the patient file to alert us to nonattendance. I may arrange formal spirometry at a laboratory or arrange practicebased spirometry at a time convenient for the patient to be performed prior to that next visit or at the time of the visit depending on availability of someone to do it. Our practice, like many other practices in Australia, is able to offer appointment times that suit working people's hours, such as towards the end of the day, early evenings or sometimes on Saturday mornings, which has been advantageous in managing our patients with chronic diseases, including asthma. Patients seem to engage in the process and appreciate the importance of planned asthma review visits if they perceive the importance that you, their treating GP, places on it and are reassured that they are not 'wasting the busy GP or practice nurse's time' just because they are currently well.

late 1980s to about 400 deaths per year in 2012). It is estimated that about 70% of deaths from asthma in Australia in people under 70 years of age are associated with preventable or modifiable factors.3 Furthermore, asthma causes a significant burden of disease in young and middle-aged adults, being ranked eighth in the list of conditions causing most years of healthy life lost in people who should be the most

productive in the community.

Studies have shown that patients who effectively manage their asthma have reduced nocturnal asthma as well as fewer hospitalisations, emergency room visits, unscheduled visits to the doctor and days off work or school. GPs and other members of the primary healthcare team have an important role in enabling asthma self-management by implementing systems that identify patients with asthma and prompt periodic clinical assessments.

Our role as GPs includes assessment, diagnosis, prescription of regular medications, education, provision of written action plans and regular review but the reality is that one of the most common reasons patients with asthma present in general practice is acute deterioration, when they have reached the point of needing help.<sup>4</sup> As the patient's GP, you competently manage this acute deterioration (flare-up) and keep the patient safe and away from the emergency department and hospital (unless unavoidable), and then encourage an often time-poor patient to return for review in the recovery phase and again when more stable. A patient who is now well after their flare-up (and also now possibly more dollar-stretched) may not appreciate the need to return to see the GP who they consider to also be time-poor and whom they 'do not want to bother unnecessarily' or 'may cost too much' (Box 1). Many patients will choose to 'self-manage' in their own way, such as only seeking medical attention when the next crisis happens or 'sneaking in' for repeat prescriptions of their medicines when they need them, or maybe going to that 'other practice down the road from work in my lunch break'. This is the reality of general practice as many of us know it.

### **MANAGEMENT CENTRED ON** ASTHMA CONTROL

The current Australian guidelines for adults with asthma continue to emphasise that achieving and maintaining asthma control is the basis of management. However, assessment of 'severity' is no longer a priority at diagnosis and assessment of patterns of asthma (i.e. intermittent to persistent mild/moderate/severe) in adults is no longer recommended as it is not the best guide to treatment.

Good asthma management in primary care incorporates the following:1,5

periodic assessment of both recent asthma symptom control and the identification of risk factors that predict poor asthma outcomes

- · managing factors contributing to poor control and adjusting therapy to achieve good control
- reviewing the response and monitoring to maintain control.

The current Australian guidelines for managing asthma reinforce the following principles for managing asthma in adults (Box 2):1

- confirming the diagnosis
- assessing recent asthma symptom control and risk factors
- identifying management goals in collaboration with the patient
- choosing initial treatment appropriate to recent asthma symptom control, risk factors and patient preference
- reviewing and adjusting drug treatment periodically
- providing information, skills and tools for self-management, including:
  - training in correct inhaler technique
  - information and support to maximise adherence
  - a written asthma action plan
  - information about avoiding triggers, where appropriate
  - managing flare-ups when they occur
- managing comorbid conditions that affect asthma or contribute to respiratory symptoms
- providing advice about smoking, healthy eating, physical activity, healthy weight and immunisation.

### **ASSESSING ASTHMA CONTROL AND IDENTIFYING RISK FACTORS**

### **Current level of asthma** symptom control

Asthma symptom control is usually assessed based on the frequency of symptoms over the previous four weeks, with or without lung function testing. In many patients with asthma being managed in primary care, symptoms, reliever use and lung function are useful surrogate measures of the degree to which the underlying disease process is controlled. The Australian guidelines classify control as good, partial or poor depending on the frequency of symptoms (Table 1).1

Questionnaire-based tools for reviewing of asthma symptoms are available. Depending on how a practice is structured and whether the patient has already been diagnosed as having asthma, some of them can be completed in the waiting room and then scored by the clinician. Studies have shown their effectiveness when they have been administered via an application on handheld personal electronic devices or by telephone. 6-8 The following three questionnaires are available on the Australian Asthma Handbook website (http://www. asthmahandbook.org.au/management/ adults/reviewing-asthma/planning-reviews - under 'Assessing recent asthma control in adults: symptoms').

- **Primary care Asthma Control** Screening tool (also known as the **Pharmacy Asthma Control** Screening [PACS] tool). This has five 'Yes/No' questions about the person's asthma control over the previous month, with the answer 'Yes' to any question indicating that the person may have poorly controlled asthma and so more detailed assessment is needed.9 It has demonstrated reliable assessment of asthma control at twoweekly intervals in clinical practice settings. As it provides a quick and easy way of confirming whether asthma control is good and identifying those who need further assessment, it can be particularly useful when seeing patients opportunistically, such as those wanting script renewals or those presenting with other issues and in whom time constraints do not permit detailed assessment of asthma control at that moment. It allows 'triage' as to the urgency of scheduling the next asthma review visit, with 'Yes' answers to two or three questions leading to review preferably within the next few days.
- **UK Royal College of Physicians** '3 Questions'. This asks three 'Yes/No'

### 2. KEY MESSAGES OF CURRENT **AUSTRALIAN ASTHMA GUIDELINES, THE AUSTRALIAN** ASTHMA HANDBOOK1

### For adults and adolescents\*

- · Ensure the diagnosis of asthma is correct
  - Reconfirm the diagnosis if there is uncertainty
  - Document confirmation of diagnosis in clinical record
- · Assess asthma symptom control and identify and manage risk factors
  - Assess asthma symptom control over previous four weeks
  - Assess patient's risk factors for future flare-ups, life-threatening asthma, declining lung function and adverse effects of treatment
  - Exclude factors contributing to poor control before intensifying preventer treatment (i.e. treatment adherence, inhaler technique and appropriate device, symptoms due to other conditions)
- Treat and adjust therapy to achieve good control
  - All patients should have a reliever inhaler for as-needed use
  - Most patients can achieve well controlled asthma with low-dose
  - Trial low-dose ICS before ICS/ LABA combination therapy
  - When appropriate, step down treatment
- All patients should have an asthma action plan to assist in recognising and managing worsening asthma symptoms
- · Review response and monitor to maintain control
  - Review diagnosis and treatment regularly
  - Monitor to maintain control
- \* The Australian Asthma Handbook also covers the age-specific management of asthma in children. ABBREVIATIONS: ICS = inhaled corticosteroid; LABA = long-acting beta-agonist.

### TABLE 1. DEFINITION OF LEVELS OF RECENT ASTHMA SYMPTOM CONTROL IN ADULTS (REGARDLESS OF CURRENT TREATMENT REGIMEN)\*

### **Good control**

### All of:

- Daytime symptoms ≤2 days per week
- Need for reliever ≤2 days per week<sup>†</sup>
- · No limitation of activities
- No symptoms during night or on waking

### **Partial control**

### One or two of:

- Daytime symptoms >2 days per week
- Need for reliever >2 days per week<sup>†</sup>
- Any limitation of activities
- Any symptoms during night or on waking

### Poor control

Three or more of:

- Daytime symptoms >2 days per week
- Need for reliever >2 days per week<sup>†</sup>
- Any limitation of activities
- Any symptoms during night or on waking

questions about sleeping, usual daytime asthma symptoms and whether asthma interferes with usual activities. 'No' to all three questions indicates good control, 'Yes' to two or three questions indicates poor control and 'Yes' to one question indicates that more detailed questioning is needed to assess level of asthma control (using another validated questionnaire or by asking about frequency of daytime symptoms, reliever requirement, limitation of activities and symptoms at night or on waking during the previous month). Like the PACS, this questionnaire can be used as a quick screening tool, but its specificity for poor asthma control is not as good as with the PACS.9

• Asthma Score (also known as Asthma Control Test). This test consists of five scored questions, with a score below 20 (out of 25) indicating partly or uncontrolled asthma. The test is available in print as a pad of tear-off sheets and electronically on the Asthma Australia website (http://www.asthmaaustralia.org.au/Asthma Score) as well on as the Australian Asthma Handbook website.

### Risk factors for future adverse outcomes

In addition to periodically assessing asthma symptom control, good asthma management involves identifying risk factors that are known to be associated with poor asthma outcomes, no matter what the level of recent symptom control. Poor asthma outcomes include flare-ups (exacerbations), hospitalisations or even death, decline in lung function above that expected as part of ageing and treatment-related adverse effects. There has been an increasing emphasis on the importance of identifying and managing these risk factors as more studies have highlighted their role in adverse asthma outcomes.

Regarding risk factors, the following points should be noted:

- any asthma flare-up in the past 12 months and/or poor asthma control is associated with increased risk of flare-up in the future
- blood eosinophilia (an indicator of ongoing airway inflammation) is also associated with an increased risk of flare-ups
- people with asthma who already have poor lung function are at risk of flare-ups and, possibly, even further decline in lung function
- those who smoke or who are exposed to environmental tobacco smoke are at increased risk of flare-ups and/or lung function decline
- patients with mental health conditions are at particular risk of flare-ups and life-threatening asthma. Their higher rate of cigarette smoking contributes to decline in lung function and also to other

respiratory diseases such as chronic obstructive pulmonary disease (COPD) and lung cancer.

Treatment side effects are much higher in patients using high-dose ICS in the long term or oral corticosteroids (OCS) frequently. Patients who become euphoric with corticosteroids are at risk of inappropriate corticosteroid use and subsequent side effects. Some people who suffer from anxiety and also have asthma may be poor perceivers of their symptoms – either under- or over-perceiving. Poor perceivers tend to underuse their medication, and over perceivers are at risk of overuse or become reluctant to reduce their ICS despite good control and therefore are at increased risk of medication side effects.

Studies of deaths and life-threatening asthma have been enlightening as to the many other factors associated with such incidents (Box 3). Time should be taken to identify these at the assessment consultation.

### Managing factors contributing to poor control

An important component of every encounter with a patient who has asthma is to enquire about factors that may be contributing to either poor current control or loss of control in the future, especially in those who have risk factors for adverse outcomes as discussed above, and especially before intensifying preventer treatment. These factors include poor adherence to

<sup>\*</sup> Reproduced with permission from Australian Asthma Handbook (2014); asset ID: 33.1 Adapted from: Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention, 2014.5

<sup>†</sup> Not including short-acting beta<sub>2</sub>-agonist taken prophylactically before exercise. (Record this separately and take into account when assessing management.) Note: Recent asthma control is based on symptoms over the previous four weeks.

### 3. RISK FACTORS ASSOCIATED WITH POOR ASTHMA OUTCOMES<sup>1</sup>

- Asthma flare-up in past 12 months
- · Poor asthma control, including:
  - intubation or admission to intensive care unit due to asthma (ever)
  - two or more hospitalisations for asthma in past year
  - three or more emergency department visits for asthma in the past year
  - hospitalisation or emergency department visit for asthma in the past month
  - high reliever use (more than two canisters SABA per month)
- · History of delayed presentation to hospital during flare-ups
- · History of sudden-onset acute asthma
- Long-term high-dose ICS therapy or frequent OCS therapy
- Inadequate treatment
- Experience of side effects of OCS use (may contribute to undertreatment or delayed presentation to hospital during flare-ups)
- · Lack of written asthma action plan
- Eosinophilia
- · Poor lung function
- · Smoking, or passive smoking
- · Mental health conditions
- · Cardiovascular disease
- · Sensitivity to unavoidable allergens (e.g. common moulds such as Alternaria)
- · Socioeconomic disadvantage
- · Living alone
- Use of alcohol or illegal substances
- · Poor access to health care (e.g. rural/remote region)

ABBREVIATIONS: ICS = inhaled corticosteroid; OCS = oral corticosteroid; SABA = short-acting beta<sub>2</sub>-agonist.

treatment, incorrect inhaler technique and presence of comorbidities.

### Treatment adherence and inhaler technique

At least 50% of people prescribed long-term asthma therapy do not take their asthma preventer medicines as directed, at least part of the time. 5 Most people with asthma do not use their inhaler correctly, preventing them from receiving the correct dose and therefore maximum benefit from their medicines, and thus impacting on their asthma control and increasing their risk of adverse asthma outcomes (in particular, flare-ups, hospitalisations and need for OCS).10,11 Questions that may be asked when assessing adherence to treatment are listed in Box 4.1

Sometimes the inhaler device is not of the most suitable type for the patient, and prescribing clinicians should take responsibility to ensure that patients are actually able to use the devices they have been prescribed. Patients with arthritis may have difficulty using a metered dose inhaler and may benefit from an attachment that helps in the holding and pressing of the inhaler canister or changing to a breath actuated or dry powder device, although these can still be difficult to use for patients with very arthritic hands. Patients with cognitive impairment may have difficulty retaining skills after instruction in the use of an inhaler and may require the assistance of a carer.

Health professionals should check and correct a patient's inhaler technique regularly and be able to demonstrate correct inhaler device use. The task may be delegated to another appropriately trained health professional such as a practice nurse, an asthma educator if available (e.g. at a community service or local Asthma Foundation) or a pharmacist via a home medicines review. This regular checking and correction can improve clinical outcomes. The National Asthma Council has videos on its website that demonstrate correct use of the various inhaler devices (http://www. nationalasthma.org.au/how-to-videos/

### 4. SUGGESTED QUESTIONS TO **ASK WHEN ASSESSING ADHERENCE TO ASTHMA** TREATMENT\*

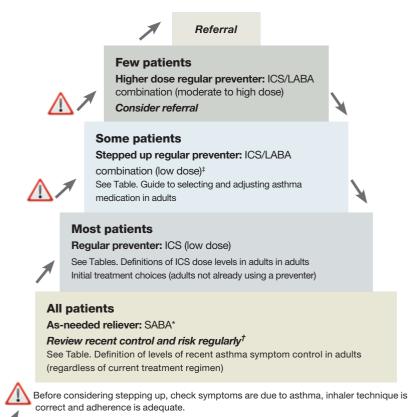
- · Many people do not take their medication as prescribed.
  - In the past four weeks, how many days a week would you have taken your preventer medication? None at all? One? Two? (etc)
  - How many times a day would you take it? Morning only? Evening only? Morning and evening? (or
  - Each time, how many puffs would you take? One? Two? (etc)
- Do you find it easier to remember your medication in the morning or the evening?
- \* Reproduced with permission from Australian Asthma Handbook (2014); asset ID: 38.

using-your-inhaler). The National Prescribing Service/National Asthma Council inhaler technique checklists provide a handy reference to the correct steps for different inhalers (http://www.nps.org. au/\_\_data/assets/pdf\_file/0010/256195/ asthma-inhaler-device-techiques-checklist. pdf).

Australian and international guidelines recommend that adherence and inhaler technique be assessed at every visit and especially before considering any step-up in treatment.1,5

### Comorbidities and other causes of worsening symptoms

Comorbid medical conditions such as uncontrolled allergic rhinitis/rhinosinusitis, gastro-oesophageal reflux disease, nasal polyposis, obesity and upper airway dysfunction may affect asthma control. Medications used to treat coexisting conditions, such as beta-blocker eye drops and NSAIDs, have been implicated in several deaths due to acute hypersensitivity reactions in people with asthma and, therefore, patients should be warned about the



Consider stepping up if good control is not achieved.

When asthma is stable and well controlled for two to three months, consider stepping down (e.g. reducing ICS dose, or stopping LABA if ICS dose is already low).

ABBREVIATIONS: ICS = inhaled corticosteroid; LABA = long-acting beta-agonist; SABA = short-acting beta, -agonist. \* Reliever: SABA (or low-dose budesonide/eformoterol combination for patients using this combination as both maintenance and reliever).

- <sup>†</sup> Montelukast can be added to ICS as an alternative to switching to ICS/LABA, but is less effective
- <sup>‡</sup> In addition, manage flare-ups with extra treatment when they occur, and manage exercise-related asthma symptoms as indicated.

Figure. Stepped approach to adjusting asthma medication in adults.\* (The tables on definition of levels of recent asthma symptom control and definitions of ICS dose levels referred to in this diagram are Tables 1 and 2, respectively, in this article. The other tables referred to are available online in the Australian Asthma Handbook: asset ID 32 - http://www.asthmahandbook.org.au/management/adults/initial-treatment and asset ID 5 - http://www.asthmahandbook.org.au/management/adults/stepped-adjustment.) \* Reproduced with permission from Australian Asthma Handbook (2014); asset ID: 31.1

potential for worsening asthma and be given advice about how to respond to worsening symptoms and a written asthma action plan.

People who have asthma and are overweight can significantly improve their asthma by losing as little as 5 to 10 kg. Physical activity in people with asthma

improves cardiopulmonary fitness and quality of life.

Even in patients who have a confirmed diagnosis of asthma, an increase in respiratory symptoms is not necessarily due to the asthma. For example:

breathlessness and feelings of chest tightness associated with exercise

- may be due to poor fitness or, more crucially, undiagnosed ischaemic heart disease
- breathlessness and 'wheezing' with exercise may be due to vocal cord dysfunction or poor fitness
- increased cough with sputum production and frequent chest infections may be due to bronchiectasis or COPD
- increased cough may be due to postnasal drip in a patient with allergic rhinitis
- many patients with both asthma and allergic rhinitis have improved asthma control when their allergic rhinitis is treated effectively.

For patients with a diagnosis of asthma made in the past or elsewhere (such as at another practice), it is worth considering whether the diagnosis is correct as it has been shown that 25 to 35% of people with a diagnosis of asthma in primary care may not actually have asthma.12-15

The current Australian asthma guidelines now give clear guidance as to how to undertake the process of confirming the asthma diagnosis, whether or not the patient is already on preventer therapy. Another article in this supplement emphasises the important role that spirometry plays in this.

### **ADJUSTING THERAPY TO ACHIEVE GOOD CONTROL**

Good asthma management involves stepwise medication adjustment to achieve good symptom control and minimise the risk of adverse outcomes such as death, hospitalisations, flare-ups and/or worsening of lung function.

Once good asthma control is achieved, medication doses can be reduced to the lowest effective dose to minimise adverse outcomes of the treatment. This is graphically illustrated in the Figure, which indicates that all patients with asthma require reliever medication (either short-acting beta, agonist [SABA] or lowdose budesonide/eformoterol for patients on the Symbicort SMART™ [Symbicort Maintenance and Reliever Therapy

regimen) and that most patients who do require preventer therapy can be managed on low-dose ICS, with only some patients requiring ICS/long-acting beta-agonist (LABA) combination therapy to achieve good control of their asthma.1 It is worth noting that the new Australian asthma guidelines now refer to only two classes of asthma medicines, namely relievers and preventers. The previous additional term 'symptom controller' for LABAs is no longer used as it created confusion because preventers are called 'controller therapy' in other parts of the world.

### When and how to commence preventer therapy

The Australian Asthma Handbook has now given greater guidance to prescribers about when and how to commence preventer therapy taking into account the pattern of asthma symptoms and/or the presence of risk factors (see http://www. asthmahandbook.org.au/management/ adults/initial-treatment/preventers/generalconsiderations).1 It is now recommended that all patients who have at least monthly symptoms should be commenced on preventer therapy, with this usually being low-dose ICS. The definitions of low, medium and high dose levels for four ICSs are given in Table 2. An additional ICS, fluticasone furoate, will be available from December 2014 only in combination with the LABA vilanterol for the regular treatment of moderate to severe asthma  $(100 \mu g/25 \mu g \text{ and } 200 \mu g/25 \mu g)$ ; this ICS is more potent than fluticasone propionate and the combination product should only be prescribed as one inhalation daily.

Even the patient with infrequent symptoms (on average, less than twice per month) but who has required OCS for a flare-up of asthma within the past year will benefit from being commenced on regular ICS starting at low dose. Low-dose ICSs are of minimal cost and some (budesonide and ciclesonide) are suitable for once-daily dosing schedules. Taken correctly and regularly, ICS will lead to good asthma control for most patients, and reduce the risk of

<b>TABLE 2. DEFINITIONS OF INHALED CORTICOSTEROID DOSE LEVELS</b>	
IN ADULTS*	

Inhaled corticosteroids		Daily dose (µg)		
corticosteroids	Low	Medium	High	
Beclomethasone dipropionate	100-200	250-400	>400	
Budesonide	200-400	500-800	>800	
Ciclesonide	80–160	240-320	>320	
Fluticasone propionate	10-200	250-500	>500	
* Penyadyaad with narmissian from Australian Asthma Handhaak (2104); seest ID; 201				

hospitalisation with minimal cost and inconvenience to the patient.

The patient with newly diagnosed asthma whose symptoms are severely uncontrolled or very troublesome (such as night-time waking and/or low lung function) may benefit from commencing a high-dose ICS, with a view to early and regular review to assess control and aiming for the patient to be on the lowest dose of ICS that maintains control. Alternative strategies would include prescribing a short course of OCS combined with ICS or a combination of ICS and LABA.

Many patients are inappropriately commenced on asthma preventer therapy, in particular ICS/LABA combination therapies, for various respiratory symptoms, often when they have an acute respiratory tract infection. It is imperative to appreciate that wheezing and other respiratory symptoms do not always mean that a person has asthma.<sup>16,17</sup> Airflow limitation demonstrated on spirometry can be transient and does not necessarily mean that the person has asthma (e.g. when recorded during a severe acute viral infection of the respiratory tract). These patients can be managed with intermittent SABA therapy for symptom relief, and then reviewed with spirometry to confirm airflow limitation when they do not have a respiratory tract infection. More information about making a correct asthma diagnosis is available in the Australian Asthma Handbook (see http://www.asthmahandbook.org.au/diagnosis/adults/

making-a-diagnosis).1

The Australian guidelines recommend ICS/LABA treatment in favour of increasing the dose of ICS for adults and adolescents whose asthma remains poorly controlled or who have ongoing exacerbations despite using low-dose ICS with good adherence and demonstrating correct inhaler technique.1 When a LABA is needed, combination inhalers are preferred over separate inhalers. This ensures that the patient takes both ICS and LABA together, thus avoiding the possibility of LABA monotherapy, which is associated with an increased risk of asthma flare-ups and death due to asthma.

### Asthma action plans

Written asthma action plans enable people with asthma to intervene early when their asthma symptom control deteriorates and thus prevent or reduce the severity of acute asthma episodes. Providing written asthma actions plans to adults as part of appropriate self-management is associated with about:18,19

- 40% fewer hospital admissions
- 20% fewer emergency department visits
- 30% fewer unscheduled visits to the doctor
- 20% fewer days off work or school
- 30% less nocturnal asthma.

Despite the promotion of asthma action plans in asthma guidelines since 1990 and evidence from Cochrane reviews over a decade ago for their role in improving

### 5. WRITING AN ASTHMA ACTION PLAN<sup>1</sup>

A written asthma action plan should include all the following:

- a list of the person's usual medicines (names of medicines, doses, when to take each dose), including treatment for related conditions such as allergic rhinitis
- · clear instructions on how to change medication (including when and how to start a course of oral corticosteroids) in all the following situations:
  - when asthma is getting worse (e.g. when needing more reliever than usual, waking up with asthma, more symptoms than usual, asthma is interfering with usual activities)
  - when asthma symptoms get substantially worse (e.g. when needing reliever again within three hours, experiencing increasing difficulty breathing, waking often at night with asthma symptoms)
  - when peak flow falls below an agreed rate (for those monitoring peak flow each day)
  - during an asthma emergency
- instructions on when and how to get medical care (including contact telephone numbers)
- the name of the person writing the action plan, and the date it was issued

asthma outcomes, asthma action plan ownership in Australia remains low. Australian Bureau of Statistics data indicate that in 2011-12 only 24% of people with asthma reported having a written asthma action plan, although this was an increase from 16% in 2004-05 and 21% in 2007-08.20

Adults aged 25 to 44 years were the least likely to have a written action plan (17%) compared with the other age groups. There are probably several reasons for the lower rate in this age group but contributing factors may be lack of access to GPs for

comprehensive assessment at times that accommodate the busy lifestyles and work and family commitments of young adults and a lack of appreciation of the seriousness of asthma, which the community seems to think only affects children and older people adversely.

For most patients, written asthma action plans based on symptoms are just as effective as those using peak expiratory flow rate (PEFR) measurements, measured using peak flow meters. Action plans need to be individualised and appropriate for the patient's treatment regimen, asthma severity, culture, language, literacy level and ability to self-manage (Box 5), and should be reviewed every year for adults or whenever there is a significant change in treatment or asthma control status, for example after a flare-up.1 Sources of templates for written asthma action plans are listed in Box 6.1 It should be noted that software for developing electronic pictorial asthma action plans is UK based and probably not suitable for Australian practices due to use of slightly different names of medicines. However, an electronically generated asthma action plan for children is available at http://digitalmedia.sahealth. sa.gov.au/public/asthma.

Peak flow monitoring is no longer routinely used in Australian but is still recommended for some patients such as those with very severe asthma, frequent flare-ups or poor perception of airflow limitation. Furthermore, action plans based on PEFR measurements have been shown to only be effective if personal best PEFR measurements are used and not percentage predicted PEFR. Further information about how to instruct patients to properly undertake and document peak flow monitoring is available in the Australian guidelines (http://www.asthmahandbook.org.au/ management/adults/self-management/ education).

### Specific advice to include in action plans

Asthma action plans should contain specific advice about when to take action if asthma

### 6. RESOURCES FOR ASTHMA ACTION PLANS<sup>1</sup>

- Templates for written asthma action plans are available from National Asthma Council Australia (http:// www.nationalasthma.org.au/ health-professionals/asthma-actionplans) and include:\*
  - National Asthma Council Australia Asthma Action Plan, a colourcoded plan available as a printed handout that folds to wallet size and as the Asthma Buddy smartphone application
  - Asthma Cycle of Care Asthma Action Plan
  - plans specifically designed for patients using budesonide/ eformoterol combination as maintenance and reliever therapy
  - Remote Indigenous Australian Asthma Action Plan
  - Every Day Asthma Action Plan (designed for remote Indigenous Australians who do not use written English - may also be useful for others for whom written English is inappropriate)
- Software for developing electronic pictorial asthma action plans is also available online

deteriorates. For example, for patients using peak expiratory flow monitoring the following actions should be advised:

- when PEFR is below 80% of personal best reading, it is best to recommence/ increase ICS appropriate to clinical severity
- when PEFR is below 60% of personal best reading, it is best to start an emergency course of OCS
- when PEFR is below 40% of personal best reading, it is best to seek emergency help.

Evidence supports the safe use by adults of patient-held prednisolone tablets for

<sup>\*</sup> Some written asthma action plans are available in several languages.

use as indicated in the action plan when symptoms/peak flow rates deteriorate substantially.

An action plan should contain advice to patients to increase their reliever medication and also to increase their ICS dose substantially. The Australian Asthma Handbook contains a useful table 'Options for adjusting medicines in a written asthma action plan for adults' that explains how to write instructions in action plans for increasing therapy for the various preventer medicine regimens that patients may be following (asset ID: 42; see http://www.asthmahand book.org.au/table/show/42).1 A large increase in ICS dose is recommended (e.g. to at least 1500 µg fluticasone propionate or 2400 µg budesonide per day) as there is poor evidence for the efficacy of the 'double-up' maintenance approach that has been widely used in the past.

Most importantly, patients need to have specific advice about when and how to seek medical care (e.g. call an ambulance on 000; call doctor/locum service/hospital/ emergency department on [list number], depending on location and other factors). A recent review of asthma deaths in Australia showed that in 73 deaths (30% of all cases) the deceased person was found after death and that 63 deceased persons (26% of all cases) were deemed to have delayed seeking assistance for their fatal asthma attack.3 Patients with asthma in rural and remote areas are especially at risk as the same study showed that these areas have a disproportionate rate of asthma deaths. This highlights the importance of patients with asthma in rural and remote areas being better prepared to recognise and manage worsening asthma symptoms and having the skills to intervene early, because of their less readily available access to emergency care compared with their metropolitan and regional counterparts.

Respiratory viral infections are recognised as the most important causes of asthma exacerbations but not always perceived as a risk or reason to seek asthma care. However, they are a precursor to many fatal asthma exacerbations. The

regular use of ICS will reduce flare-ups by about 50%, and increasing ICS doses when symptoms worsen, rather than only using a SABA for symptom relief, further reduces exacerbation rates. In the event of a flare-up occurring in association with a respiratory infection, an appropriately completed and discussed asthma action plan will help the patient recognise worsening of asthma symptoms and take action that may reduce the severity of the flare-up.

### Improving uptake of action plans

A possible contributing factor to the previous poor uptake of asthma action plans in our community, despite the resounding evidence about their worthiness, was the confusion and difficulty that many practitioners found in writing them and knowing how to advise their patients to adjust their medicines in response to worsening symptoms. Do you double the ICS dose? But then I heard that is not helpful? You quadruple it - that seems a lot! When do you do that? How long for? How do you do that? What if my patient is on a LABAcontaining preventer: how do I increase the ICS then, if you're telling me I shouldn't increase salmeterol above 100 µg per day?

As mentioned earlier, the options for adjusting treatment are outlined in Table 42 (asset ID: 42) of the Australian Asthma Handbook (see http://www.asthmahand book.org.au/table/show/42).1

Taking as an example the last of the listed questions above, 'What if my patient is on a LABA-containing preventer: how do I increase the ICS then, if you're telling me I shouldn't increase salmeterol above 100 μg per day?' For a patient taking fluticasone/salmeterol metered dose inhaler (MDI) combination therapy at the usual two puffs twice a day, the options given in this table are to either increase the ICS dose by adding a separate fluticasone propionate inhaler (e.g. multiply ICS dose by four times) for seven to 14 days or start a short course of prednisone (e.g. 37.5 to 50 mg each morning for five to 10 days) in addition to the usual dose of fluticasone propionate/salmeterol. Advice is also given to

remind those patients who have reduced their fluticasone propionate/salmeterol intake to increase it if necessary to achieve a total daily dose of salmeterol 100 µg (i.e. the recommended therapeutic, and maximum, dose of salmeterol).

For patients on combination preventer therapy regimens containing the LABA eformoterol, which has different pharmacokinetics from salmeterol, increasing therapy is less complex.

### **REVIEWING THE RESPONSE AND MONITORING TO MAINTAIN** CONTROL

Setting a date to review response when commencing a new treatment regimen or making any adjustments to a previous treatment regimen helps ensure ineffective  $or\,unnecessary\,medication\,is\,not\,continued$ and that the patient has not inappropriately stopped taking the treatment. A date about six to eights weeks later is appropriate. It is also helpful to flag the patient's medical record with a reminder to ask about the following at the next visit after a treatment

- whether they thought the treatment change was helpful
- whether they are still taking that dose. Patients who need long-term high-dose ICS to maintain good asthma control or frequent courses or long-term use of OCS should have their bone mineral density and glucose metabolism status monitored. These patients should also be advised to:
- have regular eye examinations (for cataract formation, a possible association with long-term use of high-dose ICS and long-term OCS)
- reduce risk of bone loss by:
  - participating regularly in weight-bearing physical activity
  - having an adequate dietary calcium intake
  - maintaining adequate vitamin D levels.

### **Reviewing asthma**

With many patients seeking their healthcare needs across a number of different

practices, it has become more challenging to implement good asthma management. It is not unusual to find that what the patient was prescribed at your practice last time has now been changed to something else by another practitioner, making it essential to re-affirm which asthma medicines they are using, in a nonjudgemental and empathic manner, and to ask about flare-ups because these may have been treated elsewhere. Furthermore, it is not uncommon, for many and varied reasons, for patients to reduce or cease their medication. Hence the emphasis in all guidelines to check current medicines and doses before stepping up therapy.

Asthma assessments should be scheduled at least annually but there are several circumstances in primary care when either the GP or the practice nurse can opportunistically review a patient's asthma.1 These include:

- when a patient requests repeat asthma prescriptions
- when a patient presents with increased respiratory symptoms
- at visits for reasons other than asthma.

Asthma should also be reviewed at the following times:

- follow up after an asthma flare-up
- follow up one to three months after starting preventer treatment or adjusting the dose
- every four to six weeks during pregnancy.

Planned asthma check-ups Planned asthma check-ups should be made at intervals determined by both the patient's level of recent asthma symptom control and risk factors. The following is a guide:

- one to three months after each adjustment to medications
- yearly for a person with no flare-up in the past 12 months and good symptom control for at least a year
- every six months for a person who has had a flare-up within the past 12 months or who has other risk

- factors for flare-ups or life-threatening asthma (e.g. smoking, previous recording of poor lung function on spirometry, history of admission to an intensive care unit for asthma)
- at least every three months for a person with severe asthma, workexacerbated asthma, poor perception of airflow limitation, frequent rhinosinusitis symptoms or other comorbid conditions that affect asthma control
- every four to six weeks for pregnant women.

At the asthma check-up, the following points should be covered:

- discuss any problems the person is having with their asthma
- confirm their current prescribed treatment
- ask how often they take their preventer, if one is prescribed
- assess level of recent asthma symptom control, including reliever use
- ask about flare-ups (unscheduled GP visits, emergency department visits) during the past 12 months
- assess risk factors for flare-ups (lifestyle factors, especially smoking, comorbidities, psychosocial)
- assess inhaler technique and correct if required
- check the person has a written asthma action plan, and ask if it is followed and if so, how helpful it is
- be alert for treatment-related adverse effects.
- for patients requiring a long-term high-dose ICS to maintain good asthma control, or those taking frequent courses of OCS, monitor bone mineral density and glucose metabolism status
- if possible, assess lung function via spirometry every one to two years or more frequently when asthma control worsens or good asthma control is not achieved
- be alert for signs of accelerated decline in lung function
- organise the next review visit

### 7. CHRONIC DISEASE MANAGEMENT MEDICARE ITEMS FOR ASTHMA\*†

Patients with asthma are eligible for the following Chronic Disease Management Medicare Benefits Schedule (MBS)

- Preparation of a GP Management Plan (Item 721)
- · Review of a GP Management Plan (Item 732)
- · Coordination of Team Care Arrangements (Item 723) for patients who need ongoing care from a multidisciplinary team of at least three healthcare providers
- · Coordination of a Review of Team Care Arrangements (Item 732)
- · Contribution to a multidisciplinary care plan being prepared by another health or care provider (Item 729)
- Contribution to a multidisciplinary care plan being prepared for a resident of an aged care facility (Item 731).

GPs can be assisted by practice nurses, Aboriginal and Torres Strait Islander health practitioners, Aboriginal health workers and other health professionals.

\* Reproduced with permission from Australian Asthma Handbook (2014), 'Management goals/ Health initiatives that support asthma care' section.1

<sup>†</sup> As noted in the article text, patients who only have asthma (i.e. no other chronic diseases) are unlikely to meet the criteria to claim both Chronic Disease Management and Asthma Cycle of Care MBS items.

(appointment and/or reminder in medical record).

Opportunistic review of asthma At requests for repeat asthma scripts, depending on time, the following points should be covered:1

- screen patients for poor asthma control (see section on control)
- ask about the medicines they are

### 8. ASTHMA CYCLE OF CARE\*1

The Asthma Cycle of Care is an Australian Government initiative to support primary care health professionals (GPs, other medical practitioners and trainees) to provide asthma care. It is implemented through the Practice Incentives Program (PIP) Asthma Incentive and applies to the clinical care of people with moderate-to-severe asthma, generally defined as people with (any of):

- · symptoms on most days
- · use of preventive medication
- · bronchodilator use at least three times per week
- · hospital attendance or admission following an acute asthma flare-up.

The Asthma Cycle of Care involves at least two asthma-related consultations within 12 months for a patient with moderate-to-severe asthma, of which at least one visit is a planned asthma review. Each consultation includes:

- · documenting the diagnosis, assessing asthma severity and assessing level of recent asthma symptom control
- · reviewing the patient's use of and access to asthma medicines and inhaler devices
- providing a written asthma action plan (or documented alternative, if the patient is unable to use a written action plan)
- · providing asthma self-management education
- · reviewing the written or documented asthma action plan.
- \* Reproduced with permission from Australian Asthma Handbook (2014), 'Management goals/ Health initiatives that support asthma care' section.1
- $^{\dagger}$  As noted in the article text, patients who only have asthma (i.e. no other chronic diseases) are unlikely to meet the criteria to claim both Chronic Disease Management and Asthma Cycle of Care MBS items.

### 9. HEALTH SYSTEM INITIATIVES **FOR ABORIGINAL AND TORRES** STRAIT ISLANDER PEOPLE\*

Health system initiatives to support the care of Aboriginal and Torres Strait Islander people include:

- Health Assessment Medicare items
- The Indigenous Chronic Disease Package
- The Asthma Spacer Ordering System
- \* Reproduced with permission from Australian Asthma Handbook (2014), 'Management goals/ Health initiatives that support asthma care' section.1

using, including both reliever and preventer, and adherence to preventer in a nonjudgemental, empathic manner

- check for significant risk factors (emergency department visits, flare-ups, smoking, comorbid conditions that either increase risk or affect control)
- ask whether the person has a written asthma action plan that they understand and can follow (and whether they know where it is)
- arrange an asthma check-up with the time interval dependent on the above, with the patient given an appointment time before they leave and/or a reminder made in their medical record.

Review of asthma during visits for respiratory symptoms

When a person presents with respiratory symptoms, the cause should be sought, taking into consideration causes other than asthma. If current symptoms are probably due to asthma, the following should be assessed:1

- level of recent asthma symptom control, including symptoms and reliever use
- flare-ups during the previous 12 months
- lung function (if possible)
- other risk factors (e.g. smoking,

- exposure to other triggers) or comorbid conditions
- current treatment, including adherence to preventer if prescribed do not assume the person is taking the dose most recently prescribed; ask which asthma medicines the person is using, in a nonjudgemental, empathic manner
- inhaler technique observe the person use their inhaler and correct the technique if needed
- whether the person has a written asthma action plan – if they do, ask if they have followed it and whether it has helped
- arrange next review visit (appointment made before leaving and/or a reminder in the medical record).

### **HEALTH SYSTEM INITIATIVES THAT** SUPPORT ASTHMA CARE

The various Federal Government initiatives supporting the care of patients with asthma include the Chronic Disease Management Medicare items, the Asthma Cycle of Care and several specific initiatives for Aboriginal and Torres Strait Islander people (Boxes 7, 8 and 9). It is worth noting however, that, unlike with diabetes health system initiatives, it is unlikely patients who only have asthma will meet the criteria to claim Chronic Disease Management Medicare items and Asthma Cycle of Care items concurrently unless they have an additional chronic disease that entitles the patient to the Chronic Disease Management initiatives.

### **SUMMARY**

The recently updated Australian guidelines for asthma management, the Australian Asthma Handbook, contains more detailed information than its predecessor, based on more evidence supporting its recommendations, and provides practical guidance for the diagnosis and management of asthma within a primary care chronic disease management framework. There is an emphasis on the accurate diagnosis of asthma even if the patient is

already using preventer therapy and the management of asthma based on assessments of asthma control and identification of risk factors for adverse outcomes. The guidelines also encourage the use of written asthma action plans to help patients self-manage their asthma.

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COMPETING INTERESTS: Dr Hancock has received honorariums and speaker fees for facilitating meetings, developing educational resources and attendance on advisory boards for pharmaceutical companies (Novartis, Menarini, Mundipharma, GlaxoSmithKline, AstraZeneca, Boehringer Ingelheim) who undertake research, develop and/or market medicines to treat people with respiratory disorders.



### Its role in diagnosing and managing asthma

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Asthma is a disease with variable symptoms and excessive variation in lung function. Diagnosis and management need to be based on airflow assessment with spirometry to prevent overdiagnosis and overtreatment in children and underdiagnosis and undertreatment in older adults.

sthma affects around 10% of the population in Australia, although the prevalence has fallen slightly since 2001. In adults the prevalence is higher in females but in children up to the age of 14 years more males are affected; Aboriginal and Torres Strait Islander Australians have a prevalence that is nearly twice as high overall (17.5% age-standardised). Although the death rate from asthma in Australia has fallen from a peak of 6.6 per 100,000 in 1989 to 1.5 per 100,000 in 2011, there were still 378 asthma deaths in 2011 and potentially avoidable risk factors are common.<sup>1,2</sup>

Asthma is usually diagnosed and managed in primary care, where it accounts for around 2% of GP-patient encounters, making it the most common chronic respiratory condition managed by GPs in Australia.<sup>3</sup> Improvements in primary care-based management have been recommended following recent informative reviews of asthma deaths in Australia and the

UK.2,4 Potentially avoidable factors identified in primary care asthma management included failures to perform asthma reviews, to provide patients with personal asthma action plans, to identify life-threatening risk factors and to follow up patients after asthma attacks.<sup>4,5</sup>

Against this background of the need to improve asthma management in general practice, it is timely to review the potential role of spirometry in contributing to improving asthma outcomes. The current evidence-based Australian guidelines for managing asthma, the Australian Asthma Handbook, continue to stress the importance of spirometry in the diagnosis of asthma but have reduced the emphasis on it for the long-term management of the condition.6

### DIAGNOSIS

It is important to establish an accurate diagnosis of asthma. Asthma is defined clinically as the combination of variable respiratory symptoms

### Key points

- · The diagnosis of asthma is based on the characteristic pattern of symptoms, physical examination and documented variable airflow limitation on spirometry.
- · Individuals' perceptions of airflow limitation vary and there is poor correlation between asthma symptoms and the level of airflow limitation in chronic disease.
- · Spirometry identifies younger people with asthma at risk for progressive decline in airflow and can track development of airflow limitation.
- Spirometry is recommended every one to two years for ongoing risk assessment and when asthma control has worsened or an exacerbation has occurred.
- · Although there is little strong evidence for regular use of spirometry in asthma management in primary care and integrated asthma clinics, regular spirometry is likely to improve care if delivered systematically.

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(e.g. paroxysmal wheeze, shortness of breath, cough and chest tightness) with excessive variation in lung function.<sup>6,7</sup> Thus, diagnostic criteria for asthma are based on a history of the characteristic pattern of symptoms, physical examination and documented variable airflow limitation on spirometry. A significant proportion (around 30 to 40%) of adults with an asthma diagnosis recorded in general practice may be misclassified.<sup>8,9</sup> This misdiagnosis occurs particularly in older people, who may in fact have chronic obstructive pulmonary disease (COPD; i.e. fixed airflow limitation post-bronchodilator) or both asthma and COPD, the so-called 'overlap syndrome'.10,11

The core issues regarding accuracy of asthma diagnosis are the condition's relative overdiagnosis (and therefore overtreatment), especially in children, and underdiagnosis (and therefore undertreatment) in older adults (over 60 years of age), with consequences that include increased risk of mortality.<sup>12</sup> In both cases, much of the problem relates to lack of objective assessment with spirometric measurements.

### **SPIROMETRY TO IDENTIFY AIRFLOW** LIMITATION

Spirometry is now the recommended test for adults and children for measurement of lung function to detect airflow limitation (recommended as such in the National Asthma Council Australia's Australian Asthma Handbook and the Global Initiative for Asthma's Global strategy for Asthma Management and Prevention 2014).<sup>6,7</sup> It is more reliable than measuring peak expiratory flow because it allows clearer identification of airflow limitation and the results are less dependent on effort.13 However, as spirometry readings are not reproducible between visits, only a change in forced expiratory volume in one second (FEV<sub>1</sub>) of greater than 0.2 L and 12% from baseline for adults or at least 12% from baseline for children can be considered clinically meaningful.6 Variable airflow limitation is defined in the Box.6

Most children aged 6 years and older can perform spirometry reliably to acceptable standards.14 Modern spirometers include age-specific predicted values for interpretation and identification of poor lung function relative to normal age-defined values.15

### **DEFINITION OF VARIABLE AIRFLOW LIMITATION USING SPIROMETRY**

Excessive variation in lung function can be demonstrated by:<sup>6</sup>

- a clinically important increase in forced expiratory volume in one second (FEV<sub>1</sub>) of at least 200 mL and 12% from baseline for adults or at least 12% from baseline for children, 10 to 15 minutes after administration of bronchodilator, or
- · measuring on separate visits clinically important variation in lung function over time (suggested to be at least 20% change in FEV<sub>1</sub>).

Observing such a response to treatment with a bronchodilator or after a trial of four or more weeks of treatment with an inhaled corticosteroid would confirm the diagnosis in some patients, but lack of response does not rule out asthma, especially if the baseline value was relatively good. This is because asthma is variable, especially early in the course of the illness, and the patient may have been seen on a 'good day'.6

Alternatively, variable airflow limitation may be documented on the basis of the following, although these tests are usually performed in a respiratory function laboratory:

- · a clinically important reduction in lung function after exercise, or
- a clinically important reduction in lung function during a test for airway hyper-responsiveness.

It is recommended that such objective evidence for asthma diagnosis be documented, especially before starting asthma preventer/controller treatment.6

ABBREVIATION: FEV<sub>1</sub> = forced expiratory volume in one second.

Spirometry for patients of all ages needs to be conducted by well-trained personnel, and the usefulness of spirometry tests is subject to quality standards being met, which unfortunately is often not the case when testing is carried out in general practice.15,16 Regular audit of spirometry testing competence is necessary, but although training to perform spirometry is fairly widely available for GPs and practice nurses, follow-up quality assessment is not regularly implemented. An online initiative for spirometry training and feedback trialled in South Australian general practices was shown to be feasible but is not yet widely used.17

### **SPIROMETRY PROVISION**

Barriers to conducting spirometry in primary care (additional to lack of access to a wellmaintained spirometer and lack of expertise in performance and interpretation) include lack of time on the GP's part to assess bronchodilator reversibility, the increased cost to patients for longer consultations and the low remuneration available for the procedure under the Medicare Benefits Schedule (MBS) in Australia.18

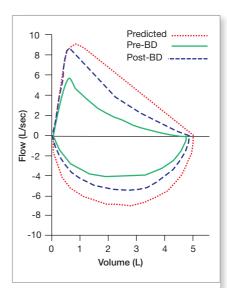


Figure. Example of a spirometry flow-volume loop for a 20-year-old man with asthma. The patient had a history of episodic wheeze and chest tightness, particularly in the early morning and during exercise. He had never smoked. (BD = bronchodilator.) COURTESY OF DR DAVID JOHNS, UNIVERSITY OF TASMANIA

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Spirometry tests performed in primary care are remunerated under MBS item 11506, 'Measurement of respiratory function involving a permanently recorded tracing performed before and after inhalation of bronchodilator'.

The alternative to conducting spirometry in a general practice setting is to refer the patient to an accredited respiratory function laboratory (http://www.thoracic. org.au/respiratory-function-laboratoryaccreditation) for spirometry and measurement of flow-volume loops. Additional lung function tests may also be performed, such as lung diffusion capacity for emphysema and body plethysmography to measure absolute lung volumes, with a report from a respiratory specialist. Additional tests such as bronchial provocation tests, skin prick tests and exhaled nitric oxide [NO] measurement to help confirm or exclude asthma can be performed in most lung function laboratories and also by some pathology providers.

### MONITORING ASTHMA

The primary goals of asthma management are to achieve good symptom control and minimise the future risk of exacerbations and excessive loss of lung function while avoiding (as far as possible) side effects of treatment.7 Measuring lung function in people with asthma is important in achieving good control because individuals' perceptions of airflow limitation vary. A chronically lower FEV<sub>1</sub> and higher degree of airway hyper-responsiveness are associated with a lower degree of 'perceptiveness' for bronchoconstriction during challenge testing.19 The perception of asthma symptoms by people with the condition is less accurate during prolonged airway limitation than during the acute onset of limitation, and in children a significant proportion of episodes of airflow limitation may not be recognised.<sup>20,21</sup>

Irreversible airflow limitation develops in some patients with asthma and is related to poorer prognosis. Lower FEV<sub>1</sub> and less bronchial reversibility are predictors of later development of overt fixed airflow limitation.<sup>22</sup> Further, there is a strong association between lower FEV, percentage predicted and risk of asthma exacerbations over subsequent years in children.<sup>23</sup>

Thus, spirometry-derived objective measures of lung function are needed to:

- assess risk for adverse asthma outcomes
- identify younger people with asthma at risk for developing a progressive decline in airflow
- track development of airflow limitation from childhood to adulthood and then throughout life
- monitor response to inhaled corticosteroid treatment and after dose adjustment
- monitor people who have poor perception of airflow limitation.

Modern spirometry includes the measurement of maximal flow-volume loops, which is now recommended periodically for ongoing risk assessment, usually every one to two years, and when asthma control has worsened or an exacerbation has

occurred to ensure that baseline values have been re-established (Figure).<sup>6,7</sup> The flowvolume loop can potentially give more information on early small airway changes.

FEV<sub>1</sub> is still considered important in assessing asthma, although there is poor correlation between asthma symptoms and the level of airway limitation in both adults and school-aged children. Many children will have an FEV<sub>1</sub> greater than 80% of their predicted value independent of their asthma severity.24 With treatment, subjective improvement in asthma symptoms may occur without improvement in the level of airway obstruction, making objective measurement of airway limitation essential when assessing both adults and children with chronic asthma.

### **EVIDENCE BASE FOR SPIROMETRY** IN ASTHMA MANAGEMENT

Unfortunately, there is still a lack of highgrade published evidence to confirm the outcome value of spirometry in primary care management of asthma, even in adults. Indeed, no randomised controlled trial (RCT) comparing monitoring of symptoms only with monitoring of symptoms plus FEV<sub>1</sub> to achieve asthma control has been conducted specifically in a paediatric population. This lack of evidence is especially challenging in children because their absolute FEV, will increase as they grow and get older.

Two studies conducted mainly in adults in Australia failed to demonstrate any significant benefits of spirometry for asthma control in mixed-age primary care populations. An RCT of spirometry was conducted jointly in South Australia and Tasmania, in which training was given to GPs and practice nurses to perform spirometry within general practices, although without external interpretation of spirometry data.25 The intention was that asthma management would be guided by spirometry and lead to improved asthma outcomes, but in practice only 7% of patients with asthma in either 'spirometry-trained' or usual care practices had a spirometry test during the six months of assessment. Not

surprisingly, the trial did not find any improvement in quality of life, days off work or school, asthma exacerbations or daytime or nocturnal symptoms in either adults or children with asthma.

Another RCT in Victoria compared externally-performed three-monthly spirometry, in which reports were rapidly returned to the practice, plus regular medical review by the GP with spirometry only at baseline and one year but without a report supplied to the practice during the study period, and with a final comparator of usual medical care in the practice.26 In this study, 82% of participants had asthma (14% had COPD), and in the first published analysis there were no significant changes in quality of life between the three study groups after one year, nor in respiratory symptoms, asthma attacks, ownership of written asthma action plans, days lost from usual activities or health care utilisation. When a second analysis was restricted to participants with asthma ranging in age from 14 to 70 years, and with results for the latter two groups pooled into a single comparator, the odds of change from baseline in the proportion of patients whose asthma was 'controlled' in the spirometry plus regular review group was significant. However, this positive result was present only at six months and not at either three- or 12-months, making the robustness of the conclusions somewhat doubtful.27 If there was an effect, one cannot differentiate the effect of regular review and the use of spirometry; it is also unclear whether GPs always noted and acted on the supplied spirometry reports.<sup>26</sup>

### SPIROMETRY FOR MANAGING **ASTHMA IN PRIMARY CARE**

In spite of the mainly negative results of the two RCTs, it is still difficult to draw conclusions on the potential for spirometry in managing asthma in primary care because of the poor implementation and lack of systematisation and integration of spirometry in practice routines in studies done to date. Participation in a trial also affects the performance of health professionals.

In a RCT in the USA involving people

with asthma aged between 12 and 20 years and in which a strict protocol-based management (including use of spirometry) was compared with the same management plus added measurement of a marker of airway inflammation (the fraction of exhaled NO), there was good control of symptoms throughout the study period in both groups.28 There was no additional benefit in the fraction of exhaled NO measurement group in terms of differences in annual rate of prednisolone courses or admissions to hospital, unscheduled use of health care or asthma exacerbations.

This study, unlike the Australian studies outlined above, had good adherence to protocol including spirometry, and adherence to treatment averaged 87%, both factors unlikely to be reflected in real-world conditions. Indeed, it was noteworthy that there was a noticeable improvement in asthma control during the run-in period prior to the study starting in both groups, with an increase in the average doses of inhaled corticosteroids and long-acting beta-agonists.<sup>28</sup> However, this study does not indicate whether spirometry itself contributed to asthma control, although it does indicate that having the supervision and adherence to treatment that occurs on entering a study can be effective compared with usual care, i.e. improvement is possible.

### **ORGANISATION OF ASTHMA CARE** IN GENERAL PRACTICE

Proactive asthma care is increasingly being delivered through organised asthma clinics within the primary care setting that include spirometry and review of lung function, review of inhaler technique and asthma education.<sup>29</sup> However, evidence for benefits compared with nonorganised care is also currently inconclusive. Only a small number of studies could be included in a metaanalysis in terms of exacerbation, symptoms or quality of life; the lower likelihood of a hospital admission for asthma in two studies was not statistically significant (OR 0.32; 95% confidence interval 0.09 to 1.21).30

Primary care asthma clinics can, however, systematise the use of spirometry in practice routines and thus contribute to implementing the Asthma Cycle of Care. This initiative involves at least two asthma-related consultations within 12 months for a patient with moderate to severe asthma, for which the Asthma Service Incentive Payment may be claimed through the MBS.

### OTHER TESTS OF LUNG FUNCTION

### **Forced oscillation**

Forced oscillation (impulse oscillometry) is another technique that can be used to obtain measures of airway function. The method involves the application of pressure waves to the airway through a mouthpiece and measurement of respiratory system impedance, from which resistance and reactance can be derived. It does not require expiratory effort and only requires tidal breathing.

Good data can be obtained using forced oscillation, even with preschool children younger than 6 years of age and in children who are not able to perform spirometry, even with coaching. The results have reasonable agreement with spirometric measures of lung function in children with asthma.31 Availability is essentially restricted to specialist and research centres at present.

### Peak expiratory flow

Although measurement of peak expiratory flow should not be routinely used in the diagnosis of asthma, peak expiratory flow monitoring can be used in some patients in the assessment of suspected work-related asthma. It is important for the patient to use the same peak flow meter on each occasion.

### **ASTHMA IN PREGNANCY**

Ideally, women with asthma who are intending to become pregnant should have their recent asthma symptom control assessed and baseline spirometry performed. During pregnancy the severity of asthma may change; around one-third of women it worsens, with lower pulmonary function during pregnancy being associated with adverse pregnancy outcomes (such as increased gestational hypertension and prematurity).32 Maternal asthma is associated with an increased risk of low birthweight, preterm delivery and preeclampsia but the risks are removed by active asthma management during pregnancy.<sup>33</sup>

Spirometry is the preferred method of assessing pulmonary function in pregnancy, and testing, including bronchodilator reversibility assessment, is safe to perform in pregnancy. As FEV<sub>1</sub> does not change substantially as a result of pregnancy itself, spirometry should remain part of the routine assessment of asthma control during pregnancy and should be performed at least monthly for women with persistent asthma.<sup>34</sup>

### **SUMMARY**

Documentation of objective variable airflow limitation in terms of change in  $FEV_1$  is an essential part of asthma diagnosis. Spirometry is the recommended test for adults and children, and can generally be performed adequately by children aged above 6 years. There is, however, poor correlation between symptoms and airflow limitation graded on  $FEV_1$  level. To achieve good asthma control, minimising the future risk of exacerbations and avoiding excessive loss of lung function, regular lung function testing by spirometry is needed.

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COMPETING INTERESTS: None

### **Key points**

- · There is high-quality evidence that Symbicort SMART™(Symbicort Maintenance and Reliever Therapy) reduces asthma exacerbations.
- · Days in which relievers need to be used frequently are less common with SMART than with standard fixed dose inhaled corticosteroid/ long-acting beta-agonist (ICS/LABA) maintenance treatment.
- · Patients using SMART who continue to use reliever doses regularly should not automatically be switched to conventional maintenance treatment as they are the ones most likely to benefit from this approach to asthma treatment.
- Analysis of data from trials comparing SMART with fixed dose ICS/LABA indicates that asthma control was not destabilised before treatment randomisation.
- There is clear evidence that control of airway inflammation is similar for SMART and fixed-dose maintenance treatment.
- Prevention of asthma exacerbations is associated with higher peak reliever use than previously thought, but this pattern of use appears to be safe.



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The findings of recent clinical trials and systematic reviews should allay concerns that were expressed following the introduction of budesonide/eformoterol combination therapy for the maintenance and reliever treatment of asthma. This therapy now has an established role in asthma management.

he use of an inhaled corticosteroid (ICS) in combination with the rapid-onset, long-acting beta-agonist (LABA) eformoterol as both maintenance and reliever treatment has an established place in the management of asthma. In Australia, only the combination therapy budesonide/eformoterol (Symbicort) is registered for this indication. The trademarked term for this regimen is Symbicort SMART™ (Symbicort Maintenance and Reliever Therapy). For the remainder of this article this treatment approach is referred to as SMART. The optimal place of SMART is for patients who have required oral corticosteroids or hospital care for asthma exacerbations. In Europe,

another ICS/formoterol combination is licensed for maintenance and reliever treatment so the language in the recent Global Initiative for Asthma revision refers to maintenance and reliever treatment more generically.1

The aim in this article is not to argue for expansion of the scope of the use of SMART or to review in depth the rationale and best implementation strategy, as that has been reviewed previously.<sup>2</sup> Rather the intention is consider the major concerns expressed about SMART, now generally allayed, and to review recent data and analyses to understand better the mechanisms by which asthma exacerbations are prevented using this treatment strategy.

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In the cut and thrust of robust academic discussion that follows treatment innovation, some authors have viewed the SMART data unfavourably,<sup>3,4</sup> and have been reluctant to draw the same conclusions as the authors of guidelines. The criticisms raised can be summarised as follows and are discussed in detail below:

- caution should be observed in the implementation of this strategy because a Cochrane review did not find SMART to be superior to current best practice
- SMART did not satisfy the dogma of the time that asthma should, and can consistently, be controlled in a way that reliever use becomes minimal
- trial design may have favoured SMART by destabilising subjects' asthma control prior to randomisation
- concerns were expressed, and at least one study suggested, that airway inflammation may have been worsened on a SMART regimen compared with fixed dosing.

### **COCHRANE REVIEWS OF SMART**

The first Cochrane review that included SMART was published in 2009. While noting that SMART was associated with superior outcomes compared with ICS preventer monotherapy, the authors cautioned that, at the time of that review, it had not been compared with modern guideline-based strategies.5 Such strategies would have included using a higher dose of ICS as a part of ICS/LABA fixeddose therapy. A second Cochrane review did examine SMART in studies that compared it with current best practice.6 Although noting a reduction in severe exacerbations with SMART, the authors downgraded the evidence rating because of the lack of blinding in most of these studies.

However, the question of whether SMART is superior to higher fixed-dose ICS/LABA in well-blinded studies has now been answered in an updated Cochrane review published in 2013.<sup>7</sup> Key

conclusions were that there is moderatequality evidence that SMART improves lung function but high-quality evidence that it reduces asthma exacerbations. Asthma exacerbations were defined as those for which patients needed oral corticosteroids or which led to an emergency department visit or hospitalisation, although data were lacking for hospitalisation as a lone end-point. The populations studied were similar to patients for whom SMART is recommended in the *Australian Asthma Handbook*.8

### PATTERNS OF RELIEVER USE IN COMPARATIVE TRIALS

One key aim of asthma management is to reduce symptoms and reliever use. Very simplistically, a strategy in which reliever treatment is a key treatment component rather than just a fall back for rescue when maintenance treatment fails might be seen as counter to that aim. Philosophically, this is inconsistent with the concept of 'total control', which emerged during and after the GOAL study.9 Total control is a state of near absence of symptoms from asthma and its treatment. Adherents to this plan may never embrace SMART but they miss key points. When reliever use is infrequent, SMART and fixed-dose treatments are indistinguishable. Reliever use with SMART is only problematic, firstly, if it is used more frequently than comparator treatments and, secondly, specifically if it confers no benefit.

Self-reported reliever use occurred in the SMART studies on about 50% of days and averaged close to one per day for SMART in addition to the maintenance dose. <sup>10-12</sup> In each study, additional reliever dosing was similar to that used in the standard fixed-dose comparator treatment arm.

In a recent study of once-daily maintenance treatment with fluticasone furoate/vilanterol 100/25 µg, reliever use also occurred on around 50% of days. Neither SMART nor once-daily fluticasone furoate/vilanterol should be criticised for failure to achieve 'total control' in trial subjects who

were frequent reliever users and who entered that trial without a particular expectation that reliever use should decline sharply. As discussed later in this article, directly recorded reliever use suggests that there may be more reliever-free days than self-reporting suggests, although this would apply to all of the studies discussed here.

Another key aim of asthma management is to reduce the risk of exacerbations. More frequent reliever use itself is associated with a higher risk of exacerbations. In the SMART studies and the fluticasone furoate/vilanterol study mentioned above,13 patients who had exacerbations had higher reliever use well before and well after the exacerbations. The extent to which frequent reliever use reflects either a state of asthma that predisposes to asthma exacerbations or symptom awareness that leads to medical intervention during periods of above-average symptoms is not known. In all relevant trials, severe exacerbations were defined not as a disease state but by the treatment sought and administered in response to symptoms. Importantly, it is quite incorrect to exclude those patients who continue to use reliever regularly from ongoing use of SMART because they are the ones most likely to benefit, and comparator fixed-dose treatment is inferior.

### WAS ASTHMA CONTROL DESTABILISED BEFORE RANDOMISATION?

In the key studies comparing SMART with fixed dose ICS/LABA that formed the basis of the most recent Cochrane review, 7,10-12 various approaches were taken to treatment in the pre-randomisation period. In the SMILE study, all subjects were changed from their previous maintenance dose to budesonide/formoterol 200/6 µg (metered dose) twice daily. The average prescribed ICS dose was approximately halved whereas in 41% of subjects there was addition of LABA to previous ICS monotherapy. The effect of this was that during run-in mean FEV<sub>1</sub> increased by 15% in each of the three study groups, after which time FEV<sub>1</sub> remained similar for the 12-month period of randomised treatment.

In the COMPASS study, the pre-trial ICS dose was maintained but subjects ceased LABA use from 72 hours before run-in and for the two-week run-in period. Despite this, during the run-in FEV<sub>1</sub> increased by about 10%, with a slightly smaller increase seen during the six-month treatment period.

In contrast, in the AHEAD study no change was made to the maintenance treatment during run-in. FEV<sub>1</sub> increased by 10% during this two-week run-in period and by a similar amount during the six-month treatment period, the increase being similar for SMART treatment and for fixed-dose salmeterol/fluticasone.

What is to be taken from this? Asthma control in patients entering the SMART studies was not destabilised before randomisation. More importantly, in each of these clinical trials, patients with moderate and severe asthma were provided with simple asthma education, including advice on inhaler technique, and probably improved their adherence, as is known to occur when patients participate in clinical trials. This resulted in rapid and marked improvement in lung function. Simple attention to detail in asthma care is critical when asthma control is not satisfactory.

### IS AIRWAY INFLAMMATION **AGGRAVATED BY SMART?**

As a treatment strategy that may result in a lower regular maintenance LABA/ICS dose than fixed-dose treatments, it would be concerning if there was associated worsening of airway inflammation. An initial study conducted by Sears found that sputum eosinophil counts were in the controlled range for patients taking SMART and a comparator group prescribed treatment according to guidelines.14 This study was criticised, however, for its open design.

This criticism was addressed in a blinded 12-month study conducted by Pavord et al.<sup>15</sup> Budesonide/formoterol 200/6 µg twice daily plus as-needed (maintenance and reliever therapy group) was compared with very high-dose budesonide/

formoterol 800/12 µg twice daily with terbutaline as needed (high fixed-dose group). Mean budesonide dosages were 604 μg/day and 1600 μg/day in the two groups, respectively. Eosinophil counts in both sputum samples and bronchial biopsies were within the range of clinical control for both treatment groups. They were further reduced, within the controlled range, with the use of an additional 1000 µg/day of budesonide in the fixeddose group. However, noting that lung function, reliever use, exacerbation frequency, total inflammatory cells and basement membrane thickness (a feature of long-term airway remodelling) were similar in the two groups, the authors themselves questioned the significance of the lower eosinophil counts.

### **EFFECTS OF RELIEVER USE ON EXACERBATION RISK**

Conceptually, SMART should reduce severe asthma exacerbations by its effect of additional doses of budesonide/eformoterol combination being taken during a period of increasing symptoms that precedes an exacerbation. This has been confirmed. Days during which trial subjects report use of more than four reliever doses are associated with a high but far from inevitable risk of an exacerbation in the subsequent 21 days. Focusing on days when at least six reliever doses are needed, SMART has dual effects of reducing the frequency of exacerbations and the chance that a severe exacerbation will follow. The full extent of SMART on the reduction in exacerbations is achieved by a composite of these effects.16 Even so, reported high reliever use days with SMART are infrequent.

In the COMPASS study, use of four or more reliever doses in subjects on SMART were reported on only 7.4% of days, more than six on 1.9% and eight or more on 0.65%. As the first two reliever doses were required to match the total daily ICS/LABA dose in the fixed-dose comparator group in the study, it is counterintuitive that this reported dosing pattern should effectively

reduce exacerbation frequency.11

Considerable insight into this has been provided by a study conducted in Wellington, New Zealand, where SMART was compared with fixed-dose treatment and date/time chips were attached to all inhalers.<sup>17</sup> The patient groups were similar in reported lung function and other characteristics to those in the COMPASS study. In both studies average daily reliever use was one dose per day. In the Wellington study, a high use day was defined as more than eight reliever doses of SMART or 16 of salbutamol being used and was seen in 56% of subjects randomised to SMART and on approximately 3% of study days. This was lower than for the standard comparator (with short-acting beta<sub>2</sub>-agonist reliever). Medical attention was infrequently sought and adverse events related to overuse were not seen.

Based on self-reporting in the COMPASS study, where specific caution was advised in relation to high use on single days, only 4% of subjects reported the use of more than 10 reliever doses, and on only 0.2% of days. The implication is that selfreporting underestimates high reliever use days and overestimates use on 'lowreliever' days. The use of dose-recording inhalers is now essential for similar studies.

### SMART VS ONCE DAILY LABA/ICS

The advent of once-daily fixed-dose ICS/ LABA will be welcomed by many clinicians and patients. Marketed doses achieve outcomes that are similar to fluticasone propionate/salmeterol twice daily with similar rates of exacerbations.13 Understanding the role of fluticasone furoate/ vilanterol in severe asthma and particularly in patients with higher exacerbation risk urgently requires a study comparing this treatment to SMART. Until evidence from such a trial is generated, budesonide/eformoterol combination therapy as both maintenance and reliever should be the preferred management approach in people with asthma who are at above average risk of severe exacerbations.

### **SUMMARY**

SMART has a well-established role in asthma management reflected in guidelines and systematic reviews. The criticisms about this role have been addressed by recent studies and systematic reviews. We now understand that prevention of exacerbations is associated with higher peak reliever use than previously thought. This pattern of use appears to be safe and high reliever use days are less common with SMART than with standard fixed dose maintenance ICS/LABA approaches. It remains the case that accurate diagnosis of asthma, sensible attribution of symptoms to asthma rather than a comorbidity, and asthma education are required to maximise SMART's benefits.

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COMPETING INTERESTS: Professor Peters has previously served on an Advisory Board for AstraZeneca and received honoraria for lectures and presentations.

### ASTHMA ACTION PLAN

Take this ASTHMA ACTION PLAN with you when you visit your doctor

NAME	DOCTOR'S CONTACT DETAILS	EMERGENCY CONTACT DETAILS	
DATE		Name	
NEXT ASTHMA CHECK-UP DUE		Phone	
NEXT ASTIMA ONEON-OF BOE		Relationship	
WHEN WELL Asthma und	er control (almost no symptoms)	ALWAYS CARRY YOUR RELIEVER WITH YOU	
Your preventer is:	OTHER INSTRUCTION	Peak flow* (if used) above:	
(NAME & STRENGTH)  Takepuffs/tablets.  □ Use a spacer with your inhaler	(e.g. other medicines, tr	rigger avoidance, what to do before exercise)	
Your reliever is:			
(NAME) Take puffs			
When: You have symptoms like wheezing, coughing			
☐ Use a spacer with your inhaler			
	ma getting worse (needing more reliever e.g. n e symptoms than usual, asthma is interfering w	nore than 3 times per week, waking up with asthma, vith usual activities	
	oo, mpromo man usuur, usunna is interiei ing W	Peak flow* (if used) between and	
Keep taking preventer:  (NAME & STRE	NGTH) OTHER INSTRUCTION		
Take puffs/tablets	times every day (e.g. other medicines, w	when to stop taking extra medicines)	
☐ Use a spacer with your inhaler			
V			
Take puffs (NAME)			
☐ Use a spacer with your inhaler			
IF SYMPTOMS GET W	ORSE Asthma is severe (needing reliever waking often at night with asthma s	again within 3 hours, increasing difficulty breathing, ymptoms)	
War taking any salah		Peak flow* (if used) between and	
Keep taking preventer:  (NAME & STR)	OTHER INSTRUCTION	<u> </u>	
Take puffs/tablets	times every day  (e.g. other medicines, w	vhen to stop taking extra medicines)	
☐ Use a spacer with your inhaler		each morning for days	
Your reliever is:	Take	333g 101	
Takepuffs			
☐ Use a spacer with your inhaler			
	emergency (severe breathing problems, ns get worse very quickly, reliever has	NationalAsthma 🕥	
little or	no effect)	CouncilAustralia )	
DIAL COSTOR	Peak flow (if used) below:	leading the attack against asthma	
	Call an ambulance immediately		
	Say that this is an asthma emergency  Keep taking reliever as often as needed  www.nationalasthma.org.au		
Keep tak	ung redever as orien as needed	January Grad	

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### **ASTHMA ACTION PLAN** what to look out for

### WHEN WELL

### THIS MEANS:

- you have no night-time wheezing, coughing or chest tightness
- you need reliever medication only occasionally or before exercise
- you can do your usual activities without getting asthma symptoms

### WHEN **NOT WELL**

### THIS MEANS ANY ONE OF THESE:

### **SYMPTOMS GET WORSE**

### **THIS MEANS:**

- you have increasing wheezing, cough, chest tightness or shortness of breath
- you are waking often at night with asthma symptoms
- you need to use your reliever again within 3 hours

THIS IS AN ASTHMA ATTACK



### THIS MEANS:

- · your symptoms get worse very quickly
- you have severe shortness of breath, can't speak comfortably or lips look blue
- you get little or no relief from your reliever inhaler

**CALL AN AMBULANCE IMMEDIATELY: DIAL 000** SAY THIS IS AN ASTHMA EMERGENCY.

**DIAL 000 FOR AMBULANCE** 



**DANGER** 

**ASTHMA** 

**MEDICINES** 

### **PREVENTERS**

Your preventer medicine reduces inflammation, swelling and mucus in the airways of your lungs. Preventers need to be taken every day, even when you are well.

Some preventer inhalers contain 2 medicines to help control your asthma (combination inhalers).

### **RELIEVERS**

Your reliever medicine works quickly to make breathing easier by making the airways wider.

Always carry your reliever with you - it is essential for first aid. Do not use your preventer inhaler for quick relief of asthma symptoms unless your doctor has told you to do this.

To order more Asthma Action Plans visit the National Asthma Council website. A range of action plans are available on the website - please use the one that best suits your patient.

www.nationalasthma.org.au

Developed by the National Asthma Council Australia and supported by GlaxoSmithKline Australia. National Asthma Council Australia retained editorial control.



National Asthma Council Australia leading the attack against asthme GP: GP:	Asthma emergency	■ SIGNS OF AN ASTHMA EMERGENCY:	<ul> <li>Symptoms getting worse quickly</li> <li>Extreme difficulty breathing or speaking</li> <li>Little or no improvement from Symbicort reliever inhalations</li> <li>ISHOULD DIAL OOD FOR AN AMBULANCE AND SAY I AM HAVING A SEVERE ASTHMA ATTACK.</li> <li>WHILE I AM WAITING FOR THE AMBULANCE START MY ASTHMA FIRST AID PLAN:</li> <li>Sit up right and stay calm</li> <li>Take 2 inhalations of Symbicort. Wait 1–3 minutes. If there is no improvement take another 2 inhalations of Symbicort (up to a maximum of 12 inhalations)</li> <li>If only Ventolin® is available, take 4 puffs as often as needed until help arrives</li> <li>Start a course of prednisolone tablets (as directed) while waiting for the ambulance</li> <li>Even if my symptoms appear to settle quickly, I should see my doctor immediately after a serious asthma attack</li> </ul>
Name: Name: Argundant Substitution of the Sales of the Sa	Asthma flare-up	■ IF OVER A PERIOD OF 2-3 DAYS:	• My asthma symptoms are getting worse OR not improving OR • I am using more than 12 Symbicort reliever inhalations a day.  I should:  © Continue to use my regular everyday treatment PLUS 2 inhalations of Symbicort whenever needed to relieve symptoms  □ Start a course of prednisolone  □ Contact my doctor  COURSE OF PREDNISOLONE TABLETS:  Take 2 × 25 mg or mg prednisolone tablets per day for days OR  I PLED MORE THAN 24 SYMBICORT INHALATIONS (TOTAL) IN ANY DAY,  I must see my doctor or go to hospital the same day
My Symbicort Rapinger Asthma Action Plan Symbicort Symbicort Maintenar ce formoterol for a symbic or Maintenar ce formoterol	Normal mode	■ MY SYMBICORT ASTHMA TREATMENT IS:	Symbicort Rapihaler 50/3 mcg OR Symbicort Rapihaler 100/3 mcg  MY REGULAR TREATMENT EVERY DAY:  Take inhalation(s) in the morning and inhalation(s) in the evening, every day  RELIEVER: Use Symbicort 2 inhalations whenever needed for relief of my asthma symptoms  I should always carry my Symbicort Rapihaler  MY ASTHMA IS STABLE IF:  I can take part in normal physical activity without asthma symptoms  AND  I do not wake up at night or in the morning because of asthma  OTHER INSTRUCTIONS:

Printed copies of the Symbicort SMART symptom-based asthma action plans are available on request from AstraZeneca on 1800 805 342. Pdf versions are available for download from the National Asthma Council website at http://www.nationalasthma.org.au/health-professionals/asthma-action-plans

### Symbicort<sup>®</sup> budesonide/

eformoterol

# Frequently Asked Questions



### Reliever Therapy? What is Symbicort Maintenance And

reliever and continues to work for at least 12 hours. Symbicort can be used in this way because it is an effective (salbutamol) or Bricanyl® (terbutaline) is not necessary. symptoms. A separate rescue inhaler such as Ventolin<sup>®</sup> maintenance treatment AND for relief of breakthrough this schedule, Symbicort is used BOTH for regular daily Symbicort dosing schedule for managing asthma. With Symbicort Maintenance And Reliever Therapy is a

## Why is this treatment approach different?

require two or more medications for different situations. a preventer and reliever. Other treatment approaches Therefore, you only need one inhaler to work as both underlying problem in asthma) with every inhalation. relieves symptoms, but also treats inflammation (the Symbicort Maintenance And Reliever Therapy not only

## Can I use any other inhaler the same way?

or 100/3 as directed asthma medications other than Symbicort Rapihaler 50/3 Treatment dosing schedule should **not** be used with any treats inflammation. This Symbicort Maintenance And Reliever lasts at least 12 hours, as well as an inhaled corticosteroid that has rapid onset of action (1–3 minutes) for symptom relief that both maintenance and reliever treatment. This is because it No. Symbicort is the only asthma inhaler that can be used for

## Do I still need a separate reliever inhaler?

you if you need any other inhaler in addition to Symbicort. Bricanyl® is not necessary if you are using Symbicort as Maintenance and Reliever therapy. Your doctor will advise NO, a separate reliever inhaler such as Ventolin® or

- Symbicort has been shown to effectively relieve symptoms when they occur.
- preventer and reliever treatment. So, Symbicort also Unlike other relievers, Symbicort is a combination of a treats inflammation to help prevent symptoms.

## inhalations that I can take in one day? What is the maximum number of Symbicort

on a single occasion or more than a total of 24 inhalations the same day. any day you should see your doctor or go to the hospital on any one day. If you require more than 24 inhalations in more as long as you follow your written Asthma Action Plan. It's uncommon to need more than a couple of extra reliever You should not take more than 12 inhalations of Symbicort inhalations of Symbicort in one day. At times, you can use

### with me? Do I need to carry my Symbicort Rapihale

at all times for use as a reliever Yes, you should carry your Symbicort Rapihaler with you

Is there an increased risk of side effects using

do not feel well while you are using Symbicort Rapihaler. tell your doctor or pharmacist as soon as possible if you of side effects with Symbicort Maintenance And Reliever which is available from your doctor or pharmacist, for a and reliever? Symbicort as both my regular daily maintenance Therapy if taken as instructed by your doctor. You should See the Consumer Medicine Information (CMI) leaflet effects are rare with Symbicort Rapihaler All asthma medicines can have side effects. Serious side full list of potential side effects. There is no additional rish

## How long do I use it?

Symbicort Rapihaler helps control your asthma, but does stop taking it. not cure it. Keep using it unless your doctor tells you to Use Symbicort Rapihaler every day even if you feel well





