



Preface

Considerable progress has been made in the care of asthma patients in the last decade, and information on the subject has been disseminated worldwide. The Global Initiative for Asthma (GINA) published their first Global Strategy for Asthma Management and Prevention in 1995 and last updated it in 2006 (1). In 1996, the International Union Against Tuberculosis and Lung Disease (The Union) published a Guide on the management of asthma in adults in low-income countries (2) based on current knowledge about asthma management but adapted to the context of less industrialised countries. The Union Asthma Guide has drawn heavily on the GINA guidelines since it was first published. After the Guide was published, pilot studies were conducted in several low- and middle-income countries to evaluate the feasibility of the measures it recommended. The results were presented in a workshop held by The Union Asthma Division in Paris in December 2000 (3), which brought together physicians who had undertaken the studies and other international experts. The principal conclusions of the workshop were as follows: the technical measures set out in the Guide could be applied by health care providers; they were effective, with reductions in the degree of severity of asthma for the majority of patients, along with almost complete disappearance of visits to emergency services and hospitalisations. The pilot studies (4, 5) also concluded that the measures were cost-effective, given the dramatic reduction in health care costs as a result of the reduced need for emergency treatment.

The recommendations of the workshop (3) formed the basis of the second edition of the Guide with the following changes: the focus was expanded to include children aged 5 years and over; the section on the diagnosis of asthma was improved; and the treatment card and asthma register were simplified (6).

However, the continued high costs of inhaled corticosteroids constituted a major obstacle to patients' access to treatment in several countries (7). The Union's response to the low affordability for patients of essential asthma medicines has been the creation of the Asthma Drug Facility (ADF) (8, 9, 10). Low- and middle-income countries can buy good quality essential asthma medicines at low prices through the ADF (http://www.GlobalADF.org). The ADF promotes the correct use of these medicines and quality standardised care by providing ADF clients with training materials and by undertaking regular monitoring of their asthma case management. The third edition of the Guide addresses issues raised at the launch of the ADF: treatment guidelines have been updated, given the availability of chlorofluorocarbon-free (CFC-free) metered-dose inhalers; and simpler tools, including an electronic database, have been developed for the monitoring of patients treated with asthma medicines purchased through the ADF.

As in the previous editions, the third edition of the Guide proposes that the model adopted for management of tuberculosis in the health services should be applied to implement The Union's "package of technical measures" for asthma management. The health structures of the first level of referral are selected as the organisational base for the management of asthma patients, and patient care is provided in the context of the general health services. This edition of the Guide has also integrated experience gained from the evaluation of the implementation of The Union Guide, the results of which were published in 2006. The following colleagues were involved with Profs Nadia Aït-Khaled and Donald A Enarson in these evaluations: Prof N Bencharif, Algeria; Dr F Boulahdib, Morocco; Dr LM Camara, Guinea; Prof E Dagli, Turkey; Dr TK Djankine, Mali; Prof B Keita, Mali; Dr B Karadag, Turkey; Prof BN Koffi, Ivory Coast; Dr J Odhiambo, Kenya; Dr S Ottmani, Morocco; Dr DL Pham, Vietnam; Prof O Sow, Guinea; Prof Y Mohammad, Syria; and Prof N Zidouni, Algeria.

Other experts have given technical advice on various topics during the preparation of this edition of the Guide:

- Clinical Care: Prof C Jenkins, Australia; Dr H Reddel, Australia.
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- Lung Function: Prof P Bakke, Norway; Prof R Abboud, Canada; Dr MR Miller, United Kingdom and Dr H Reddel, Australia.

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We hope that this new edition of the Guide, as well as the services of the Asthma Drug Facility and the international collaboration represented by GINA, the Global Alliance for Respiratory Disease (GARD) (11) and the WHO Practical Approach to Lung Health (PAL) (12) will reduce the suffering from asthma worldwide.

<u>References</u>

- Global Initiative for Asthma. Global strategy for asthma management and prevention. NHLBI/WHO workshop report. Bethesda, MD: National Institutes of Health. National Heart, Lung, and Blood Institute Publication 95-3659. January 1995. Revised in 2006.
- Aït-Khaled N, Enarson DA. Management of asthma in adults. A Guide for Low Income Countries. International Union Against Tuberculosis and Lung Disease. Frankfurt am Main; Moskau; Sennwald, Wien: pmi-Verl.-Gruppe, 1996.
- Aït-Khaled N, Enarson D A, Behbehani N, Chan Yeung M, Irisen E. The Asthma Workshop. Report of a workshop organised by the International Union Against Tuberculosis and Lung Disease, Paris, 15-16 December 2000. Int J Tuberc Lung Dis. 2001;5:973-977.
- 4. Aït-Khaled N, Enarson DA, Bencharif N, Boulahdib F, Camara LM, Dagli E, et al. Implementation of asthma guidelines in health centres of several developing countries. Int J Tuberc Lung Dis. 2006:10:104-109.

- 5. Aït-Khaled N, Enarson DA, Bencharif N, Boulahdib F, Camara LM, Dagli E, et al. Treatment outcome of asthma after one year follow-up in health centres of several developing countries. Int J Tuberc Lung Dis. 2006;10:911-6.
- Aït-Khaled N, Enarson D. Management of asthma in adults. A Guide to the Essentials of Good Clinical Practice. Paris, France, International Union Against Tuberculosis and Lung Disease, 2005. Available on The Union web site: <u>www.iuatld.org</u>
- Aït-Khaled N, Auregan G, Bencharif N, Camara L M, Dagli E, Djankine K, et al. Affordability of inhaled corticosteroids as a potential barrier to treatment of asthma in some developing countries. Int J Tuberc Lung Dis. 2000;4:268-71.
- 8. Billo N. Do we need an Asthma Drug Facility? Int J Tuberc Lung Dis. 2004:8:391.
- 9. Billo N. 2006. ADF from concept to reality. Int J Tuber Lung Dis. 2006 10:709.
- 10. Ait-Khaled N, Enarson DA, Bissell K, Billo N. Access to inhaled corticosteroids is key to improving quality of care for asthma in developing countries. Allergy. 2007;62:230-6.
- 11. Global Alliance against Chronic Respiratory Diseases (GARD) http://www.who.int/gard/en/
- 12. Ottmani SE, Scherpbier R, Pio A, Chaulet P, Aït-Khaled N, Blanc L, et al. Practical Approach to Lung Health (PAL). A primary health care strategy for the integrated management of respiratory conditions in people five years of age and over. WHO/HTM/TB/2005.351. Geneva: World Health Organization, 2005.

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I. Introduction

1. Why publish a guide on asthma management?

Asthma is common

As many as 300 million people are currently living with asthma (1). International surveys on childhood asthma and allergies have shown that asthma is frequent in most countries of the world. The prevalence of asthma symptoms in children aged 13-14 years was highest in New Zealand (25%) and high in most industrialised countries, but it was also high in certain African (10%) and Latin American cities (13%) and has been shown to be increasing in many developing countries (2, 3). Asthma occurs most frequently in those under the age of 45 years. In children, the disease is more common in boys than girls while in adults the prevalence is higher in women than in men. In low- or middle-income countries, an increase in the prevalence of asthma may be expected due to the young age of the population, demographic growth, reduced prevalence of infectious diseases, increase in urbanisation and industrialisation and the progressive changes in lifestyle.

Asthma kills

More than 250,000 people die from asthma each year (1). In industrialised countries, the mortality rate is usually around 1 per 100,000 population per year, but may reach 9 per 100,000. The lack of information in many low-income countries makes it difficult to estimate the asthma mortality rate. Despite a better understanding of the disease and the availability of more effective treatment, an increase in the number of avoidable deaths due to asthma has been noted in the last thirty years, mainly among the young. In industrialised countries, it is much greater among the poor. The most obvious reason for mortality due to asthma is inadequate long-term management of patients.

Asthma in the world: More than 300 million cases More than 250,000 deaths per year

The cost of asthma is very high

The number of disability adjusted life years (DALYs) lost worldwide due to asthma has been estimated at about 15 million per year, which accounts for about 1% of all DALYs lost, "similar to that for diabetes, cirrhosis of the liver, or schizophrenia" (1).

The cost of the disease is high and includes not only the direct costs of the medicines and use of health services, but also indirect costs linked to loss in productivity and other costs to the patient and the patient's family, which are often high but difficult to assess. The direct costs of health service utilisation, as well as the indirect and intangible costs, can be decreased when long-term care of patients is correctly determined and well organised.

The average annual cost of medicines varies widely among countries. In 2002, the minimum annual cost of medicines to treat one case of moderate persistent asthma using the standardised treatment regimen recommended in the Guide varied from US\$54 in Algeria to US\$288 in Sudan, to US\$650 in Kuwait. The high cost of asthma medicines is one of the main obstacles to the organisation of long-term management of patients, not only in low-income countries but also in other countries, and particularly for patients who come from the poorest population groups. Most of these patients earn too little to buy the necessary medicines on a regular basis, and in many countries their health expenses are not covered by social services. In 2002, however, the use of generic medicines would have allowed a case of moderate persistent asthma to be treated for approximately US\$36 (5).

Rational treatment reduces the burden of asthma

Regular use of asthma medicines can result in clear reductions in the burden of disease. The asthma management programme implemented in Finland in 1990 showed a gradual nationwide decrease in mortality and in the number of days of hospitalisation for asthma, with a simultaneous increase in the number of patients who, thanks to the programme, have had access to correct treatment in the last decade (4). The political commitment of countries to provide affordable, good quality essential medicines through the ADF for their asthma patients could decrease the burden of disease in many poor countries by improving access to standardised cost-effective care of asthma patients.

2. What is the purpose of the Guide?

The purpose of this Guide is to propose a method of asthma management applicable in any country, including low-income countries, and to introduce standardised treatment to improve the care of patients and to reduce the cost of such care (5). It aims to complement the vision of the ADF to provide improved access to the necessary medicines for treatment.

This Guide is not a medical textbook. It simply proposes essential measures for the management of the majority of patients with persistent asthma. Other measures that may be necessary to manage specific forms of asthma and for the minority of patients whose asthma is poorly controlled by the treatment recommended, are the responsibility of specialist referral services and are not described in this Guide.

3. What are its objectives?

- 1. To promote precise assessment, accurate diagnosis and correct classification of a patient's asthma.
- 2. To identify the list of essential medicines required for asthma management.
- 3. To establish a long-term treatment plan for the management of asthma patients.
- 4. To adopt a method of classification for asthma attacks.
- 5. To introduce a sound method of managing these attacks.
- 6. To define the content, the methods and the mode of health education.
- 7. To determine the functions of the different levels of the health services in the management of asthma patients.
- 8. To determine the training needs of health personnel involved in the management of asthma patients.
- 9. To introduce an information system that will provide the basis for the management of supplies and for evaluation.

References

- 1. Masoli M, Fabian D, Holt S, Beasley R. Global Burden of Asthma. Developed for The Global Initiative for Asthma (GINA). Available from: http://www.ginasthma.com
- 2. The International Study of Asthma and Allergies in Children (ISAAC) Steering Committee. Worldwide variation in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and atopic eczema: (ISAAC). Lancet. 1998;351:1225-1232.
- 3. Asher MI, Montefort S, Björksten B, Lai CKW, Strachan DP, Weiland SK, Williams H and the ISAAC Phase Three Study Group. Worldwide time trends in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phases One and Three repeat multicountry cross-sectional surveys. Lancet. 2006;368:733-43.
- 4. Haahtela T, Tuomisto LE, Pietinalho A, Klaukka T, Erhola M, Kaila M, Nieminen MM, Kontula E, Laitinen LA. A 10 year asthma programme in Finland: major change for the better. Thorax. 2006;61:663-70.
- 5. Aït-Khaled N, Enarson DA, Bousquet J. Chronic respiratory diseases in developing countries: the burden and strategies for prevention and management. Bull World Health Organ. 2001;79:971-9.

II. What is asthma?

Asthma is a disease that is characterised by the spontaneous occurrence of attacks of breathlessness and wheezing, often at night. The condition occurs with varying severity over a period of several years and sometimes throughout life. With good management the symptoms may diminish and even disappear, allowing the patient to lead a normal professional and social life. When asthma is poorly controlled, however, it can:

- become chronic with permanent airflow limitation;
- cause serious physical and social disability;
- be fatal due to severe attacks.

An understanding of the mechanism by which asthma develops provides the basis for the methods of treatment currently proposed for its management. Asthma is considered to be caused by many factors in individuals who often have a genetic tendency towards the disease.



Some of the various determinants are factors that cause chronic inflammation of the airways leading to airway hyperresponsiveness. These are known as *causal factors*.

Other factors acting on the hyperresponsive airways provoke airflow limitation of varying severity and cause asthma symptoms. These are known as *trigger factors*.

Symptoms of asthma occur during episodes of airway narrowing and mucous production in people with airway inflammation and airway hyperresponsiveness. These episodes may be triggered by a range of external and internal factors, such as viral infections, allergens, occupational sensitisers, irritants, exercise and,

sometimes, emotional factors, foods and medicines. These factors may also aggravate inflammation and hyperresponsiveness but the underlying cause of these abnormalities remains uncertain. Treatment of the underlying disorder makes people with asthma less susceptible to airway narrowing, mucous production and their accompanying symptoms. This treatment can effectively control the disease in most people with asthma.

1. What are the definitions of asthma?

The pathophysiological understanding of this condition is the basis for the definition of asthma proposed in the global strategy for asthma management and prevention (1).

Technical definition

"Asthma is a chronic, inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation causes an associated increase in airway hyperresponsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment."

This chronic inflammation causes pathological changes in the airways that can be irreversible, such as hypertrophy of the smooth muscle, new vessel formation, and deposition of collagens beneath the epithelium. Studies based on autopsies of patients who have died from asthma have demonstrated acute and chronic inflammation of the airways, including the smallest airways (less than 2 mm in diametre). These results underscore the importance of using inhaled corticosteroids.

Operational definition

While the technical definition focuses on the underlying mechanism of the disease, an operational definition is needed for health services. The following definition is proposed:

Any patient who presents to the health services with chest symptoms (including cough, breathlessness and/or wheezing, often at night) that come and go, vary from day to day, and especially if they cause the patient to wake up and sometimes to get up at night, should be suspected of having asthma. Such patients should be carefully examined; if no other cause is found and the symptoms persist for some period of time, they should be considered to have asthma.

2. What factors are associated with the development of asthma?

Predisposing factors

Allergy is the most important predisposing factor in asthma. It is reflected in the

tendency to produce abnormally high levels of immunoglobulin E (IgE) in response to exposure to substances in the environment. Heredity also plays a predisposing role in asthma, and a family history of asthma is common among asthma patients.

Causal factors

Some substances are capable of stimulating the immune system to react by producing specific IgE antibodies. When a predisposed individual is exposed to such an allergen, the T-lymphocytes in the immune system become Th2-lymphocytes. The Th2 cells release cytokines, which act on B lymphocytes and plasma cells and stimulate them to produce specific IgE. The person has thus become sensitised to the allergen. When the person is exposed to the same substance again, an immune reaction will occur which leads to symptoms. The inflammatory process is triggered by cell mediators from mast cells activated by the reaction between the allergen and the IgE. Mediators are also produced by other cells, such as macrophages, lymphocytes and eosinophils.

The causes of asthma are not known in the majority of patients. There are many causal factors, and asthma is generally caused by a combination of these:

- Allergens in the home such as: house dust mites, which are principally found in bedding, carpets and rugs; moulds; animals (cats, dogs, rats); insects (cockroaches). Outdoor allergens such as pollens and moulds have also been linked to the presence of asthma in some, but not all, epidemiological studies. However, there is a lack of consistent evidence that avoidance of these factors prevents the onset of asthma. In particular, recent trials of house dust mite avoidance for the prevention of asthma have generally been disappointing in this regard.
- Workplace exposure to substances of chemical origin or contained in dusts (a regularly updated list of professions at risk of exposure can be found on the site: http://asmanet.com).

Contributing factors

A number of other factors may also contribute to the development of asthma or asthma-like symptoms:

- Indoor air pollution
 - *Environmental tobacco smoke*: passive smoking is a very important risk factor for the development of asthma in young children, and mothers who smoke during pregnancy increase the risk of asthma in their children.
 - Cooking and/or heating using biomass fuel: In many low- and middleincome countries, biomass fuel is used for cooking and/or heating and is a source of indoor air pollution.
- Outdoor air pollution plays a role in triggering symptoms, but its role in the development of asthma remains uncertain.
- The role of acute respiratory infections in the development of asthma is complex. The occurrence of a severe infection, particularly due to respiratory syncytial virus, before the age of 1-2 years, may favour the development of asthma. Viral infections in both children and adults are a common trigger for asthma attacks in people with asthma. In some cases it

is difficult to be sure whether a preceding viral infection has caused the onset of asthma or simply exposed pre-existing, unrecognised asthma.

Some factors may protect against the development of asthma:

- Living in a rural environment, on a farm in contact with livestock (the 'hygiene' hypothesis for the development of asthma);
- Exposure during the first years of life to domestic pets;
- Having older siblings or being exposed in early life to older children.

3. What are the main trigger factors of asthma?

In addition to the causal factors that can lead to the development of asthma, there are other factors that have little or no effect on the development of asthma but are capable of triggering an attack. Often the same factors consistently trigger symptoms in an individual, even though that individual's overall susceptibility may vary over time and with treatment. It is important to identify trigger factors in order to plan preventive measures adapted to each patient. Trigger factors include:

- irritants: smoke from wood and other biomass, household aerosols, vehicle pollution, and environmental tobacco smoke;
- bacterial or viral infections in the upper and lower airways, in both adults and children;
- exercise: particularly in children and people who engage in sports;
- weather changes: fall in temperature, humidity and fog;
- gastro-oesophageal reflux;
- pregnancy, menstruation or menopause in some women;
- stress and emotional situations.

4. What are the clinical features of asthma?

Principal symptoms of asthma

Principal symptoms of asthma are chest tightness, breathlessness and wheeze. None of these is specific for asthma, and all may occur with other chest conditions. As a result, the symptoms of asthma are sometimes attributed to other conditions and hence treated inappropriately or not treated at all. Asthma must always be considered in the following settings:

- episodes of breathlessness, particularly those occurring mainly at night and that wake the patient, especially in the early hours of the morning;
- symptoms that disappear either spontaneously or after taking bronchodilator medication;
- symptoms that appear in recurrent attacks;
- a history of coughing spells not explained by other causes;
- symptoms brought on by a variety of factors such as dust, cold air or sudden changes in the weather;
- a patient who has periods during which the symptoms improve;
- a patient with a personal history of allergies (allergic rhinitis, eczema) or with allergies in the family (allergic rhinitis, eczema, asthma).

Clinical patterns

The typical pattern of asthma is characterised by frequent episodes of wheezing, cough and breathlessness that vary in duration and severity. Symptoms at night are particularly characteristic but do not occur in all people with asthma. The periods between episodes vary and are punctuated by brief symptomatic episodes that resolve spontaneously when the condition is mild or moderate. Persistent breathlessness can occur in the most severe form of the condition due to the progression from reversible to irreversible airflow limitation. Severe progression of asthma is rare, and is linked to the development of irreversible airway fibrosis.

Less typical clinical features are observed mainly in children:

- recurrent attacks of cough, particularly in the evening and/or at night, which do not respond to symptomatic treatment;
- chest tightness with wheezing that occurs only after exercise;
- a clinical pattern that is similar to that of an acute respiratory infection: moderate fever, accompanied by respiratory symptoms with or without breathlessness and wheezing. In such cases, a diagnosis of asthma is often only considered after episodes have recurred several times over a relatively short period of time (more than three times in one year).

Specific, rarer forms must be identified, as they sometimes require more specialised care: individual management and, if possible, referral to a specialist.

A minority of patients with asthma are allergic to aspirin and/or other non-steroidal anti-inflammatory drugs. These individuals may also experience other allergic manifestations when they take aspirin such as urticaria (hives), angioedema (swelling of the lips and tongue) or even anaphylaxis (shock). It is very important that patients with a history of a reaction such as this avoid taking aspirin and non-steroidal anti-inflammatory drugs, as they may lead to very severe and even fatal attacks.

Occupational asthma should be considered if symptoms occur in the workplace or during the night after work and if they disappear or improve while the patient is away from work either on weekends or on vacation. If patients with occupational asthma are identified early, some can be cured, and most have significant improvement if further exposure to the substances causing the asthma is avoided. Patients suspected of having occupational asthma should be referred to a specialist for confirmation of the diagnosis, for assessment of disability and for initiation of necessary legal processes (change of occupation, compensation).

Seasonal asthma is a more common, specific form of asthma. Symptoms occur in the same season every year over several consecutive years. The asthma is often due to sensitisation to specific pollens or moulds. Pollen-induced asthma is often preceded or accompanied by allergic manifestations, such as allergic rhinitis, which always occur during the same season. It can worsen after several years and become chronic due to progressive sensitisation to other risk factors.

Patients with difficult-to-control asthma, who remain severely symptomatic and poorly controlled despite implementing the treatment recommendations described

later in this Guide, should be referred for specialised care where this is possible.

<u>Reference</u>

1. Global Initiative for Asthma. Global strategy for asthma management and prevention. NHLBI/WHO workshop report. Bethesda, MD: National Institutes of Health. National Heart, Lung, and Blood Institute Publication 95-3659. January 1995. Revised in 2006.

III. Methods for assessing the patient for asthma

Every time a patient is seen in the health service for anything to do with asthma, two methods need to be applied to assess the patient – clinical evaluation and lung function testing. This is true whether it is a new patient who has never previously been assessed or a patient returning to the health service while under care for asthma.

1. What is clinical evaluation?

Clinical evaluation relies on the report of the patient concerning the usual frequency and severity of the clinical symptoms over the specified period being assessed (*over the previous twelve months*, if it is at the time of initial evaluation or annual evaluation; or *since the last consultation*, if it is a follow-up visit after the initial evaluation and is not an annual evaluation). Collecting information on the symptoms is only partly reliable because of its subjectivity, as it is based on the judgment and memory of the patient and also, to a certain extent, on the judgment of the health care provider.

Clinical symptoms that should be assessed when considering asthma are primarily those of the chest and especially wheeze, attacks of breathlessness or chest tightness but can also include other symptoms such as cough.

At initial evaluation

When a patient presents with symptoms, one should estimate the severity of the symptoms, as follows:

- Intermittent: symptoms disappear for long periods. When they return, they occur less than once a week (< weekly). The periods of attacks last only a few hours or a few days; when there are nocturnal symptoms, they occur less than twice a month.
- **Persistent**: symptoms never disappear for more than one week. When symptoms occur more than once a week, they are called persistent:
 - **mild** persistent: symptoms occur less than once a day *(weekly)* and nocturnal symptoms occur more than twice a month;
 - **moderate** persistent: symptoms are *daily* and attacks affect activity and sleep patterns more than once a week;
 - **severe** persistent: symptoms are *continuous* with frequent attacks, limiting physical activity, and often occurring at night.

In the specific case of seasonal asthma, which is often linked to a pollen allergy, the severity of the symptoms will be determined according to their frequency during that season in order to decide on the long-term treatment the patient will need at least during that season.

At follow-up visits and annual evaluation

Symptom severity over the specified period should be assessed. On occasion, a patient will have had no symptoms over the period being assessed. In this case, the severity of symptoms is classified as **asymptomatic**. Therefore, at follow-up visits and annual evaluations, there are five categories of symptom severity:

asymptomatic, intermittent, mild persistent, moderate persistent, and severe persistent.

2. What is lung function testing?

Lung function tests should be conducted for all persons who are being assessed for asthma (1). The recommended approach is the peak expiratory flow (PEF) measurement using a simple peak flow meter, which identifies airflow limitation. It correlates well with the forced expiratory volume in one second (FEV₁), which is measured by spirometry. Due to its simplicity, the peak flow meter is the most practical tool for testing lung function.

The peak flow meter is reliable, robust and cheap. The degree of airflow limitation can be evaluated by comparing the patient's PEF level with the 'predicted' or 'normal' value of PEF, which is given in tables by age, sex and height for adults, and by height only for children. Predicted values should be obtained from studies of 'normal' or 'healthy' individuals of the same sex, age and height (anthropometric characteristics) and, where relevant, ethnic characteristics of the patient being tested. Ideally, reference values are calculated using equations derived from measurements observed in a representative sample of healthy individuals in a general population (1).

Performing the measurement of PEF

The PEF should be measured whenever the patient attends the health service. Each time it is performed, it is important to ensure that the test has been carried out correctly. Equipment needed for PEF measurement includes a peak flow meter and cardboard disposable (or plastic reusable) mouthpiece. Patients must be taught how to perform the test properly if the measurement is to be reliable. The PEF is measured as follows:

- Fit a mouthpiece to the end of the peak flow meter, and set the marker at the zero level (bottom of the scale).
- Have the patient stand up and hold the peak flow meter by the other end, horizontally without restricting the movement of the marker.
- Explain the necessary movements to the patient as follows: 'take a deep breath, seal your lips around the mouthpiece and blow as quickly as possible (as if blowing out a candle)'. The marker will go up to a different level: record the result in litres per minute (I/min) shown by the marker.
- Repeat the measurement two more times: the highest of the three readings will be noted (patient PEF in I/min).

Expressing the result

The patient PEF should now be expressed as a percentage of their predicted PEF value, so that the patient's lung function can be evaluated by comparing it with 'normal' values. If tables of predicted PEF values are available in your country, consult them. Almost all peak flow meters include a table of predicted PEF values that can be used. Appendix 4 provides an example of Tables of predicted PEF values. Calculate the patient PEF in % of predicted PEF by using the following formula:

Patient PEF in % of predicted PEF =	<u>patient PEF in I/min</u>	V 100
	predicted PEF in I/min	A 100

Other tests (measurement of airway hyperresponsiveness, allergy skin tests, measurement of specific and total IgE and of eosinophils) add little to the assessment of a patient in routine practice and are relatively costly. These tests can be used in the specialised referral centres for cases that are difficult to diagnose, for unusual forms of asthma or for research.

IV. Diagnosing and classifying the severity of asthma

Before treating a patient for asthma, it is necessary to *establish the diagnosis* of asthma and to *classify the severity* of asthma. The same two elements are used for diagnosis and for classification: the clinical history and lung function measurement.

1. How is the diagnosis of asthma established?

When should asthma be suspected?

The most characteristic symptoms are wheeze, chest tightness, breathlessness and cough; in particular, recurrent attacks, mainly at night, of breathlessness with wheezing. Nevertheless, any chest symptom can be due to asthma. The symptoms generally occur in episodes, and their occurrence and severity vary over time, even in patients with continuous symptoms. The symptoms can vary:

- over a day;
- from one day to the next;
- from one season to the next, and
- from one episode to the next.

History of the disease

In taking the clinical history it is important to use simple words, in a manner that is easy for the patient to understand.

Open-ended questions are asked to obtain information about the course of the disease.

Specific questions are asked to identify

- o chest symptoms;
- o their variability over time;
- o causal and trigger factors, as well as
- o factors that can improve the symptoms.

If the patient is examined during an attack, the diagnosis is usually obvious. It is more difficult if the patient has never been seen during an attack. If the patient presents during a symptom-free period, the clinical examination is often less useful. The presence of wheeze is consistent with asthma while the presence of crackles is suggestive of other conditions. The absence of wheeze does not exclude asthma, as during symptom-free periods it may be not be present.

Differential diagnosis

In some cases the clinical history is less typical, and it may be possible that the patient is suffering from another condition with similar symptoms. The interview should therefore include questions that will help to confirm or exclude the diagnosis of other common conditions. The differential diagnosis is different if the patient is an adult or a child.

In the adult patient:

- Productive cough every day with little change from one day to the next is more likely to be due to *chronic bronchitis*, particularly if the patient has a long history of smoking, works in a dusty environment or uses biomass fuel in the home.
- Breathlessness after exercise which gradually worsens over time, suggests *chronic obstructive lung disease*.
- Chronic productive cough with purulent sputum that occurs when the patient is in specific positions, suggests *bronchiectasis*.
- Chest pain or tightness which comes on with exercise and is relieved by rest, pain that spreads toward the neck or the left arm, or breathlessness on lying down, suggests *heart disease*.
- A sensation of breathlessness, with no other chest symptom, and which generally occurs during the day, accompanied by a feeling of numbress or tingling in the fingers, panic or fear, may be due to *hyperventilation*.

In children:

- Acute respiratory infections are most frequent, particularly when the respiratory episode is accompanied by fever. If the condition recurs a number of times in one year, however, the more likely diagnosis is asthma.
- In the case of wheezing, *inhalation of a foreign body* should be considered, particularly if the wheezing is unilateral.
- *Bronchiectasis* is characterised by chronic productive cough with purulent sputum, particularly if the patient has a history of severe infection as an infant, such as post-measles chest disease.

In both adults and children, *tuberculosis* is suspected when symptoms are prolonged (more than three weeks) and, in children, when there is history of contact with an active case. Consequently, in patients newly presenting with prolonged chest symptoms, the first test to be undertaken before further investigation is sputum smear examination for tuberculosis.

How is the diagnosis of asthma confirmed?

The confirmation of asthma is based on the variability between several PEF measurements. The patient PEF will vary depending on the situation. For example, PEF values that are lower than normal will improve after treatment, and PEF values that are normal will decrease when the symptoms return (especially during an attack).

When a patient first presents with persistent chest symptoms consistent with asthma, and other diagnoses have been excluded, PEF measurements should be taken:

- measure the PEF before inhalation of salbutamol (PEF before bronchodilator);
- ask the patient to inhale two puffs of salbutamol either directly from a metered-dose inhaler or with a spacer;
- ask the patient to hold their breath for 10 seconds to facilitate diffusion of the salbutamol;
- wait 10 -15 minutes, and then measure the PEF (**PEF after bronchodilator**).

If the PEF before bronchodilation is less than the PEF predicted and/or if the patient has some asthma symptoms on the day of the consultation, an initial treatment should be started immediately with medicines capable of rapidly reducing the inflammation of the airways and relieving the symptoms. In most cases this consists of a short course of oral prednisone, together with inhaled beclomethasone and inhaled salbutamol, administered at the following dosages:

For adults:

- 0.5 mg/kg prednisone
- 800 µg of inhaled HFA-Beclomethasone at 100 µg (i.e. 8 puffs)
- 1 to 2 puffs of inhaled HFA-Salbutamol at 100 µg as needed.

For children aged 5 years and over:

- 0.5 mg/kg prednisone, and/or
- 400 µg of inhaled HFA-Beclomethasone at 100µg (i.e. 4 puffs)
- 1 to 2 puffs of inhaled HFA-Salbutamol at 100 µg as needed.

After one or two weeks, the patient should be completely stabilised and the symptoms should have improved or disappeared. The PEF before bronchodilator is measured and recorded (**PEF before bronchodilator, after initial treatment and/or after a trial of oral corticosteroids).** Then, the PEF after bronchodilator is measured and recorded (**PEF after bronchodilator, after initial treatment and/or after a trial of oral corticosteroids).** Then, the PEF after bronchodilator is measured and recorded (**PEF after bronchodilator, after initial treatment and/or after a trial of oral corticosteroids).**

The health care provider considers the various PEF measurements that have been recorded for the patient on the asthma treatment card (see Document 2), and selects the highest PEF and the lowest PEF out of the four PEF measurements (see also 2.1 Assessment of lung function) in order to calculate the variability of patient PEF according to the following formula:

PEF variability =	<u>best PEF – lowest PEF (in l/min)</u>	X 100
	lowest PEF (in I/min)	

A **PEF** variability of greater than or equal to 20% (\geq 20%) is judged as significant and confirms the diagnosis of asthma.

The following patients should be considered as having asthma and managed with asthma treatment:

- **Confirmed asthma**: a patient with symptoms that are typical of asthma and PEF variability ≥ 20%;
- **Probable asthma**: a patient with symptoms that are typical of asthma and a history of disease that is characteristic of asthma, after exclusion of other diagnoses but without confirmation that PEF variability is ≥ 20%.

Inability to confirm asthma by peak flow variability can be due to several reasons:

- A peak flow meter may not be available;
- A patient may not be able to perform the test adequately;
- A doctor may judge that the patient has asthma, even without confirmation.

2. How is the severity of asthma classified?

Classification of asthma severity is an essential component of patient management, as it allows the health care provider to determine appropriate treatment and to evaluate the effectiveness of asthma management. It is based on clinical evaluation and lung function testing (see Chapter III). Using these two methods it is possible to specify the severity of asthma based on the severity of the symptoms and the level of lung function. It must be specified at the end of the initial evaluation and at each annual evaluation after starting long term treatment.

2.1 Assesssment of lung function

At initial evaluation

In addition to the clinical evaluation, an initial evaluation of asthma severity usually requires four measurements of PEF. Three attempts should be made for each measurement and the highest result from the three attempts should be recorded as the PEF value for that measurement. The four measurements are:

- PEF before bronchodilator
- PEF after bronchodilator
- PEF before bronchodilator, after initial treatment and/or after a trial of oral corticosteroids
- PEF after bronchodilator, after initial treatment and/or after a trial of oral corticosteroids

The highest PEF of the four measurements at initial evaluation is called the **best PEF**, and is usually the **PEF after bronchodilator, after initial treatment and/or after a trial of oral corticosteroids**. The level of lung function is determined by **best PEF** at initial evaluation as a percentage of predicted PEF, using the following formula:

Best PEF in % predicted PEF = <u>best PEF in l/min</u> predicted PEF in l/min
x 100

The level of lung function is determined by the following:

- Absence of airflow limitation: Best PEF ≥ 80% of predicted PEF
- Moderate airflow limitation: Best PEF 60-79% of predicted PEF
- Severe airflow limitation: Best PEF < 60% of predicted PEF

The best PEF in % predicted PEF value when the patient is in a stable state allows the functional severity of the disease to be assessed during the initial evaluation. The best PEF must be recorded on the asthma patient card (Document 1) and on the front side of the asthma treatment card (Document 2).

At follow-up visits

During the patient's regular follow-up visits, the evolution of lung function will be followed by comparing the patient's current **PEF after bronchodilator** with the patient's **best PEF** at initial evaluation.

At annual evaluation

If the patient is not experiencing an acute attack of asthma at the time, an annual evaluation requires only two PEF measurements, (before and after bronchodilator)

of which **PEF** after bronchodilator is usually the best **PEF**. If the patient *is* experiencing an acute attack at the time, an annual evaluation requires four PEF measurements (as for the initial evaluation), of which **PEF** after bronchodilator after initial treatment and/or after a trial of oral corticosteroids is usually the best PEF.

2.2 Classification of severity of asthma

At initial evaluation

In most cases there is a correlation between the severity of symptoms and the level of lung function. When there is a lack of agreement between the clinical evaluation and the lung function evaluation, the higher grade of severity noted by either of the two evaluations will be used to define the grade of asthma severity (Table below). It is better to overestimate than underestimate the severity of asthma (underestimation would result in inadequate treatment).

Classification of severity of asthma

Intermittent asthma	Intermittent (< weekly) symptoms and absence of airflow limitation (Best PEF \ge 80% of predicted PEF)	
Mild persistent asthma	Mild persistent (weekly) symptoms and absence of airflow limitation (Best PEF ≥ 80% of predicted PEF)	
Moderate persistent asthma	Moderate persistent (daily) symptoms and less than severe airflow limitation (Best PEF ≥ 60% of predicted PEF)	
	or Moderate airflow limitation (Best PEF 60-79% of predicted PEF) and less than severe persistent symptoms (< continuous)	
Severe persistent asthma	Severe persistent (continuous) symptoms whatever the level of airflow limitation (PEF) or Severe airflow limitation (Best PEF < 60% of predicted PEF) whatever the severity of the symptoms	

In the rare cases of children or elderly people for whom accurate PEF values cannot be obtained, the classification of the condition will be based only on clinical examination and response to treatment. In cases of seasonal asthma, the asthma severity will be determined by the clinical and functional evaluation during the season when symptoms occur.

If a patient is already taking regular treatment, the severity of the condition is more difficult to determine. It is based on the patient's current PEF level and the minimum long-term treatment necessary to control the asthma.

At annual evaluation

The classification of asthma severity uses the same categories as for the initial

evaluation. However, one category is added from the second annual evaluation onwards: **remission**. Patients who remain asymptomatic throughout one year following the discontinuation of inhaled corticosteroids and whose **PEF after bronchodilator** is normal (\geq 80% of predicted PEF) are classified as **remission**. Some patients may appear asymptomatic at the first annual evaluation, but they would not fit this definition of remission, since they have not yet remained asymptomatic for one year after discontinuing their inhaled corticosteroids. The asthma severity of asymptomatic patients who do not fit the definition of remission is classified according to their level of lung function, as follows:

- Intermittent : best PEF ≥ 80% of predicted PEF
- Moderate: best PEF 60-79% of predicted PEF
- Severe: best PEF < 60% of predicted PEF

At the end of each annual evaluation visit, the patient's information is recorded on the asthma treatment card (Document 2) and a new asthma patient card (Document 1) with updated information is provided to the patient.

Reference

1. R. Pellegrino, G. Viegi, V. Brusasco, R.O. Crapo, F. Burgos, R. Casaburi, et al. Interpretative strategies for lung function tests. Eur Respir J. 2005; 26(5): 948–68.

V. Long-term treatment for the patient with asthma

After the diagnosis is established, the management of asthma may require longterm treatment with medication, sometimes for the total duration of the patient's life. As for all patients with chronic illnesses, issues of cost, adherence, organisation of care and medicine supplies are major challenges in achieving success of treatment. Moreover, for low-income countries, the approach to treatment must be feasible and efficient.

1. What are the objectives of treatment?

The main objective of treatment is to keep the individual's asthma as well controlled as possible, for as much of the time as possible, with a minimum of side effects.

From the outset, it is important to define the objectives of treatment for each patient. These should be clearly explained to the patient, since the patient's understanding of treatment, and ability to follow it regularly, are crucial to achieving success. The patient should be informed that treatment is long-term and that it is impossible in the first few visits to determine how long it will take to attain these objectives.

When asthma is well controlled, the patient has:

- no symptoms or very mild symptoms
- no attacks
- no emergency department visits
- no limitation of activities
- no airflow limitation (PEF \ge 80% of predicted value)
- minimal bronchodilator use (< 2 times/week)
- least side effects possible

Achieving well controlled asthma with a minimum of side effects requires adjustment of treatment to find the minimum effective level of treatment intensity.

In the most severe persistent asthma cases, these objectives may not be attainable due to irreversible inflammatory lesions of the bronchial mucosa. The objectives of treatment are more modest: clinical and functional improvement, trying to obtain the best results possible with the minimum of side effects.

2. What are the essential medicines for asthma?

The most important component of treatment is medication. Two types of medication are used for treatment of asthma:

- **anti-inflammatory** medicines to treat the underlying disease; and
- bronchodilator medicines to relieve the symptoms and airflow limitation.

Inhaled corticosteroids are the most commonly used class of anti-inflammatory medicines for patients with asthma. Short-acting beta-2 adrenergic agonists are the most commonly used class of bronchodilator medicines. For the long-term treatment of the majority of asthma cases, only these two classes of medicines are

required.

The WHO Model List of Essential Medicines includes beclomethasone, an inhaled corticosteroid, and salbutamol, a short-acting beta2-agonist (1). The current GINA guidelines (Pocket Guide for Asthma Management and Prevention) provide a list of alternatives within each of these classes of medicines and their dose equivalence (2).

Inhaled medicines are most conveniently administered using metered-dose inhalers. These devices have conventionally used chlorofluorocarbons (CFCs) as propellants. In accordance with the Montreal Protocol on Substances that Deplete the Ozone Layer, CFC-based aerosols are being phased out. Metered-dose inhalers using hydrofluoroalkanes (HFAs) as a propellant have been developed to replace those using CFCs. Studies of the pharmacokinetics, efficacy, improvement in guality of life and toxicity of HFA inhalers have been conducted mainly on salbutamol and beclomethasone. HFA formulations of salbutamol have been judged comparable to those containing CFCs. However, HFA-Beclomethasone metered-dose inhalers have proved effective at lower doses. The dose equivalence between HFA-Beclomethasone and CFC-Beclomethasone is approximately 2 to 1 (3,4,5). This is due to the fact the beclomethasone is soluble in HFA and produces extra-fine particules/droplets. Other inhaled preparations of HFA-Beclomethasone, such as 250 µg (due to its excipient composition), as well as the other corticosteroids, and the bronchodilators currently available do not produce extra-fine particules (see Table on page 31).

The combination of beclomethasone and salbutamol provides one of the most cost-effective treatment regimens currently available. National authorities should take into account the availability of drugs, their cost and their accessibility for the majority of patients before recommending medicines in their national policy or guidelines. Whatever the choice of medicines, these should be clearly spelled out in a policy statement on 'standard case management'. In preparing such a statement, the following basic principles should always be respected:

- standardisation of treatment according to severity of asthma;
- prescription of long-term treatment with daily inhaled corticosteroids for all cases of persistent asthma; and
- adaptation of the dosage according to the response of the patient.

Other drugs

Although there are numerous other asthma medicines available, the control of persistent asthma necessitates the use of inhaled corticosteroids. Long-acting beta2-agonists may be used in specialised services for the few cases of asthma that are particularly difficult to control with inhaled corticosteroids alone.

Certain drugs, such as cough medications, mucolytics, antihistamines (except in the case of allergic rhinitis or other associated allergic conditions) and antibiotics (except in the case of a clear bacterial infection) are of no benefit to the patient and should not be prescribed.

3. What medicines are recommended in this Guide?

Anti-inflammatory medicines

Because of its effectiveness and low rate of side effects, **inhaled HFA-Beclomethasone** is the medication of choice for cases of persistent asthma. It progressively reduces inflammation of the airways and bronchial hyperresponsiveness, thereby diminishing the severity of asthma over the long-term.

Inhaled corticosteroids have almost no serious side effects. Local effects such as hoarseness, mild sore throat, and occasionally yeast infection of the mouth can occur if daily treatment consists of doses of 1,000 μ g or more. These side effects can be avoided by advising patients to use a large volume spacer and to rinse out the mouth after taking inhaled corticosteroids.

Systemic corticosteroids (oral prednisone) are used as follows:

- **Short-term**: they are used to treat attacks, and are stopped after only a few days when the patient's condition stabilises. In this case they have few harmful side effects.
- Long-term: they may have to be used for the most severe cases of asthma in which no other treatment can control the disease. They should be used only where absolutely required and at the lowest dose necessary to maintain adequate control, because serious side effects may result from their long-term use. These effects include:
 - o infections;
 - o diabetes;
 - high blood pressure;
 - o osteoporosis; and,
 - acute adrenal insufficiency, if long-term oral corticosteroids are suddenly interrupted.

Bronchodilators

Beta2-agonists are the most powerful bronchodilators. They relax the bronchial smooth muscle and assist in clearing the airways of bronchial secretions. Short-acting beta2-agonists are the medicines of choice for immediate relief of asthma symptoms and for preventing exercise-induced asthma. They are very well tolerated, and systemic side effects (tachycardia, tremors, hypokalaemia) are rare. **Inhaled HFA-Salbutamol** is the bronchodilator recommended in this Guide.

Essential medicines for asthma treatment recommended in this Guide

Type of medicine	Generic name	Mode of administration and dosage
Anti-inflammatory		
Corticosteroid	HFA-Beclomethasone	Metered-dose inhaler: 100 µg per puff
	Prednisone	Tablets: 5 mg
Bronchodilator		
Short-acting	HFA-Salbutamol	Metered-dose inhaler: 100 µg per puff
beta2-agonist		

4. How are the medicines given?

Except for systemic corticosteroids, all medicines should be given by inhalation. The inhalation route is the best mode of administration for both bronchodilators and corticosteroids because this route is the most effective and the least harmful. Inhaled beclomethasone provides anti-inflammatory treatment that has minimal side effects, as compared with parenteral steroids. Inhaled salbutamol is efficacious using small doses, has rapid action (attaining its maximum in a few seconds) and is accompanied by an almost total absence of side effects.

The technique of inhalation of the medicines is the most important factor for treatment success. If the technique is poor, the patient will not get the maximum benefit from treatment. This is why the patient should be carefully taught how to inhale the medicines correctly. The instructions should be repeated often. Each time the patient visits the health facility, the patient should perform the technique in front of the health care provider to check that the correct technique is being used. The difficulty of the technique is the need for coordination between the patient's breathing and the movement of the patient's hand to press on the base of the inhaler so that the aerosol penetrates deeply into the airways and does not exit via the nose. The health care provider should check that patients correctly perform each of the following steps. The patient is instructed as follows:

- 1. Remove the protective cap.
- 2. Shake the inhaler well.
- 3. Breathe out deeply to empty the lungs.
- 4. Insert the mouthpiece into the mouth, sealing the lips around the mouthpiece.
- 5. Breathe in deeply while pressing on the base of the inhaler to help the aerosol penetrate deeply into the airways.
- 6. Remove the inhaler and hold their breath for 10 seconds, without breathing out.
- 7. Breathe out, then breathe normally.

All patients taking inhaled corticosteroids should administer them using a large volume spacer. (A home-made spacer is very effective; see Chapter VII for how to make a spacer). A spacer ensures maximum delivery of the medication into the lower respiratory tract with minimal deposition in the upper airway, where it can cause local side effects and also be absorbed into the systemic circulation. In addition, the use of a spacer is easier for the patient because there is no need for coordination between the patient's breathing and the movement of the patient's hand to press on the base of the inhaler. The health care provider should check that the patient performs each of the following steps correctly when using a spacer. The patient is instructed as follows:

- 1. Shake the inhaler and insert the mouthpiece into the opening made in the base of the bottle.
- 2. Breathe out deeply to empty the lungs.
- 3. Put the opening of the bottle into the mouth.
- 4. Press the base of the inhaler to release one dose of the product into the bottle.

- 5. Inhale the air and the product in the bottle: breathe through the mouth normally but as deeply as possible for around 10 seconds.
- 6. Remove the bottle from the mouth, breathe out deeply, then breathe normally.

The patient should be instructed that HFA (CFC-free) metered-dose inhalers must be washed as recommended by the manufacturer.

5. What is the standardised approach for long-term treatment?

The '4-step approach' is the underlying principle of the management of asthma proposed in this Guide. Initial treatment is given according to the degree of severity of asthma and adapted during follow-up. If the asthma has improved, treatment is stepped down; if asthma has not improved or has deteriorated, treatment is stepped up.



How do you start long-term treatment?

Most patients present for long-term care in one or other of the following ways:

- following an attack of asthma (by far the most frequent) or
- referred either by the health service or presenting themselves because of chronic symptoms.

Long-term treatment must be started once the diagnosis of asthma has been established (See Chapter IV) - this is when the patient's condition has stabilised at the end of a period of observation either during the initial period when the diagnosis is established (described above) or after the treatment of an attack. All patients with persistent asthma should receive long-term inhaled corticosteroids at a daily dose adapted to the grade of severity of their condition (See Tables "Essential medicines for asthma treatment recommended in this Guide" and "Recommended prescription of inhaled corticosteroids for adults and children in daily number of puffs"). Patients with intermittent asthma should be prescribed inhaled salbutamol only, to be taken as needed when symptoms occur.

Priority in this Guide is given to the patient with persistent asthma, as this is the patient most at risk of severe disability or death. The appropriate doses of corticosteroids are crucial in achieving treatment success. The following recommended starting doses are for adults:

For severe persistent asthma:

- Prednisone 0.5 mg/kg/day and
- Inhaled HFA-Beclomethasone 100 µg: 800 µg/day (8 puffs: 4 puffs twice daily)

The patient must return for assessment at least once per week to determine more precisely the need for oral corticosteroids. When the patient remains stable for at least one week, with PEF at its highest possible level, the dose of prednisone can be progressively reduced. For many patients, prednisone can be discontinued and asthma controlled with the inhaled beclomethasone alone.

For moderate persistent asthma:

• Inhaled HFA-Beclomethasone 100 µg: 400 µg/day (4 puffs: 2 puffs twice daily)

For mild persistent asthma:

• Inhaled HFA-Beclomethasone 100 µg: 200 µg/day (2 puffs daily)

Whatever the severity of the asthma, patients should be advised to take salbutamol as needed for relief of symptoms (such as chest tightness, wheeze and/or shortness of breath).

Since some countries currently use inhaled corticosteroids for the long-term management of asthma other than those proposed in this Guide (e.g. CFC- or HFA-Beclomethasone 250 μ g, CFC- or HFA-Budesonide 200 μ g, CFC- or HFA-Fluticasone 125 μ g), the Table below includes the equivalence in number of puffs for each of these other drugs.

Recommended prescription of inhaled corticosteroids for adults and children in daily number of puffs*

	HFA-Beclomethasone 100 μg (extra-fine droplets)		CFC-Beclomethasone 250 µg HFA-Beclomethasone 250 µg (non extra-fine droplets) CFC- or HFA-Budesonide 200 µg CFC- or HFA-Fluticasone 125 µg	
Asthma severity	Adults	Children	Adults	Children
Severe	8 puffs	4 puffs	8 puffs	3 puffs
Moderate	4 puffs	2 puffs	4 puffs	2 puffs
Mild	2 puff	1 puff	2 puffs	1 puff

* The prescription should be adapted according to the patient's response.

How is treatment continued?

> Organise follow-up

When the patient's long-term treatment has been determined, the follow-up is organised. The doses of medicines are maintained until the next scheduled visit to the health facility. In most cases, follow-up visits can be arranged for every three months, if the patient clearly understands the long-term treatment plan, is able to use inhaled medicine properly, has a sufficient supply of the medicines and is stable. At each visit, adherence to long-term treatment and the symptom severity should be assessed. Moreover, this provides an occasion to consider what progress has been made toward the objectives of treatment:

- How frequent are daytime symptoms (times per week)?
- Is there any limitation of activities?
- Are there any night-time symptoms or awakenings due to asthma?
- How frequently is there a need for bronchodilators (times per week)?
- Has there been an exacerbation (attack) or an unplanned visit to a health facility because of asthma?
- What is the lung function? Compare the current PEF after bronchodilator with the patient's best PEF at initial evaluation and/or with the predicted PEF.

Whatever the degree of asthma control, the patient must be instructed that, should the condition become worse and not respond to agreed alterations in treatment, an earlier consultation than the one routinely planned should be arranged.

> Adapt treatment

In the majority of cases, the patient's asthma will have improved and treatment will be able to be reduced (step down). In a few cases, the asthma will be poorly controlled and treatment will have to be increased (step up).

When to step down treatment

If the patient's condition has improved and their asthma is now well controlled (infrequent daytime symptoms and need for bronchodilators, no night-time symptoms, no unplanned visits, no limitation of activities and PEF \geq 80% of patient's best PEF or predicted PEF value), the dosages are reduced to the next level down (step-down). Each change in step is considered after a minimum of three months of treatment, until the lowest dose of medication necessary to control the asthma can be determined.

The minimum dose of inhaled corticosteroids required to control the patient's asthma is generally maintained for several years. The treatment should be adapted during each three-month follow-up visit, based on symptom severity and PEF measurement.

The health care provider can stop inhaled corticosteroids if the patient's asthma remains controlled on the lowest dose with no recurrence of symptoms over a

period of one year. If the patient remains asymptomatic throughout one year following discontinuation of inhaled corticosteroids and the PEF after bronchodilator is normal (\geq 80% of predicted PEF), the patient will be considered to be in "remission".

When to step up treatment

If the patient's condition has not improved or if deterioration occurs on the treatment prescribed, even though it has been taken correctly, treatment should be intensified to the next step up. Before doing this, however, it is imperative to look for possible reasons for the poor response. It is possible that the initial treatment was inappropriate for the severity of the asthma. It is also possible that the poor response is because the symptoms are due to another condition. Other possible explanations might be that the patient:

- has not actually been taking the prescribed treatment;
- uses poor inhaler technique;
- has continued exposure to environmental trigger factors;
- develops temporary deterioration due to:
 - o acute respiratory infection,
 - exposure to an allergen.

Prior to changing the long-term treatment, it is important to rule out these factors.

6. When is a short course of oral corticosteroids prescribed?

Whatever treatment is used to control asthma, the addition of a short course of oral corticosteroids is sometimes necessary when a patient's condition deteriorates temporarily. Short courses of prednisone are prescribed at 0.5 mg/kg/day for one week. The most common indications are:

- recurrence of symptoms in an individual whose asthma was under control;
- recurrence of nocturnal attacks;
- drop in PEF to less than 80% of the patient's best PEF;
- reduced response to salbutamol, with an increase in dosage to control symptoms.

It is important to look for, and correct, the causes of this deterioration, such as:

- poor adherence to treatment;
- incidental exposure to an irritant or allergen such as:
 - o **paint**
 - o animals
 - o dust or smoke
- temporary change of residence (e.g. staying with relatives)

For some patients, identifying the cause of the deterioration can pinpoint preventive measures to be taken to limit or prevent recurrence.

7. What preventive measures can be taken?

Preventive measures consist of avoiding or controlling both the causal and trigger factors:

- Patients should be advised to avoid exposure to tobacco smoke either from their own or other people's smoking; and parents should be informed that it is harmful to expose their child to tobacco smoke;
- Patients who smoke tobacco (and members of their family who smoke) should be advised to stop smoking and be encouraged to enter a smoking cessation programme (see 'Tobacco Cessation Interventions for Tuberculosis Patients', available on www.iuatld.org);
- Patients should avoid or minimise exposure to smoke from cooking or heating fires in the home;
- Patients should be instructed how to assess their homes for damp or mould and, if present, how to control it;
- Patients sensitive to animals should not keep pets in their homes.

Specific desensitisation, which is costly and of limited effectiveness, has little place in routine practice of the management of asthma in low- or middle-income countries.

8. How is the best asthma treatment assured?

Health education is the cornerstone of asthma management and a solid partnership between health care providers and the patient should assure the quality of care with the following objectives:

- encourage patient adherence to long-term treatment;
- help the patient to recognise exacerbations;
- encourage the patient to self-manage their asthma according to a treatment plan.

The characteristic of asthma is its variability. The patient should be trained to selfmanage their asthma according to a treatment plan with 3 zones provided by the health care provider. The patient should learn how to recognise: when the asthma is stable and controlled by the usual treatment (green zone); when a deterioration is occurring and what treatment the patient needs to take (yellow zone); and when a severe deterioration is occurring and what treatment and action the patient needs to take (red zone). Health education is crucial for the success of asthma treatment and is explained in more detail in Chapter VII.

9. What other issues are there for asthma management?

Things to encourage

Regular physical exercise is useful for most asthma patients, even if they suffer from exercise-induced asthma. Occasionally, exercise can provoke an asthma attack. When this occurs frequently, it is important to verify that the patient is taking daily treatment as prescribed; the dose of inhaled corticosteroids may need to be increased. If, in spite of the above, exercise still induces an asthma attack, it can be prevented by the inhalation of two puffs of inhaled salbutamol a few minutes before starting to exercise.

Things to avoid

The use of beta blockers should be avoided as these medicines can aggravate asthma.

Other issues

Asthma may be affected by pregnancy (improvement or deterioration). Asthma medicines are not dangerous for the unborn child. In contrast, poor control of asthma due to inadequate treatment is dangerous.

If an asthma patient requires surgery, it is important to ensure that the asthma is well controlled before the operation. Before major surgery, the dose of inhaled corticosteroids should be increased by one step. For patients receiving oral corticosteroids, an increased dosage should be considered before, during and for some time after the operation.

10. Which patients require specialised care?

The following are indications for referring asthma patients to a specialist:

- A patient whose asthma is not under control despite correct management. Before referring the patient, it is important to ensure that the treatment has been followed correctly and the patient's inhalation technique is correct.
- A patient suspected of having asthma due to intolerance to aspirin and/or non-steroid anti-inflammatory medicines. These medicines should be stopped immediately.
- A patient whose asthma appears to be caused by the workplace. The diagnosis of occupational asthma will need to be confirmed.

References

- 1. World Health Organization. Model List of Essential Medicines, 14th ed. Geneva, Switzerland: WHO. March 2005.
- 2. Global Initiative for Asthma. Pocket Guide for Asthma Management and Prevention. Based on the Global Strategy for Asthma Management and Prevention, Revised in 2006.
- 3. Ederle K. Multicentre Study Group. Improved control of asthma symptoms with a reduced dose of HFA-BDP extrafine aerosol: an open-label, randomised study. Eur Rev Med Pharmacol Sci. 2003;7:45-55.
- 4. Malone DC, Luskin AT. Hydrofluoroalkane-134a beclomethasone as a dominant economic asthma therapy. Respir Med. 2003;97:1269-76.
- 5. Price D, Haughney J, Duerden M, Nicholls C, Moseley C. The cost effectiveness of chlorofluorocarbon-free beclomethasone dipropionate in the treatment of chronic asthma: a cost model based on a 1-year pragmatic, randomised clinical study. Pharmacoeconomics. 2002;20:653-64. Erratum in: Pharmacoeconomics 2002;20:853.

VI. Managing attacks of asthma

Attacks of asthma are episodes that come on suddenly and may recur from time to time. They often come on at night. They can occur in a patient whose asthma is well controlled, but often indicate a failure in the long-term management of the patient.

1. What is the first thing to do when a patient presents to the emergency services?

Since patients presenting with an asthma attack may be at imminent risk of death, rapid and accurate assessment of each patient is vital.

Step 1: Assess for signs of imminent respiratory arrest. If present, start treatment immediately with oxygen, bronchodilator and systemic corticosteroids as for a severe attack and transfer patient to the intensive care.

Any of the following characteristics define a patient in imminent arrest:

- is unable to talk;
- is drowsy or confused;
- has paradoxical chest movements;
- has no wheezing;
- has bradycardia (a slower than normal pulse rate);
- is unable to perform PEF measurement.

This condition is more easily recognised in a patient who is previously known to have asthma.

Step 2: If there are no signs of imminent arrest, assess for signs of clinical distress. If present, give oxygen.

Step 3: If the patient is not in imminent arrest, proceed with assessment and treatment in the emergency room.

2. How do you assess the patient who is not in imminent arrest?

When it is determined that the patient is not in imminent arrest, the following process of assessment is recommended:

- Measure PEF.
- Administer inhaled salbutamol.
- Question the patient to obtain the clinical history.
- Measure PEF again 10-15 minutes after administration of inhaled salbutamol.
- Perform a physical examination and classify the severity of the attack.

Measuring PEF

Measurement of the PEF before and after inhalation of salbutamol is the most objective method for evaluating the severity of the airflow limitation and its
reversibility (see Chapter III). The PEF after salbutamol should be expressed as a percentage of the patient's best PEF (or the PEF predicted, if the best is unknown). The patient should be aware of his or her best PEF and it should be recorded on the patient card (the card the patient keeps).

Questioning and examining the patient

Questioning the patient to elicit the clinical history and performing a physical examination will allow the health care provider to determine the following:

- Does breathlessness occur while walking, talking or at rest?
- Does the patient talk in sentences, phrases, words, or is the patient unable to talk?
- What is the patient's state of alertness? Is the patient agitated, drowsy or confused?
- What is the respiratory rate?
- Are the respiratory muscles contracted; is there paradoxical movement of chest and abdomen?
- Is wheeze present, moderate, loud, or on the contrary has it disappeared?
- What is the pulse rate?
- What is the patient's PEF after inhalation of salbutamol?

3. How do you classify the severity of an attack?

The management of the patient is determined by the severity of the attack. The following approach for evaluating the severity of the attack is based on the GINA guidelines (1). It identifies four grades of severity of attacks: imminent respiratory arrest, severe, moderate and mild.

Imminent respiratory arrest

This is the most serious form of attack and requires immediate recognition and transfer for care by a knowledgeable specialist in an intensive care setting.

Severe asthma attack

Such a patient will have none of the characteristics of imminent respiratory arrest but will have several, but not necessarily all, of the following characteristics:

- is breathless at rest;
- is only able to talk in individual words because of breathlessness;
- is agitated;
- has a respiratory rate greater than 30 breaths a minute;
- uses accessory muscles and has suprasternal retractions on breathing;
- has loud wheezing;
- has a pulse rate greater than 120 per minute (more than 130 per minute for children);
- has a PEF of less than 60% (< 60%) of the patient's best PEF or less than 100 litres per minute, 10 minutes after the first inhalation of salbutamol.

Moderate asthma attack

Such a patient will, in the absence of signs of imminent respiratory arrest or a severe attack, have several, but not necessarily all, of the following:

- is breathless when talking and prefers to sit up;
- is able to talk in phrases;
- is agitated;
- has an increased respiratory rate;
- uses accessory muscles and has suprasternal retractions on breathing;
- has loud wheezing;
- has a pulse rate from 100 to 120 per minute (120 to 130 per minute for children);
- has a PEF of 60 to 79% (60-79%) of the patient's best PEF, 10 minutes after the first inhalation of salbutamol.

Mild asthma attack

Such a patient has none of the characteristics of the previous grades of severity and will have several, but not necessarily all, of the following:

- is breathless when walking and can lie down;
- is able to talk in sentences;
- is agitated;
- has an increased respiratory rate;
- has no or mild suprasternal retraction on breathing;
- has moderate or end-expiratory wheezing;
- has a pulse rate less than 100 per minute (less than 120 per minute for children);
- has a PEF greater than or equal to 80% (≥ 80%) of the patient's best PEF, 10 minutes after the first inhalation of salbutamol.

When characteristics of several levels of severity of attack are present, the highest grade of severity is assigned. In addition, a higher grade of severity is assigned if specific elements are found when taking the clinical history. These elements are:

- a high risk for fatal asthma:
 - o a history of near-fatal asthma requiring intubation;
 - o current or very recent treatment with prednisone;
 - o hospitalisation or emergency services visits in the previous year;
 - o a severe psychiatric disorder;
 - o use of more than one canister of salbutamol (or equivalent) monthly.
- the patient having already attempted unsuccessfully to initiate treatment before presenting to the emergency services.

Although the clinical signs of an asthma attack are quite typical, it is important to consider other causes of acute breathlessness, in particular pneumothorax.

Parameter	Mild	Moderate	Severe	Imminent respiratory arrest	
Breathless	Walking	Talking	At rest		
	Can lie down	Prefers to sit up	Hunched forward		
Talks in	Sentences	Phrases	Words	Unable to speak	
Alertness	May be agitated	Usually agitated	Always agitated	Drowsy or confused	
Respiratory rate	Increased	Increased	Often > 30/min	Deve de l'est	
Accessory muscles and suprasternal retractions	Usually not	Usually	Usually	thoracic- abdominal movements	
Wheeze	Moderate, often only end-expiratory	Loud	Usually loud	Absence of wheeze	
Pulse/minute Adults	< 100	100-120	> 120	Bradycardia	
Child aged 5 years and over	< 120	120-130	> 130	Bradycardia	
PEF after inhalation of salbutamol (% of best PEF or % of predicted PEF)	≥ 80%	60-79 %	< 60% or (< 100 l/min adults)	Impossible to measure	

Severity of asthma attacks* (Based on the GINA Guidelines)

* Where signs from several grades of severity are present, the highest grade of severity is used to classify the attack, even if not all of the signs for that grade are present. If the clinical history indicates a factor of high risk of fatal asthma and/or an ineffective attempt to treat the attack at home, the next grade up is used to classify the attack.

4. How do you treat and manage the patient in the emergency room?

4.1 Objectives of treatment

The objectives of treatment are to:

• prevent death;

- rapidly restore functional status to its best level;
- maintain optimal function;
- prevent early relapse.

4.2 Steps in the management of patients

The following describes the steps in the management of patients in the emergency room.

Initial treatment

<u>Oxygen</u>: Since patients with attacks of asthma may be markedly hypoxic, all those that are clinically distressed should be given oxygen prior to proceeding further. The oxygen should be humidified and administered by nasal cannulae or by mask.

<u>Bronchodilator</u>: Death is a serious and real prospect for a patient with an asthma attack. It is caused by acute respiratory failure due to airflow limitation. For this reason, a bronchodilator is given immediately. Salbutamol is recommended. It promptly relieves the airflow limitation. It can be used in several forms:

- Inhalation if the patient is capable of correct inhalation technique. Inhaler used with a spacer, 2 to 4 puffs at a time.
- Nebulisation if the patient is incapable of correct inhalation technique. For each nebulisation, 1 ml of solution is used in 3-4 ml of isotonic saline solution. Nebulisation is performed either by using a nebuliser (electric or by foot-action pump) or by connecting the apparatus directly to an oxygen source.

<u>Systemic corticosteroids</u>: The underlying cause of the attack usually starts to trigger airflow limitation again, once the effect of the bronchodilator has worn off. Systemic corticosteroids are given promptly (for all except mild attacks), once salbutamol has been administered. Due to their anti-inflammatory action, they rapidly control attacks that do not respond to bronchodilators alone, and above all they prevent relapse. The clinical improvement achieved with corticosteroids takes at least 4 hours; there is therefore no obvious benefit in giving them intravenously. A dose of 0.5-1 mg/kg/day of oral prednisone (on average 30-60 mg/day in adults) is given. If the patient cannot take the oral medicines, 100 mg of hydrocortisone is administered intravenously every 8 hours.

See Table 6.1 for the essential medicines used in the treatment of an asthma attack.

Continuation of treatment and Monitoring

Depending on the severity of the attack, the patient will stay for a period of treatment and monitoring in the emergency room with reassessment at regular intervals.

Discharge or hospitalisation

Depending on the response to treatment during or at the end of the monitoring period, the patient will be discharged to their home or hospitalised.

4.3 Management of the attack according to severity

The following describes the management of the individual case according to severity.

Severe attack

Initial treatment

<u>Oxygen</u>: Oxygen therapy must be given. The oxygen should be humidified. Where emergency services do not have piped oxygen or oxygen cylinders, if electricity is available oxygen concentrators can be used: two concentrators in parallel are necessary to obtain a higher concentration of oxygen.

Bronchodilators:

Inhaled salbutamol: 4 to 8 puffs every 20 minutes during the first hour via a spacer. Nebulised salbutamol: if the patient is unable to inhale correctly (e.g. the patient is exhausted, particularly if the patient is a child), a solution of salbutamol 5 mg/ml is used, given either every 20 minutes for the first hour (using 20-25% of the vial, i.e. 1000-1250 μ g of salbutamol, at each administration) or continuously (using a vial that will be nebulised during the first hour). Nebulisation is not more effective than inhalation via a spacer and is only used when inhalation technique cannot be followed.

<u>Systemic corticosteroids</u>: Oral prednisone at a dose of 0.5-1 mg/kg/day. Intravenous hydrocortisone at a dose of 100 mg every 8 hours is given only if the patient is unable to swallow. Intravenous corticosteroid treatment is not more effective than oral treatment.

Continuation of treatment

The patient should be kept in the emergency room for at least 6 hours to continue treatment as follows:

- continuous oxygen therapy at a regular flow rate;
- inhaled salbutamol at 4-8 puffs every 2 hours;
- (intravenous hydrocortisone, if this method of administration has been selected, at the same dose, every 8 hours).

Monitoring

The objective of monitoring is to identify any evidence of immediate relapse which, although rare, is usually severe. The clinician must not leave the patient alone

during the first 15 minutes, as the state of the patient can worsen suddenly. The clinician should verify the patient's state every 20 minutes during the first hour. At one hour, and then every two hours, the patient should be reassessed to evaluate the response to treatment. The PEF should be evaluated in relation to the best PEF, or if not known, in relation to the predicted PEF.

The patient's response to treatment is assessed according to the following criteria:

Deterioration	Clinical signs of imminent arrest have appeared <u>or</u> PEF < 30%
	the patient is transferred to the intensive care ward.
No deterioration	No clinical signs of imminent arrest have appeared <u>and</u> PEF > 30%
	treatment is continued in the emergency room.

Discharge or hospitalisation

Patients with *deterioration* at any point during the monitoring period should be transferred as soon as possible to intensive care. For all other patients, a final assessment and decision is made at the end of the monitoring period according to the following criteria:

No response or Deterioration	No improvement or Deterioration of clinical signs <u>or</u> PEF < 30%.
	the patient is transferred to the intensive care ward.
Incomplete response	Improvement without disappearance of clinical signs <u>or</u> PEF 30-60 %
	the patient is hospitalised in a general medical ward.
Complete response	Total disappearance of clinical signs <u>and</u> PEF > 60%
	the patient is discharged.

Moderate attack

Initial treatment is inhaled salbutamol, using a spacer, 2-4 puffs every 20 minutes for the first hour and oral prednisone at a single dose of 0.5-1 mg/kg/day. The

patient is then reassessed. If there is a *complete response* (disappearance of clinical signs and $PEF \ge 80\%$), the patient is kept for one more hour. If stable at one hour after the last dose of salbutamol, the patient can be discharged to continue treatment at home.

In case of *no response* or *incomplete response* (no or incomplete disappearance of clinical signs or PEF < 80%), after the first or second hour, the patient should be treated as for a severe attack and be kept in the emergency room for at least 6 hours to continue treatment.

Mild attack

Initial treatment is inhaled salbutamol, using a spacer, 2-4 puffs every 20 minutes for the first hour. The patient is then reassessed. If there is a *complete response* (Disappearance of clinical signs and PEF \geq 80%), the patient is kept for one more hour. If stable at one hour after the last dose of salbutamol, the patient is discharged to continue treatment at home.

In case of *no response* or *incomplete response* (no or incomplete disappearance of clinical signs or PEF < 80%), after the first or second hour, the patient should be treated as for a moderate attack.

5. What is the duration of admission in the emergency room?

The attack should be managed in the emergency room and regular monitoring should be performed. The duration of the patient's stay will depend on the severity of the attack and the response to treatment.

Two hours

Patients with a mild or moderate asthma attack will stay for two hours if the patient has a *complete response* to initial treatment when assessed at one hour and is stable after the second hour.

At least six hours (6-12 hours)

The average duration of treatment and monitoring is 6 to 12 hours for patients with:

- a severe attack;
- a moderate attack occurring in a patient who presents one or more risk factors for fatal asthma;
- a moderate attack with *no response* or *incomplete response* to initial treatment.

These patients should be reassessed at one hour and then every 2 hours during the monitoring period. At the end of the monitoring period, the clinician will

consider discharge or hospitalisation according to the response to treatment.

6. What are the main indications for hospitalisation?

The continuity of treatment must be guaranteed before the patient is transferred out of the emergency room to another ward. The indications for hospitalisation are the following:

Intensive care ward

Immediate transfer to an intensive care ward after initiation of treatment is indicated for:

- imminent respiratory arrest;
- severe attack with one or more risk factors for fatal asthma.

During the monitoring period a severe attack with *deterioration* must be transferred to an intensive care ward.

At the end of the monitoring period a severe attack with *deterioration or no response* must be transferred to an intensive care ward.

General medical ward

At the end of the monitoring period of 6-12 hours, patients with a severe attack who have an *incomplete response* should be hospitalised in a general medical ward.

7. What are the conditions for discharge?

Patients at greatest risk of dying from asthma are those who present repeatedly to the emergency services with asthma attacks. This is why patients being sent home from the emergency services need to be carefully assessed and advised to prevent relapse and improve long-term management by:

- identifying and avoiding the cause of the attack (e.g. non-adherence to treatment, absence of long-term management, bronchial infection);
- verifying that inhalation technique is correct;
- providing a prescription that includes inhaled beta2-agonists and a short course of oral corticosteroids to prevent relapse;
- arranging follow-up at the health centre where the patient is registered, indicating the care given to the patient in hospital, the type and severity of the attack, and the medicines used to treat it.





* And moderate attacks with risk factor for fatal asthma; moderate attack with no response or incomplete response to initial treatment.

8. How can a patient avoid future attacks?

Long-term follow-up is essential for all patients, as asthma is often a life-long condition. An acute attack of asthma may cause an unidentified asthmatic to contact the health services for the first time. An acute attack may also occur during the course of the disease in an identified asthmatic that is already being treated by the health services. In either event, it should be the trigger for initiating a plan for good quality long-term care for the patient. Prior to leaving the emergency service, health care providers must outline with the patient a clear plan of follow-up.

If the patients and/or parents have received suitable health education, they should be able to recognise the signs of deterioration and to treat the episodes themselves as soon as the first clinical signs of an attack appear. For such patients, a visit to the emergency services only becomes necessary when they suffer from an attack that seems unusually severe or when it does not respond to the emergency treatment that has been recommended in their treatment plan and carefully explained by their health care provider.

References

 Global Initiative for Asthma. Global strategy for asthma management and prevention. NHLBI/WHO workshop report. Bethesda, MD: National Institutes of Health. National Heart, Lung, and Blood Institute Publication 95-3659. January 1995. Revised in 2006.

Type of medicine	Generic name	Mode of administration and dosage
Bronchodilator		
Short-acting beta2-agonist	Salbutamol	Metered-dose inhaler: 100 µg per puff Nebulising solution: 5 mg/ml
Anti-inflammatory		
Corticosteroid	Hydrocortisone Prednisone	Vial: 100 mg (IV) Tablets: 5 mg

Table 6.1 Essential medicines for treatment of asthma attacks

VII. Organising the care of asthma patients

The quality of care for patients with asthma is linked to the quality of health education and partnership built between the patient, the patient's family and the health team, and to the organisation of health services for the long-term management of patients.

1. How is health education and patient self-management organised?

The goals of health education are treatment adherence and self-management. These goals can only be accomplished if there is good communication between patient and health care provider. Health education should be ongoing, evaluated regularly, repeated and adapted to the patient's level.

Individual education must be provided by the health care provider. The messages should be simple and adapted to the level of each patient. The health care provider must assess if and when each patient is ready to receive a treatment plan. The group method can be used to reinforce individual health education, but it cannot replace it.

1.1. Establishing partnership – listen, inform, teach

Listen to the patient

The prerequisite to any health education is to listen attentively to the patient and establish good rapport. The health care provider must know:

- the patient's understanding of the disease and its treatment;
- the patient's attitude toward the disease;
- the effects of the condition on the patient's quality of life;
- the patient's social and cultural situation;
- what the patient hopes to gain from treatment.

> Inform the patient

About the disease

The patient should be clearly told that the symptoms are due to asthma. The condition should be explained using simple, non-technical words, so as to convince the patient of the need for long-term treatment and to help the patient understand what can be expected from the treatment.

About their treatment

The patient must understand the following:

- the objectives of long-term treatment;
- the types of medicines used and their action;
- the need for uninterrupted treatment;
- the inhalation route of administration.

The patient must know:

- how to recognise signs of deterioration and how to increase treatment;
- how to recognise attacks that require an immediate visit to the emergency services;
- when and where to go if symptoms worsen.

About healthy living

The patient should be advised to avoid exposure to all tobacco smoke, to known trigger factors, and to lead an active life. Even in severe cases, regular exercise is always helpful.

> Teach the techniques

The patient should be taught how to use a metered-dose inhaler. A single training session is not sufficient; the patient's technique should be verified at every consultation. Treatment failures are often linked to poor use of inhaled medicines. To enhance the efficiency of treatment, a spacer should be used. This can easily be made from a plastic bottle (see below). The patient should also be taught how to perform a PEF test if the measurement is to be reliable.

How to make and use a spacer



Making a spacer from a plastic bottle

- 1. Remove the cap of the inhaler and fit the mouthpiece of the inhaler at the bottom of a clean, empty plastic bottle at least 1 litre in size (the mouthpiece of the inhaler should be directly opposite the mouth of the bottle).
- 2. Trace the shape of the mouthpiece of the inhaler on the base of the bottle.
- 3. Cut an opening in the base of the bottle exactly the size of the line traced (the opening should be just big enough to insert the mouthpiece of the inhaler without allowing any leaks when using it).

If the bottom of the bottle is too hard, it can be pierced using a utensil that has been heated red hot; the mouthpiece can then be inserted into the softened plastic.

Using the bottle spacer

- 1. Shake the inhaler and insert the mouthpiece into the opening made in the base of the bottle.
- 2. Breathe out deeply to empty the lungs.
- 3. Hold the opening of the bottle in the mouth.
- 4. Press the base of the inhaler to release a dose of the product into the bottle.
- 5. Inhale the air and the product in the bottle: breathe through the mouth normally but as deeply as possible for around 10 seconds.
- 6. Remove the bottle from the mouth, breathe out deeply, then breathe normally.

This spacer should be made by the patient (or a family member) with the help of the health care provider.

1.2. Developing partnership and organising long-term follow-up

Choose the best treatment

Effective treatment is the most important step towards treatment adherence. Choose the treatment together with the patient by asking:

- Can the patient afford the medicines?
- Is the patient able to inhale the medicines?
- Has the patient understood the function of each medicine?
- Does the patient understand how to use short-course oral corticosteroids?

> Make it simple

Long-term treatment usually requires two medicines: inhaled beclomethasone and inhaled salbutamol. The number of times the medicines are taken should be reduced to a minimum; in most cases 1 or 2 times per day.

> Explain it clearly

The prescription must be written and explained clearly. The medicines should always be available at the clinic to show to the patients. Sufficient medicines should be provided to last until the next visit, with a little over to avoid treatment interruptions. The technique of taking the medicines must be demonstrated. The patient should be able to explain all the treatment details back to the health care provider.

> Schedule regular visits

The health care provider prepares an individual patient card (Document 1). The card contains the patient's diagnosis and best PEF, a diagram showing the correct inhalation technique and instructions on how to access emergency services. The health care provider gives the card to the patient at the first consultation.

The first follow-up visits are closely spaced (every week). The goal is to identify the best long-term treatment, to check whether the treatment is accepted by the patient and to begin the patient's health education. The subsequent appointments will be more spread out (every 3 months). During these visits, the health personnel should check:

- the number and severity of episodes since the last visit;
- number of times the patient has visited emergency services;
- PEF before and after bronchodilator;
- that treatment is actually being taken by the patient. If non-adherence to treatment is discovered, it is important to identify the cause and find a solution.

Evaluation is based on the treatment objectives. Then long-term treatment is adapted according to the patient's situation: continue the same treatment, step up or step down. If a transitory deterioration is suspected (or non-adherence identified), a short course of oral corticosteroids may be prescribed and the decision on treatment change postponed.

> Give instructions about emergency visits

During scheduled visits, the patient is instructed where to go in case of an emergency.

Only the regular health care provider should determine changes in long-term treatment. The personnel in the ambulatory clinics and those in the emergency services must work together to avoid the use of emergency services and decrease the risk of death.

1.3. Encouraging self-management and defining the treatment plan

The main goal of health education is to encourage self-management – patients manage their own asthma by following a treatment plan. Patients with moderate or

severe persistent asthma and who suffer from frequent and severe attacks are those who will benefit the most from a treatment plan.

How do you construct a treatment plan?

A treatment plan defines three 'zones' of treatment, based on the state of the patient's asthma. Such plans yield results that are equivalent to those based on PEF measurements. The plan should be recorded on a patient card that is given to the patient by the health care provider:

Red zone (attack):

- severe attack with acute breathlessness and difficulty in speaking or walking;
- treatment has been given for deteriorating symptoms, but without effect.

The patient should go to the emergency services immediately after taking treatment, which consists of several puffs of salbutamol using a spacer and oral corticosteroid treatment (1 mg/kg) in a single dose.

Yellow zone (deterioration):

- increased frequency of daytime symptoms (wheeze, chest tightness and/or shortness of breath);
- interference with usual activities;
- symptoms at night-time and/or awakening due to asthma;
- need to use salbutamol more frequently;
- symptoms worse than the previous day.

The additional treatment that the patient needs is written on the card and consists of a short course of oral corticosteroid treatment. The patient must report to the health care provider if there is no improvement. If the asthma improves, the patient can resume usual treatment after 1 week.

Green zone (stable state):

- no daytime symptoms (less than two times per week);
- no limitation of activities;
- no night-time symptoms or awakenings due to asthma;
- no need for salbutamol (less than two times per week).

In this zone, asthma is under control. The patient continues usual treatment.

When do you give a patient a treatment plan?

The health care provider should give the treatment plan to a patient only when the patient has demonstrated good adherence to the treatment and when it is clear that the patient can carry out the plan. The health care provider should verify that the patient (or parents) has perfectly understood:

- the importance of long-term treatment;
- the role of each medicine used;
- the technique of taking the medicines;
- signs of deterioration;

• how to adapt treatment.

The health care provider records the treatment plan on the patient's card (kept by the patient) and provides the patient with a supply of prednisone tablets.

2. How are services organised in the health system?

In many countries, public health services are organised in several levels of care: basic level (primary health services and first referral level health services); intermediate level (secondary referral level health services) and central level (tertiary referral level).

The Union recommends delivering services for the management of asthma patients at all the various levels of the general health services.

Level	Structure	Personnel	Equipment
Primary care Peripheral	Health centre	Health care provider	Peak flow meter
First referral level	Hospital or specialised health centre	Specialists or health care provider trained in asthma	Peak flow meter Spirometer (if possible) Oxygen Spacer Nebuliser
Secondary referral level	Hospital	Specialists	Spirometer Arterial blood gas analysis X-ray

Personnel and equipment at different levels of the health services

Good communication from one level to the other is essential. Patients should be referred to the next level if the management of the asthma is beyond the capacity of the current level. The patient should be sent back to the previous level once the problem has been resolved. A letter must always accompany the patient, explaining the reason for the referral, the patient's current state and any treatment the patient has received.

Primary care level

The tasks of this level are to:

- identify patients presenting with symptoms that suggest asthma;
- investigate these patients to determine if they have asthma;
- establish the diagnosis and determine the degree of severity;
- manage all cases of intermittent asthma;
- refer cases of persistent asthma to the first level of referral;
- refer patients who pose problems of diagnosis or treatment to the first level of referral.

First referral level

The first level of referral is often associated with a hospital and has a specialist in chest diseases or a health care provider trained in asthma. This is the level of initial assessment for asthma patients with persistent disease. Long-term follow-up is monitored at this level, even if routine care is given at primary care level. The tasks of the health care provider are to:

- determine case management for patients with persistent asthma;
- manage referred cases;
- refer patients to more specialised care if necessary;
- provide ongoing training for health personnel in the area;
- undertake, or participate in, operational research;
- record and monitor all new cases of persistent asthma in the area;
- record and monitor treatment results for all recorded cases of persistent asthma.

Key functions include recording and reporting and maintenance of supplies of medicines and equipment. Essential equipment includes peak flow meters, an X-ray machine and an emergency service capable of managing severe attacks of asthma. All emergency services should have at least a peak flow meter, a spacer and oxygen supplies.

Secondary referral level

This level is usually located in the tertiary hospitals or large, well-equipped hospitals with qualified chest specialists. Essential equipment includes:

- a spirometer and arterial blood gas analysis;
- an X-ray unit;
- an emergency services unit or intensive care service capable of mechanical ventilation.

Central level

A designated National Coordinator should be identified who is responsible for the surveillance of the number of cases, the quality of management provided to all the patients in the country, and the quality and supply of medicines. The coordinator should be supported by a larger committee of experts to carry out the following tasks:

- developing a national plan for standard case management;
- training health personnel involved in the management of asthma patients;
- evaluating the quality of care of patients with persistent asthma in the country;
- promoting and participating in research to improve the management of asthma.

Health care providers at all levels, in both private and public sectors, who are involved in the management of asthma patients should be able to participate in training sessions and should adhere to the asthma management plan adopted at the national level.

VIII. Ensuring the quality of asthma case management

Standard case management is the foundation for ensuring quality of care for services provided for asthma patients. Without it, many patients do not return to their best possible state of health and they consume an inordinate and inappropriate amount of health services. To measure the results of the implementation of this standard management, the routine collection of accurate data at initial evaluation and during follow-up of treatment is fundamental. This task is usually only accepted reluctantly by health care providers, as it is viewed as an "administrative" issue that demands additional work with no real benefit either for the patient or health care provider. It is particularly difficult to obtain reliable essential information if health care providers do not understand the importance of the information gathered. Thus it is important not only to train those who must use the system but to ensure that they understand its utility for their own work.

1. How is transparency in provision of services maintained?

Routine collection and evaluation of information about the care of each patient is essential to provide transparency in provision of services. Recording the information concerning the patient is vital for the care of the patient, for monitoring the number of patients and for evaluating their treatment outcome. This provides the information necessary to plan the provision of care, to analyse the situation, and to revise practice if the results are not satisfactory.

Patients with persistent asthma are the priority for routine surveillance because they are the sickest, they use the most resources and they are at greatest risk of dying. All patients with persistent asthma (confirmed or probable) for whom longterm treatment has been prescribed should be registered. Only when this is functioning well should the surveillance be extended to intermittent cases.

The information should be recorded on the asthma treatment card and registered in the district asthma register. The recording process should be systematic and complete, using the cohort approach. This means that all patients targeted by the health intervention (prescribed treatment of inhaled corticosteroids) are registered and evaluated; none are omitted or excluded from the evaluation. This is why it is recommended that all patients with persistent asthma (confirmed or probable) for whom long-term treatment has been prescribed should be entered in the register.

2. What should be monitored?

Indicators of quality of care include:

- the proportion of all cases whose diagnosis of asthma is confirmed;
- concordance between the assigned severity of asthma and the severity determined from clinical evaluation and best PEF level;
- concordance between the assigned severity of asthma and the treatment prescribed.

Indicators of efficiency of case management include:

• the proportion of patients who continue the treatment prescribed.

Indicators of impact of services include:

- the proportion of patients who died while on treatment;
- the frequency of emergency room visits and admissions to hospital;
- the trend in severity of disease over time.

3. What tools are needed for monitoring?

Health services in the public sector of many countries are routinely organised hierarchically, with peripheral health services provided by paramedical staff and a system of referral to higher, more specialised levels of care. At the first referral level of care (often termed 'the district hospital'), where persistent asthma is managed, the following documents are recommended:

- Patient card: kept by the patient (Document 1);
- Asthma treatment card: kept at first referral level, where the management of patients is organised (Document 2);
- Register of persistent asthma: kept at the first referral level (Document 3);
- *Quarterly report on new cases of persistent asthma*: completed by the coordinator, sent to the National Coordinator (Document 4);
- *Quarterly report on treatment outcome*: completed by the coordinator, sent to the National Coordinator (Document 5);
- *Quarterly order form for treatment supplies*: completed by the coordinator, sent to the medical store or pharmacy (Document 6).

The register of persistent asthma is the key tool for evaluating the quality of care: routine reports on new cases treated and on treatment outcome are based on the information recorded in this register. The information system proposed by The Union for asthma management is based on the successful experience of The Union for the evaluation of tuberculosis programmes implemented throughout developing countries (1).

Some countries with more advanced technological capabilities could use an electronic system for patient information. A monitoring programme for management of asthma has been developed by The Union. It uses the free software package called EpiData, which was developed with support from The Union. All the information on the asthma treatment card (except the information recorded in the section 'Follow-up at each visit') is entered directly into the database. Reports are then easy to generate using EpiData Analysis. The Union developed this programme to facilitate the monitoring of asthma management for clients of the Asthma Drug Facility. It is provided by The Union free of charge.

4. How is uninterrupted care maintained?

Successful care of a chronic disease requires regular supplies of medicines and diagnostic material. Ongoing needs and a reserve stock should be estimated from regular reports on patients managed in each area. To calculate the requirements, it has been necessary to make some assumptions. The following assumptions are based upon experience in the field:

- For each case of severe persistent asthma, there are 2 cases of moderate, 5 of mild persistent and 25 of intermittent asthma.
- A case of severe persistent asthma requires 5 mg of prednisone, 8 puffs of

inhaled HFA-Beclomethasone 100 µg and 4 puffs of HFA-Salbutamol per day.

- A case of moderate persistent asthma requires 4 puffs of inhaled HFA-Beclomethasone 100 µg and 4 puffs of HFA-Salbutamol per day.
- A case of mild persistent asthma requires 2 puffs of inhaled HFA-Beclomethasone 100 µg and 2 puffs of HFA-Salbutamol per day.
- An intermittent case requires (as an average, for purposes of maintaining supplies) 1 puff of HFA-Salbutamol per day.

As there are 200 doses of beclomethasone and salbutamol in each inhaler, requirements can be calculated, including the reserve stock.

Asthma attacks that require use of emergency services are estimated, on average, as follows:

- for severe cases, five times per year
- for moderate cases, twice
- for mild cases, once.

The Quarterly order form for treatment supplies is recommended for calculating medicine requirements. It is based on the number of cases of persistent asthma registered in an area. The order form is the tool recommended to avoid interruption to the supply of medicines for chronic diseases. Each order is based on the number of persistent cases identified each quarter and on medicines needed for each grade of severity. Medicines needed for the treatment of attacks are based on the average of attacks expected for each grade of severity. The rationale for the reserve stock is to ensure that medication supplies are never interrupted (based on the experience of treatment of millions of tuberculosis patients).

5. How is the work verified?

It is necessary to record each new patient in the health centre treated for persistent asthma. A patient should be recorded in the register once the severity of asthma has been established and long-term daily treatment prescribed. The information recorded in the register is derived from the treatment card. Information recorded in the register is crucial for the evaluation of asthma management and health care providers must be trained to carry out this task correctly. The feasibility of using this information system within routine health services has been well demonstrated in the care of tuberculosis and of childhood pneumonia.

The evaluation of asthma management will be based on two reports, which should be prepared at the end of each quarter and sent to the national coordinator:

• Quarterly report on new cases of persistent asthma

The cases of persistent asthma registered during the quarter represent a cohort. Record the distribution of the cohort by age, sex and severity, according to the instructions provided on the form.

• Quarterly report on treatment outcome

Record the outcomes for the cohort of persistent asthma cases registered in the same quarter of the previous year. The six categories of outcome are defined

below and on the form.

These reports use information from the register, which records patient information up to the first annual evaluation. Facilities that use the electronic EpiData system can record all the annual evaluations of each patient (i.e. patient's evaluation at one year and all subsequent annual evaluations). The quarterly reports are generated using EpiData Analysis.

The treatment outcome of each patient at each annual evaluation will be determined using the following definitions:

Patients not appearing for annual evaluation:

Died: whatever the cause of death.

Lost: has not appeared for follow-up appointment or within 2 months following the appointment.

Transferred: transferred to another health facility and outcome unknown.

Patients appearing for annual evaluation:

The outcome of patients appearing for annual evaluation is based on the evolution of asthma severity and of unplanned visits to emergency services or admissions to hospital since the start of long-term treatment.

- Improved: Decrease in asthma severity AND no or fewer unplanned visits as compared with initial evaluation OR patient in remission*
- Stable: Same asthma severity AND no or fewer unplanned visits as compared with initial evaluation.
- Worse: Increase in asthma severity OR more unplanned visits as compared with initial evaluation.

Table of outcomes						
Severity of asthma	Unplanned visits	Outcome				
remission*	no	improved				
decreased	no	improved				
same	no	stable				
increased	no	worse				
decreased	fewer	improved				
same	fewer	stable				
increased	fewer	worse				
decreased	more	worse				
same	more	worse				
increased	more	worse				

* The category of remission is only applicable from the second annual evaluation onwards, since the definition of remission is as follows: patient remains asymptomatic throughout one year following discontinuation of inhaled corticosteroids and patient's PEF after bronchodilator is normal (\geq 80% of predicted PEF). Patients who are asymptomatic at the first annual evaluation cannot be classified as in remission, since a patient in remission has to have discontinued inhaled corticosteroids and then remained asymptomatic for one whole year.

The evaluation of the quality of case management is based on the results after one year of follow-up of a cohort of patients (all patients registered in the calendar quarter being reported). This cohort analysis also gives an indication of the need to revise practice if the results are not satisfactory and could help determine what action to take to improve. For example, if a high rate of defaulters is observed, the cause must be investigated and, if possible, corrected. It may be due to a lack of organisation of the follow-up visits and of annual evaluation; a lack of, or insufficient, motivation and training of health care providers involved in patient management; inadequate patient education; or patients being unable to afford medicines or access health facilities.

6. How is competence developed and maintained?

All of the country's medical and nursing schools should include standard case management of asthma in their curricula.

Ongoing training of health personnel involved in the management of asthma patients is essential. When introducing standard case management, a training programme should be offered that includes:

- the scientific basis of standard case management;
- technical and organisational aspects of service provision;
- recording and reporting.

The most important element for ensuring competence consists of regular supervisory visits to health care providers. Regular (at least annual) meetings of health care providers involved in patient management should be organised at each level to discuss the notification of new cases, the results of management and to resolve any problems encountered.

7. How are appropriate services ensured?

The services should be adapted to the local situation in each country. In particular, the health service structure and national guidelines must be respected. Services should be implemented in stages:

- national adaptation of international recommendations;
- implementation in selected pilot sites;
- analysis of the results;
- possible modifications of the intervention based on the results;
- step-wise expansion of services to all other sites, with ongoing analysis of results.

8. How can services be improved?

Research is an important aspect of all health services. Research provides the new knowledge necessary for action for health. Routine information collected in practice is the starting point and allows questions to be asked for which research must find the answers.

The International Commission on the Health Research for Development recommends (2) that a fixed proportion (5%) of the budget of all public health programmes should be set aside for research. Operational research embedded within services is most appropriate. This type of research involves the personnel responsible for patient management, provides them with new knowledge and helps them resolve problems they are confronted with on a regular basis. It also inspires critical thinking, which is crucial to both research and practice.

Reference

- 1. Enarson DA, Rieder HL, Arnadottir T, Trébucq A. Management of Tuberculosis: a Guide for Low Income Countries. 5th ed. Paris: International Union Against Tuberculosis and Lung Disease, 2000.
- Evans JR, Castillo GT, Abed FH, et al. Health research: essential link to equity in development. New York: Oxford University Press, 1987; 1-136.

IX. Documents & Appendices

This part of the guide presents the tools required for monitoring and evaluation and how to fill them in.

Documents

- 1. Patient card
- 2. Asthma treatment card
- 3. Register of persistent asthma
- 4. Quarterly report of new cases of persistent asthma
- 5. Quarterly report on the treatment outcome of all cases of persistent asthma registered in the same quarter of the previous year
- 6. Quarterly order form for treatment supplies

Appendices

- 1. How to complete the treatment card
- 2. How to complete the register
- 3. How to complete the quarterly reports and order form
- 4. An example of Tables of predicted PEF values

Document 1: Patient card

	e ot issue:
Worse (needs more salbutamol) Prednisone tablets for days Double usual treatment until improvement	Patient Card
Attack (symptoms severe and/or not improved after salbutamol) Start emergency plan immediately Tree	atment centre:



Your asthma

Predicted PEF: I/min Patient's best PEF: I/min % predicted PEF Asthma severity: Usual treatment:

What to do in an emergency

1. Treatment to take:

2. If no immediate improvement, go to the emergency services

Next appointments

- 1. 2.
- 3.
- 4. 5.
- 5. 6.

Name of centre: []	
Name of patient: ^c [] Sex: ^e M [] F [] Age: ^f [] years Height: [] cm	ı
Address and telephone number: ^d [
Initial evaluation and prescription of long-term treatment within two weeks of initial visit	
[All items in bold must be entered in the register. Small italic letters indicate lo	ocation]
Clinical history	
Ever treated for asthma? Y[] N[] History of rhinitis or eczema? Y[] N[]	
Family history of asthma, rhinitis, eczema? Y [] N []	
Smoking: (check one): Non-smoker [] Ex-smoker [] Current smoker []	g
Exposures in the house: Other person(s) smoking Y [] N [] Solid fuel*: Y [] N [] Other trigger factors**: Y [] N []	
Unplanned visits in the previous year***: Emergency visits []	h
Hospital admissions []	i
Clinical evaluation: symptoms during the previous year	
Symptom severity (select number):	
1. < weekly=intermittent; 2. weekly=mild persistent; 3. daily=moderate persistent; 4. continuous=severe persistent	j
Initial evaluation of lung function	
Predicted PEF [] I/min	
PEF before bronchodilator [] I/min	
PEF after bronchodilator [] I/min	
PEF before bronchodilator, after initial treatment and/or after trial of corticosteroids [] I/min	
PEF after bronchodilator, after initial treatment and/or after trial of corticosteroids [] I/min	
Best PEF in % of predicted PEF = Dest PEF [] In I/min X 100 = [] %	
predicted PEF [] In I/min	
Enter number here Enter number $1 \ge 200/22$ 60 $700/24 \ge 600/200$	
Lung function based on best PEF in % of predicted PEF (select fullible). $1. \ge 80\%$, $3.80-79\%$, 4.80%	k
Confirmation of diagnosis of asthma	
Variability of the PEF = <u>best PEF - lowest PEF </u> in l/min x 100 = [] %	1
lowest PEF [] in I/min	
Initial evaluation of asthma severity: Enter the higher of 2 above numbers	
(definitions): 1. intermittent; 2. mild persistent; 3. moderate persistent; 4. severe persistent	m
Prescription of long-term treatment: Date of start ^a day [] month [] year [] Corticosteroids***** Inhaled: [] µg	n
Oral: [] mg	o
Patient registration number: ^b []	
* Solid fuel: If you use for heating or cooking any of the following: straw, dung, coal, peat, wood; ** Trigger factors; e.g. dust, fumes, animals, pollen;	

<u>Unplanned visits</u>: Number of visits and admissions. If none, write 0; * <u>Confirmed</u>: Y=variability ≥ 20%; N=symptoms of asthma but variability < 20% or no measurement;

***** Corticosteroids: daily dose of inhaled and oral. If none, write 0.

Asthma treatment card (back)

Follow-up at each visit

Date of follow-up	Symptom	PEF	PEF in % of	Cortico	osteroids	Unplar	ned visits	
(day, mo, yr)	severity	in l/min	predicted PEF	Inhaled	Oral	Emergency	Hospital	Comments

Annual evaluation

Date of evaluation	Symptom	Best PEF	Best PEF in % of	Asthma	Corticos	steroids	Unplann	ed visits	Outcome
(day, mo, yr)	severity	in l/min	predicted PEF	severity	Inhaled	Oral	Emergency	Hospital	
Start of treatment (date)									
1st year (date)									
2nd year (date)									
3rd year (date)									

Instructions for completion:

Symptom severity: 0=asymptomatic; 1=intermittent; 2=mild persistent; 3=moderate persistent; 4=severe persistent

PEF in % predicted PEF: Patient PEF after bronchodilator in % predicted PEF on the day of the visit.

Corticosteroids: daily dose of inhaled corticosteroids in micrograms and oral corticosteroids in milligrams. If none, write 0.

Unplanned visits: number of unplanned visits to emergency services or admissions to hospital since previous follow-up or previous evaluation.

Comments: e.g. death and cause; transfer; adherence; side effects; social problems; smoking habits.

Best PEF in I/min: Actual value of best PEF in litres per minute at initial or annual evaluation.

Best PEF in % of predicted PEF: Best PEF in % of predicted PEF at evaluation, 1. ≥ 80%; 3. 60-79%; 4. < 60%.

Asthma severity: 1=intermittent; 2=mild persistent; 3=moderate persistent; 4=severe persistent; R= remission

Outcome: Improved; Stable; Worse; Died; Lost; Transferred

Document 3: Asthma register (left-hand page)

Register of Name of centre: At the time of registration (Register all persistent asthma patients when a decision is made about long-term treatment) Unplanned visits Symptom Corticosteroids Asthma Sex ^e Age ^f Smoking ^g Emergency ^h Hospital ⁱ Best PEF ^k Confirmed ^I severity ^m Date ^a No.^b Address ^d Oral ° Name ^c severity ^j Inhaled ⁿ

Instructions

Sex: M or F; Age: in years; Smoking: N=non-smoker; E=ex-smoker; C=current smoker; Emergency: number of unplanned visits in previous year to emergency services; Hospital: number of unplanned admissions in previous year to hospital, whatever the type of service; Symptom severity: 1=intermittent; 2=mild persistent; 3=moderate persistent; 4=severe persistent; Best PEF: best PEF in % predicted PEF at initial evaluation: 1 ≥ 80%; 3=60-79%; 4 < 60% Confirmed: Y (yes): PEF variability ≥ 20% or N (no): symptoms of asthma but variability < 20% or no measurement; Asthma severity: 1=intermittent; 2=mild persistent; 3=moderate persistent; 4=severe persistent;

Corticosteroids: daily dose of inhaled (in µg) and oral (in mg). If none prescribed, write 0.

Persistent Asthma

At one year										
Patients app <u>Unplanne</u> Emergency	earing for fo <u>ed visits</u> Hospital	ollow-up evaluat Asthma severity	tion at one ye <u>Cortico</u> Inhaled	ear <u>steroids</u> Oral	<u>Outcome</u> Improved	Stable	Worse	Patients not a <u>Outcome</u> Died	ppearing at or Lost	ne year Transferred

for completion:

Outcome: Only one box should be ticked according to the outcome at one year of each patient registered:

Improved: decrease in asthma severity and no or fewer unplanned visits as compared with initial evaluation

 $\underline{Stable}: same as thm a severity and no or fewer unplanned visits as compared with initial evaluation$

Worse: increase in asthma severity or more unplanned visits as compared with initial evaluation

Died: whatever the cause of death

Lost: has not appeared for annual follow-up appointment or within 2 months following the appointment

Transferred: transferred to another health facility and outcome unknown

Document 4: Quarterly report on new cases of persistent asthma

Quarterly report on new cases of persistent asthma	Name of centre
	Cases registered inquarter of 200
Name of Centre Coordinator	

_ Date_____

New cases of persistent asthma registered in the quarter

		Age group (years)										TOTAL			
Severity at registration	5-14	1	15-2	24	25-3	34	35-4	14	45-{	54	55+				
	М	F	Μ	F	Μ	F	М	F	М	F	М	F	М	F	Total
Mild															а
Moderate															b
Severe															c
Total															d

Instructions

Quarters

1st quarter	1 January to 31 March
2nd quarter	1 April to 30 June
3rd quarter	1 July to 30 September
4th quarter	1 October to 31 December

Persistent asthma

Mild	Mild persistent (weekly) symptoms and absence of airflow limitation (Best PEF \ge 80% of predicted PEF)
Moderate	Moderate persistent (daily) symptoms and less than severe airflow limitation (Best PEF ≥ 60% of predicted PEF) or Moderate airflow limitation (Best PEF 60-79% of predicted PEF) and less than severe persistent symptoms (< continuous)
Severe	Severe persistent (continuous) symptoms whatever the level of airflow limitation (PEF) or Severe airflow limitation (Best PEF < 60% of predicted PEF) whatever the severity of symptoms

Totals

The data you enter in the total boxes (a, b, c, d) will be used when you fill out the Quarterly report on treatment outcome for this cohort in 12 months time.

Document 5: Quarterly report on treatment outcome

Quarterly report on treatment outcome	Name of centre
	Cases registered inquarter of 200
Name of Centre Coordinator	

Signature Date

Treatment outcome of all cases of persistent asthma registered in the same quarter of the previous year.

Severity at registration	Number registered	Improved ¹	Stable ²	Worse ³	Died ⁴	Lost⁵	Transferred ⁶
Mild	а						
Moderate	b						
Severe	C						
Total cases	d						

Instructions:

In the column 'Number registered', enter the total number of cases (a,b,c,d) from the 'Quarterly report on new cases of persistent asthma' from the same quarter of the previous year. For each grade of severity (i.e. mild; moderate, severe), give the number of cases for each outcome, according to the following definitions:

- ¹ Improved: decrease in asthma severity AND no or fewer unplanned visits as compared with initial evaluation.
- ² Stable: same asthma severity AND no or fewer unplanned visits as compared with initial evaluation.
- ³ Worse: increase in asthma severity OR more unplanned visits as compared with initial evaluation.
- ⁴ Died: whatever the cause of death.
- ⁵ Lost: has not appeared for annual follow-up appointment or within 2 months following the appointment.
- ⁶ Transferred: transferred to another health facility and outcome unknown.

Example: to complete the Quarterly report on treatment outcome for the first guarter 2009, give the outcomes of the cohort of new cases of persistent asthma registered during the first quarter of 2008.

Document 6: Quarter	ly order form for treatment supplies
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Medicines	Intermittent (A)	Mild persistent (B)	Moderate persistent (C)	Severe persistent (D)	Current requirements (E= A+B+C+D)	Reserve requirements (F=E/2)	Currently in stock (G)	Total Order (E + F - G)
HFA-Salbutamol inhaler, 100 μg	(B) x 5 =	x 1 =	x 2 =	x 2 =				
HFA-Beclomethasone inhaler, 100 µg	= 0	x 1 =	x 2 =	x 4 =				
Prednisone tablets, 5 mg	= 0	= 0	= 0	x 800 =				
Hydrocortisone, IV vial, 100 mg								
Salbutamol, IV vial, 0.5 mg/ml								
Salbutamol solution for nebulisation 5 mg/ml								

1) Number of inhalers needed each quarter for each grade of severity of persistent asthma: multiply the number of cases recorded for each grade of severity during the previous quarter by a factor, as follows (except for intermittent cases, see foot note 2):

Factors to use to calculate the number of HFA-Salbutamol inhalers:

- Mild persistent asthma: 2 puffs/day, i.e. on average 1 inhaler/quarter; the factor is 1
- Moderate or severe persistent asthma: 4 puffs/day x 90 days = 360 puffs/quarter, i.e. on average 2 inhalers of 200 puffs per quarter; the factor is 2, i.e. the average number of inhalers for each patient

Factors to use to calculate the number of HFA-Beclomethasone inhalers:

- Mild persistent asthma: 2 puffs/day, i.e. on average 1 inhaler/quarter; the factor is 1
- Moderate persistent asthma: 4 puffs/day, i.e. an average of 2 inhalers/quarter; the factor is 2
- Severe persistent asthma: 8 puffs/day x 90 days= 720 puffs, i.e. on average 4 inhalers/quarter; the factor is 4

2) Number of salbutamol inhalers needed for cases of intermittent asthma: 1 puff/day/patient, i.e. 1 inhaler/quarter. Given that in the community there are approximately 5 times more cases of intermittent asthma than of mild persistent asthma, the number of cases of mild persistent asthma is multiplied by a factor **5**

3) Prednisone tablets: the average number of tablets needed each quarter for each case of severe persistent asthma is 90, but as the medicine is also used for short-course oral corticosteroid and emergency treatment, a factor **800** is used, based on the expected number of emergencies discussed in the Guide.

4) For the other medicines, which are used much less often, orders will be based on consumption in the previous quarter.

Appendix 1: How to complete the treatment card

The front side of the treatment card is usually started at the first consultation and completed when the health care provider evaluates the patient after stabilisation and prescribes the long-term treatment. Each case of persistent asthma must be registered and have a treatment card completed. The treatment card can also be used for patients with intermittent asthma. However, intermittent asthma patients must not be assigned a registration number on their treatment card; their cards can instead be identified and classified by the name of the patient.

Key elements from the treatment card of a patient with persistent asthma will then be recorded on the left-hand page of the register. These key elements are indicated by a small italic letter located above the element or in the righthand margin of the treatment card. The letter corresponds to the location where this information should be entered in the register.

Front side of asthma treatment card

The following information corresponds to each step in the health care provider's evaluation of the patient and is entered on the front of the treatment card.

1. Identification

Name of centre: Health centre where patient is treated
Name of patient: Patient's first and last name
Address: Patient's full address, so patient can be traced
Telephone number: Where patient can be contacted
Sex: M for male or F for female
Age: Patient's age in years
Height: Patient's height in centimetres

2. Clinical history

For these items, please check Y for yes or N for no.

Notes:

Smoking: Check one of the 3 categories:

Non-smoker (those who have never in their lifetime smoked 20 packs of cigarettes or 12 ounces of tobacco or more, or one cigarette per day for one year)

Ex-smoker (patient who was a smoker in the past but stopped smoking at least one month before registration)

Current smoker (those who smoke currently).

Unplanned visits in the previous year:

Emergency visits: Record the number of visits patient made to emergency services during the previous year. If no visits, write 0. **Hospital admissions**: Record the number of times patient was

Hospital admissions: Record the number of times patient was admitted to hospital during the previous year, whatever the type of

service. If no admissions, write 0.

3. Clinical evaluation: symptoms during the previous year

Symptom severity

Evaluate the severity of symptoms, based on average frequency of symptoms during the year prior to patient's first visit: 1. symptoms are less than weekly = intermittent; 2. weekly symptoms = mild persistent; 3. daily symptoms = moderate persistent; 4. continuous symptoms = severe persistent. Select the number (i.e. 1, 2, 3 or 4) and enter it in the box on the right-hand side of the card.

4. Initial evaluation of lung function

In this part of the treatment card, record the **predicted PEF** and the various patient PEF measurements started at the first visit and continued until the decision is made about long-term treatment. Initial evaluation of lung function requires four measurements of PEF. Three attempts should be made for each measurement and the best result from the three attempts should be recorded as the PEF value for that measurement. The four measurements are:

PEF before bronchodilator

PEF after bronchodilator

PEF before bronchodilator, after initial treatment and/or after a trial of oral corticosteroids

PEF after bronchodilator, after initial treatment and/or after a trial of oral corticosteroids

The **Best PEF in % of predicted PEF** is calculated and used to select the **Lung function based on best PEF in % predicted PEF**. All measurements and calculations are explained in the table below

Predicted PEF	Patient's predicted PEF value in litres per minute, according to age, sex and height, as indicated in the table of norms. International norms should be used, unless country norms are available.
PEF before bronchodilator	Record patient's PEF before bronchodilator in litres per minute at the first visit.
PEF after bronchodilator	Record patient's PEF after bronchodilator in litres per minute 10 -15 minutes after inhalation of 2 puffs of salbutamol at the first visit. The salbutamol should be administered with a spacer.
PEF before bronchodilator, after initial treatment and/or trial of oral corticosteroids	Record the PEF before bronchodilator in litres per minute at the visit after the short initial treatment (if such treatment was prescribed by the doctor to obtain stabilisation).

PEF after bronchodilator, after initial treatment and/or trial of oral corticosteroids	Record the PEF after bronchodilator in litres per minute at the visit after the short initial treatment (if such treatment was prescribed by the doctor to obtain stabilisation). Measure after inhalation of salbutamol with a spacer.
Best PEF in % of predicted PEF	From the several measurements of patient PEF in I/min made since the first visit, select the highest value and calculate the best PEF at initial evaluation using the formula on the treatment card.
Lung function based on best PEF in % predicted PEF	Select the number corresponding to the patient's best PEF and enter the number in the box on the right-hand side of the treatment card: $1. \ge 80\%$; 3. 60-79%; $4. < 60%$

5. Confirmation of diagnosis of asthma

Variability of the PEF: From the several measurements of patient PEF in I/min made since the first visit, select the best and lowest values and calculate the variability using the formula on the treatment card.

Confirmed asthma: Check Y if the variability is $\ge 20\%$ and N if the variability is < 20%.

6. Initial evaluation of asthma severity

In order to determine the severity of asthma, take the higher of the two numbers recorded in the boxes above for 'Symptom severity' and for 'Lung function based on best PEF in % of predicted PEF'. Enter this number into the box on the right-hand side of the page. This number gives the **asthma severity**, as follows: 1. intermittent; 2. mild persistent; 3. moderate persistent; 4. severe persistent.

7. Prescription of long-term treatment

Date of start: day, month, year of the start of long-term treatment. (*Note*: this is not the date of the initial visit.)

Corticosteroids: Write the daily corticosteroids prescribed for long-term treatment.

Inhaled: Write the dose in micrograms (μ g). If none are prescribed, write 0.

Oral: Write the dose in milligrams (mg). If none are prescribed, write 0.

Patient registration number: A registration number is assigned to the patient after evaluation **if the patient is a persistent case**. All patients with

persistent asthma must be registered and successive numbers assigned. The first new patient with persistent asthma each year treated in the health centre will be assigned with the number 001.

Back side of asthma treatment card

The back of the treatment card is reserved for treatment follow-up and evaluation. The first table is for assessment at each follow-up visit after the initial evaluation and prior to the end of the first year. The second table rerecords the patient status at the start of treatment (in the first line) and then records patient evaluation at each annual evaluation. Record information according to the definitions, as follows:

First table: Follow-up at each visit

The following information is recorded at each follow-up visit after the start of long-term treatment.

Date of follow-up: indicate the date of visit (dd/mm/yyyy)

Symptom severity: severity of symptoms since the previous visit. 0=asymptomatic; 1=intermittent; 2=mild persistent; 3=moderate persistent; 4=severe persistent.

PEF in I/min: Patient's PEF in litres per minute.

PEF in % predicted PEF: Patient's PEF after bronchodilator in % of predicted PEF on the day of the visit.

Corticosteroids

Inhaled: Indicate daily dose of inhaled corticosteroids in micrograms (μg) . If no prescription, write 0.

Oral: Indicate daily dose of oral corticosteroids in milligrams (mg). If no prescription, write 0.

Unplanned visits

Emergency: number of unplanned visits to emergency services since previous visit.

Hospital: number of unplanned admissions to hospital since previous visit.

Comments: e.g. death and cause; transfer; adherence; side effects; social problems; smoking habits.

Second table: Annual evaluation

The following information is recorded at the initial evaluation when long-term treatment is started, and at each annual evaluation. Annual evaluation is done each year after the start of long-term treatment. If patient is experiencing an acute attack of asthma at the time, first provide treatment to
stabilise the patient's asthma attack, then measure PEF before bronchodilator and PEF after bronchodilator again within 2 weeks after the patient has stabilised.

Date of evaluation: indicate the date of visit (dd/mm/yyyy)

Symptom severity: severity of symptoms based on their frequency since the previous year. 0=asymptomatic, 1=intermittent, 2=mild persistent, 3=moderate persistent; 4=severe persistent

Best PEF in I/min: Patient's best PEF in litres per minute.

Best PEF in % predicted PEF: If the patient is not experiencing an acute attack of asthma at the time, an annual evaluation requires two PEF measurements, of which **PEF after bronchodilator** is usually the **best PEF**. If the patient *is* experiencing an acute attack at the time, an annual evaluation requires four PEF measurements (as for the initial evaluation), of which **PEF after bronchodilator after initial treatment and/or after a trial of oral corticosteroids** is usually the **best PEF**. Write 1 if \geq 80%; 3 if 60-79%; 4 if < 60%

Asthma severity: take the higher of the two numbers recorded for 'Symptom severity' and 'Best PEF in % predicted PEF'. 1=intermittent, 2=mild persistent, 3=moderate persistent; 4=severe persistent. If in remission (patient remains asymptomatic throughout one year following discontinuation of inhaled corticosteroids and PEF after bronchodilator is \geq 80% of predicted PEF), write R.

Corticosteroids:

Inhaled: Indicate daily dose of inhaled corticosteroids in micrograms (μg) . If no prescription, write 0.

Oral: Indicate daily dose of oral corticosteroids in milligrams (mg). If no prescription, write 0.

Unplanned visits:

Emergency: number of unplanned visits to emergency services in past year since initial evaluation or since previous annual evaluation. **Hospital:** number of unplanned admissions to hospital in past year since initial evaluation or since previous annual evaluation.

Outcome:

Improved: decrease in asthma severity AND no or fewer unplanned visits, as compared with initial evaluation, or in remission.

Stable: same asthma severity AND no or fewer unplanned visits, as compared with initial evaluation.

Worse: increase in asthma severity OR more unplanned visits, as compared with initial evaluation.

Died: whatever the cause of death.

Lost: has not appeared for follow-up appointment or within 2 months following the appointment.

Transferred: transferred to another health facility and outcome unknown.

Appendix 2: How to complete the register

Left-hand page of the register

Date: From 'a' on the treatment card.
No.: From 'b' on the treatment card. This is the patient registration number.
Name: From 'c' on the treatment card.
Address: From 'd' on the treatment card.
Sex: From 'e' on the treatment card.
Age: From 'f' on the treatment card;
Smoking: From 'g' on the treatment card.
Unplanned visits:

Emergency: From 'h' on the treatment card;
Hospital: From 'i' on the treatment card.

symptoms using the following codes: 1 = intermittent; 2 = mild persistent; 3 = moderate persistent; 4 = severe persistent.

Best PEF: From 'k' on the treatment card.

Confirmed: From 'l' on the treatment card.

Asthma severity: From 'm' on the treatment card. Record the severity of *asthma* using the following codes: 2 = mild persistent asthma; 3 = moderate persistent asthma; 4 = severe persistent asthma.

Corticosteroids:

Inhaled: From 'n' on the treatment card; **Oral**: From 'o' on the treatment card.

Right-hand page of the register

This page is used for the annual evaluation of the patient at one year after the initial evaluation. Two large columns are provided.

First large column, for those patients appearing for annual evaluation at one year.

This column is divided into 8 sub-columns.

Emergency: Number of unplanned visits to emergency services during the previous year. If none, write 0.

Hospital: Number of unplanned hospital admissions during the previous year. If none, write 0.

Asthma severity: Record the severity of *asthma* as assessed during this annual evaluation. Use the following codes: 1 = intermittent asthma; 2 = mild persistent asthma, 3 = moderate persistent asthma; 4 = severe persistent asthma.

Corticosteroids:

Inhaled: Record daily dose of inhaled corticosteroids in micrograms (μg) prescribed for the patient during this annual evaluation. If none, write 0;

Oral: Record daily dose of oral corticosteroids in milligrams (mg)

prescribed for the patient during this annual evaluation. If none, write 0.

Outcome:

Check one of the following:

Improved: decrease in asthma severity AND no or fewer unplanned visits as compared with the initial evaluation.

Stable: same asthma severity AND no or fewer unplanned visits as compared with the initial evaluation.

Worse: increase in asthma severity OR more unplanned visits as compared with the initial evaluation.

Second large column, for those patients not appearing at one year.

Outcome:

Check one of the following:

Died: whatever the cause of death.

Lost: has not appeared for annual follow-up appointment or within 2 months following the appointment.

Transferred: transferred to another health facility and outcome unknown.

Note: A patient can only have one of the six outcomes.

Appendix 3: How to complete the quarterly reports and order form

At the end of each quarter, three reports should be prepared and sent to the national coordinator.

1. Quarterly report on new cases of persistent asthma

The cases of persistent asthma registered during the quarter represent a cohort. Record the distribution of the cohort by age, sex and severity, according to the instructions provided on the Quarterly report form.

2. Quarterly report on treatment outcome

Record the outcomes for the cohort of persistent asthma cases registered in the same quarter of the previous year. The six categories of outcome are defined on the Quarterly report form.

3. Quarterly order form for treatment supplies

The uninterrupted availability of medicines is crucial for the successful implementation of standardised asthma management. To calculate medicine requirements, use the Quarterly order form.

Appendix 4. An example of Tables of predicted PEF values for use with EU/EN13826 scale PEF meters

PEF average for men in I/mn

Age in years	20	25	30	35	40	45	50	55	60	65	70	75	80
Height in cm		20											
155	528	516	503	490	477	464	451	438	425	412	399	387	374
160	547	534	521	508	495	482	469	457	444	431	418	405	392
165	565	552	539	527	514	501	488	475	462	449	436	423	410
170	584	571	558	545	532	519	506	493	480	468	455	442	429
175	602	589	576	563	551	538	525	512	499	486	473	460	447
180	621	608	595	582	569	556	543	530	517	504	492	479	466
185	639	626	613	600	587	574	562	549	536	523	510	497	484
190	657	644	632	619	606	593	580	567	554	541	528	515	503
195	676	663	650	637	624	611	598	585	573	560	547	534	521
200	694	681	668	656	643	630	617	604	591	578	565	552	539

PEF average for women in I/mn

Age in years	20	25	30	35	40	45	50	55	60	65	70	75	80
Height in cm		20	00										
155	409	400	391	382	373	364	355	346	337	328	319	310	301
160	425	416	407	398	389	380	371	362	353	344	335	326	317
165	442	433	424	415	406	397	388	379	370	361	352	343	334
170	458	449	440	431	422	413	404	395	386	377	368	359	350
175	475	466	457	448	439	430	421	412	403	394	385	376	367
180	491	482	473	464	455	446	437	428	419	410	401	392	383
185	508	499	490	481	472	463	454	445	436	427	418	409	400
190	524	515	506	497	488	479	470	461	452	443	434	425	416
195	541	532	523	514	505	496	487	478	469	460	451	442	433
200	557	548	539	530	521	512	503	494	485	476	467	458	449

PEF average for children

Height in cm	100	110	120	130	140	150	160	170	180
PEF in l/min	110	145	185	225	270	320	375	435	495