Development of a Pharmaceutical Care Model for the Long-term Management of Asthma in Malaysia

A thesis submitted to University of Strathclyde for the Degree of Doctor of Philosophy by

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This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed: 

Wong Pei Se

Date: **12 January 2012**

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Presentations and Publications

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Lists of Abbreviations

AIRIAP	Asthma Insights and Reality in Asia-Pacific
BDP	Beclomethasone Dipropionate
BTS	British Thoracic Society
BUD	Budesonide
CIC	Ciclesonide
CPD	Continuing Professional Development
DPI	Dry powder inhaler
FP	Fluticasone Propionate
GAPP	Global Asthma Physician and Patient
GINA	Global Initiative for Asthma
GIT	Gastrointestinal tract
ICS	Inhaled Corticosteroids
LABA	Long-acting β_2-agonists
LTRA	Leukotriene Receptor Antagonist
MDI	Metered Dose Inhaler
MoH	Ministry of Health
PEF	Peak expiratory flow
SABA	Short acting β_2-agonists
SIGN	Scottish Intercollegiate Guideline Network
SMART	Single-inhaler maintenance and reliever therapy
US	United State
WHO	World Health Organisation

Abstract

Asthma is one of the most common chronic diseases affecting adults and children in the world. To date, it is estimated to affect over 300 million of the world population and presents a significant healthcare burden in all countries. In the United State (US) and Europe, asthma control is reported to be achievable by only 5% of asthmatics. Asthma is also one of the top 5 conditions, which impact on healthcare expenditures in the US.

Asthma affects 4.6% of the population in Malaysia and has major effects on morbidity, mortality and healthcare costs. The development of a pharmaceutical care model for the long-term management of asthma patients in Malaysia has the goal of increasing patients' and professionals' levels of understanding of the pharmacological management of the disease, by developing a framework for the provision of pharmaceutical care. Within that framework, pharmacy services are aimed at promoting the management of prescribed medicines and securing better disease control through decision support and education provided to other health professionals and patients.

The overall aim of the current research is to develop a pharmaceutical care model for the long-term management of asthma in Malaysia. This thesis presents the series of research studies undertaken to achieve the aim of study.

Chapter 1 of the thesis reviews the intention of the research plan and provides insights into the disease of asthma. The status of the healthcare system in Malaysia and the concept of pharmaceutical care are also discussed.

Chapter 2 and Chapter 3 of the thesis discuss the assessment of pharmaceutical needs by means of quality assessment using clinical audit and a direct patient-facing clinical exploratory method. A design and validation

processes generated a tool, an Asthma Medication Assessment Tool (MAT_{AST}) that can be used not only for quality assessment purpose, but comparison at the international level. The field-testing process of the MAT provides preliminary insights into gaps in asthma clinical management and, potentially, the need for decision support. The direct patient-facing clinical exploratory study uses two methods; semi-structured interviews with individual patients and focus groups of patients to improve understanding of patients' needs. The outcomes of these studies are a list of gaps of care from clinical audit and patients' views or perceptions from patients' interviews which are critically appraised in Chapter 4.

Chapter 5 of the thesis discusses a consensus process used to establish a pharmaceutical care model and roles of pharmacists in that model of care. The objective of the consensus process is to establish the activities for in a pharmaceutical care model for asthma management in Malaysia. This study also includes a consensus process of the agreed activities by pharmacists within the pharmaceutical care model.

Chapter 6 presents a study to evaluate the self-management ability of patients by means of an educational intervention using an action plan. Asthma self-management is a globally relevant component of care, which is not commonly practised in Malaysia and has never been studied in this country. This study revealed ways of improving the action plan and the patients use of it; the findings provide a framework for asthma self-management interventions in Malaysia.

Chapter 7 critically appraises the implications of the findings in the thesis for practice and education as well as future research in the provision of pharmaceutical care in the asthma population.

Chapter 1

1 Background Information

1.1 Asthma

1.1.1 Prevalence

Asthma affects more than 300 million of the world population[1]. The prevalence of asthma is believed to increase with urbanisation in many countries and is estimated to affect an additional 100 million people by 2025. The prevalence of asthma varies up to 15-fold in the differences between countries; ranging from 1-18% of populations. In general, prevalence is also found to be higher in Western countries compared to the Asia Pacific region.

In Western countries such as Australia, New Zealand, United Kingdom/Europe and Republic of Ireland, asthma affects about 15% of the populations[2]. In Asia Pacific countries, the prevalence of asthma range from 1.1% of population in Indonesia to 6.5% in Thailand. Asthma is estimated to affect about 5% of the population in Malaysia, and is the most common chronic respiratory disease seen in healthcare clinic[1, 3].

Childhood asthma is common. The survey of current asthma symptoms in childhood from the International Study of Asthma and Allergies in Childhood (ISAAC) reported prevalence of current wheeze (within 12-month periods) among 13-14 year old children between countries, ranging from 2.1–4.4% in Albania, China, Greece, Georgia, Indonesia, Romania and Russia, to 29.1–32.2% in Australia, New Zealand, Republic of Ireland and the UK[4, 5]. The latest phase 3 ISAAC also reported global variations in asthma symptoms ranging from 0.8% in China to 32.6% in New Zealand in

the 13–14 years old group, and from 2.4% in India to 37.6% in Costa Rica in the group 6–7 years old[6].

1.1.2 Pathophysiology and Clinical Features

"Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular, mast cells, eosinophils, lymphocytes, macrophages, neutrophils, and epithelial cells" [7].These cells lead to the secretion of over 100 mediators that act either directly or indirectly to cause the complex inflammatory response in the airways [8, 9]. These inflammation responses involve modulation of airway smooth muscle tone, vascular permeability, neurons, mucus secretion, and structural changes in the airway[10].

In chronic asthma, the persistent level of inflammation may lead to increase in airway hyper-responsiveness to stimuli and narrowing of the airway. The airway narrowing leads to paroxysmal or persistent clinical features of asthma such as dyspnoea, chest tightness, wheezing, sputum production and cough, particularly at night or in the early morning. The persistent inflammatory response may also lead to remodelling of the airway connective tissue, which involves thickening of basement membrane, mucus metaplasia, myocyte hyperplasia and irreversible airway changes[11].

Asthma can present different patterns in terms of frequency and duration of the attacks, varying from intermittent but mild symptoms to persistent symptoms with chronicity[12]. The Global Initiative for Asthma (GINA) classifies asthma into four categories: Intermittent, Mild Persistent, Moderate Persistent, or Severe Persistent based on level of symptoms, airflow limitation, and lung function variability (**Table 1.1**)[2].

Table 1.1: Classification of Asthma Severity [7]

Intermittent
Symptoms less than once a week Brief exacerbations Nocturnal symptoms not more than twice a month • FEV_1 or PEF≥ 80% predicted • PEF or FEV_1 variability <20%
Mild Persistent
Symptoms more than once a week but less than once a day Exacerbations may affect activity and sleep Nocturnal symptoms more than twice a month • FEV_1 or PEF ≥ 80% predicted • PEF or FEV_1 variability <20 – 30%
Moderate Persistent
Symptoms daily Exacerbations may affect activity and sleep Nocturnal symptoms more than twice a month Daily use of inhaled short-acting β_2-agonist • FEV_1 or PEF 60- 80% predicted • PEF or FEV_1 variability > 30%
Severe Persistent
Symptoms daily Frequent exacerbations Frequent nocturnal asthma symptoms Limitation of physical activities Daily use of inhaled short-acting β_2-agonist • FEV_1 or PEF ≤ 60% predicted • PEF or FEV_1 variability > 30%

1.1.3 Goals of Asthma Management

In the absence of a cure for asthma, achieving clinical control of asthma becomes the primary goal of asthma management. GINA guidelines describe the goals of asthma management as good control of asthma symptoms, normal lung function and free from medicines side effects (**Table 1.2**)[13].

Table 1.2: Goals of Asthma Management[13]

- Minimally (ideally no) chronic symptoms including nocturnal symptoms
- Minimal (infrequent) exacerbations
- No emergency visits
- Minimal (ideally no) use of β_2-agonist
- No limitations on activities, including exercise
- PEF circadian variation of <20%
- (Near) normal PEF
- Minimal (or no) adverse effects from any medicines

1.1.4 Impact of asthma

There is increasing evidence of uncontrolled asthma worldwide leading to considerable mortality, morbidity and healthcare costs.

In the USA alone, asthma leads to up to 470,000 hospitalisations annually [7]. The Asthma Insights and Reality in Europe (AIRE) survey reported suboptimal control of asthma among children and adult asthmatics[14]. Hospitalisation in the previous one year was reported by 4-10% of adults from seven Western European countries. Unscheduled urgent care in the

previous one year was reported to be highest among participants from Spain (34%). Absence from work was also reported among 12% to 28% of asthmatics from the different European country.

In Asia Pacific, more than 40% of asthma patients required hospitalisation or urgent care i.e. emergency treatment within the past one year [13]. The rate of hospitalisation in the past one year was higher as compared to the European survey and the Asthma in America survey (9%)[15]. Asthma was also found to restrict daily and physical activities in more than 30% surveyed patients.

Asthma also presented a major economic burden in many countries. In mid-1980s, the cost of asthma where was estimated to be USD4.5 billion. In 1998, the cost of asthma has been estimated to increase to USD 12.7 billion [16]. The average annual per patient cost for adults in Europe was estimated to be €566. Urgent care among adults accounted for close to 60% of total direct costs.

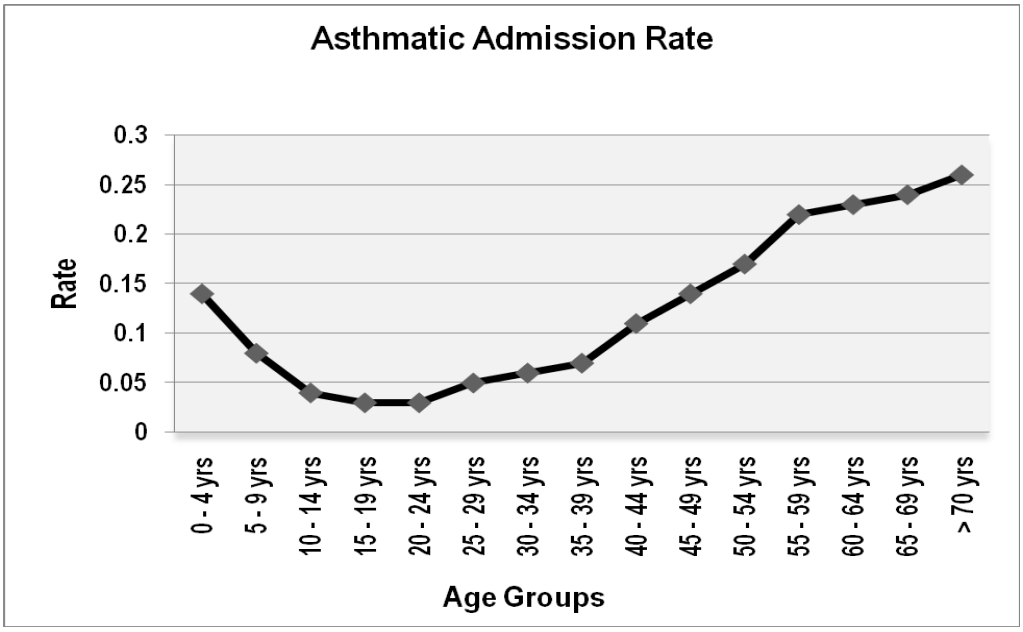
The direct annual cost per patient was estimated to be USD 108±13 in Malaysia[17]. A substantial cost was contributed by the urgent care costs (USD 68±12) as compared to maintenance care costs (USD 40±3). Malaysia has a lower proportion of patients using urgent care than some countries in Asia Pacific region such as Hong Kong (63% vs. 83%).

1.2 Asthma Control in Malaysia

Based on the Third National Health and Morbidity Survey done in 2006, the prevalence of asthma in adults in Malaysia is estimated to be 4.5%. The survey also revealed that 20% of asthmatics sought emergency treatment for severe attacks. Of those who received emergency treatment, more than 15% needed two or more emergency treatments within the same year.

Based on a survey done in 2002, asthma cases account for about 1.6% of total admissions in Malaysia [18]. Admission rates were found to be higher among 0-4 years and 30 years onwards age groups of patients (**Figure 1.1**). Close to 80% of total admissions comprised of the severe form of asthma. The rate of admission was highest among Indian, then Malays and then Chinese.

Figure 1.1: Asthmatic admission in government hospital in Malaysia[18]



There is little data on asthma related mortality in Malaysia. The mean mortality rate for asthmatics admitted to government hospitals was 6.6% in 2002. Several states, Selangor, Perak, Negeri Sembilan, Sabah and Kelantan have higher case mortality rates of 14.5%, 11.6%, 9.8%, 8.8% and 8.3% respectively.

Based on estimates of deaths by cause reported by WHO in 2004, there were 101 fatalities per 100,000 of South East Asia populations. In comparison, the estimates of fatalities were only 16 per 100,000 populations in America and

36 per 100,000 populations in Europe[19]. Denmark among European countries had been reported to have the highest annual case fatality rate in Europe, with 9.3 fatalities per 100,000 asthmatics every year. In UK, there were more than 1,400 deaths from asthma and 69,000 hospital admissions for asthma in 2002[20]. Over two thirds of deaths from asthma involved patients aged over 65.

1.3 Management of Asthma

The effective management of asthma involves various strategies including asthma preventative measures, appropriate medication use and constant monitoring by healthcare providers.

In view of the episodic nature of asthma, medication to control the condition long term is necessarily the most important care component. It is important to recognise that healthcare providers' roles in asthma management are therefore highly associated with medication use. These roles could include monitoring to assess drug effectiveness or safety, education to ensure drugs are used correctly and counseling on compliance to medication regimens.

Asthma requires long-term medication to control the disease. The essential medication to manage asthma can generally be classified into the use of medication as 'controllers' and 'relievers'. 'Controllers', also known as 'preventers', are medications taken on a regular and long-term basis to achieve good control of asthma and prevent asthma attacks. Inhaled corticosteroids are the most important controllers in asthma treatment. Other 'controllers' include leukotriene modifiers, long-acting inhaled β_2-agonists, sustained-release theophylline, cromones and other systemic steroid-sparing therapies. 'Relievers' are medications used during asthma attack or on an 'as

required' basis. The most common relievers are the short and rapid-acting inhaled β_2-agonists.

1.3.1 Inhaled Corticosteroids

The use of anti-inflammatory drugs in asthma was first documented in the mid-20th century, when injected adrenocorticotrophic hormone and oral cortisone were shown to improve asthma [21]. Use of oral corticosteroids became a common practice in asthma treatment. With the increased use of oral corticosteroids, there were escalating incidences of undesirable drug-induced systemic side effects. Topical delivery by means of aerosol to increase drug deposition in the lung, with minimal systemic absorption, quickly gained interest among the researchers. In 1972, beclomethasone dipropionate in pressurised aerosol form was introduced. The aerosol form was shown to be effective in asthma with reduced risk of systemic effects [22]. Inhaled corticosteroids (ICS) were first used as a means to reduce the total dose of oral corticosteroids in asthma management. Over time, with discovery of new inhalation devices, ICS use increased and replaced the continuous use of oral corticosteroids.

Furthermore, in the early 1990s, inflammatory mechanisms were recognised as the basis of asthma. Since then, ICS was established as the mainstay of asthma treatment. Direct inhibitory effects of ICS on inflammatory cells and mediators have been shown to reduce asthma symptoms, improve airway calibre and airway hyper-responsiveness[23, 24]. When used as long term therapy, ICS have reduced asthma hospitalisation, improved pulmonary function, improved quality of life and reduced the risk of asthma deaths [25].

Now, ICS are the first line anti-inflammatory therapy for patients with persistent asthma. They are recommended for regular use among patients with the following conditions [26]:-

- asthma exacerbations within the last 2 years
- regular use of inhaled β_2-agonists three times or more within a week
- symptomatic asthma three times or more within a week

The commonly used ICS are beclomethasone dipropionate (BDP), fluticasone propionate (FP) and budesonide (BUD). Ciclesonide (CIC) inhaler was also made available some 2 years ago. **Table 1.3** shows the pharmacokinetic and pharmacodynamic differences between the ICS. These properties shape the efficacy and safety of these agents[27-29].

Table 1.3: Comparison of Pharmacokinetic and Pharmacodynamic Parameters of Inhaled Corticosteroids[30]

Parameters	BDP	BUD	FP	CIC
Oral Bioavailability	<1%	11%	< 1%	< 1%
Pulmonary deposition	51%	28%	16%	52%
Local activation	Little	None	None	Yes
Receptor binding affinity	53	935	1,800	12
Esterification	None	Yes	None	Yes
Lipophilicity	Mod/high	Low	High	V. high
Protein binding: free fraction	87%:13%	88%:12%	90%:10%	99%:1%
$t_{1/2}$, hr	0.5	2.8	7.8	0.36
Vd, L	20	183	318	207
Clearance , L/hr	15	84	69	152

BDP = beclomethasone dipropionate, BUD = budesonide, FP = fluticasone propionate, CIC = ciclesonide, $t_{1/2}$ = half-life, Vd = volume of distribution, Mod/high = moderate to high, V. high = very high.

Despite the variations in potency and bioavailability, there is little evidence of differences in clinical efficacy at recommended doses of ICS[30, 31]. **Table**

1.4 shows the estimated equipotent daily doses of commonly used ICS in clinical practice for the management of asthma.

ICS have minimal systemic side-effects as compared to oral or parenteral corticosteroids. These side-effects include hypothalamic–pituitary– adrenal-axis function suppression, growth rate reduction (in children and adolescents), osteoporosis, skin thinning, and cataract formation[32]. These systemic effects are recognised to exhibit in a dose-related fashion. Higher doses of ICS therefore are more likely to cause concerns.

Table 1.4: Estimated Equipotent Daily Doses of commonly used Inhaled Corticosteroids[13]

Generic Name	Daily Dose (µg)		
	Low	Medium	High
Beclomethasone Dipropionate	200-500	>500-1000	>1000-2000
Budesonide	200-400	>400-800	>800-1600
Fluticasone Propionate	100-250	>250-500	>500-1000
Ciclesonide	80-160	>160-320	>320-1280

Systemic effects of ICS are contributed by drug absorption from the lung and the gastrointestinal tract (GIT). On inhalation, a significant proportion of ICS of 50% to 90% are deposited in the mouth and pharynx. This portion of ICS may cause local side-effects. If it is not rinsed out from the mouth, it may be swallowed and absorbed from the GIT [33]. ICS that is absorbed from the GIT will undergo first pass metabolism. Drug escaped from inactivation by first pass metabolism enter the systemic circulation and causes the systemic side effects. The first pass hepatic metabolism is estimated at 99% for fluticasone and 89% for budesonide[34]. This explains the lack of evidence of these systemic effects with low dose of budesonide, and fluticasone. Newer ICS, ciclesonide has demonstrated more than 50% lung deposition [35].

It is converted to its active metabolite, des-ciclesonide in the lungs. Ciclesonide and des-ciclesonide have low systemic bioavailability due to the high first pass metabolism and low risk of systemic adverse events.

The dosage regimen of ICS is determined by the patient's response to therapy. Once asthma control is achieved, the dose can be titrated to the minimum dose needed to maintain the asthma control.

1.3.2 β_2-agonists

The history of adrenergic agents in respiratory disease reveals the first documented use of *ma huang* in 3000BC, although the principal action was only recognised with the development of the first synthetic β-agonist, epinephrine in the 1900's. Subsequent β-agonists; isoproterenol, metaproterenol and isoetharine were developed for the treatment of asthma. With the increased use of β-agonists in 1960s, a rise in asthma mortality was observed. The rise was associated with the introduction and use of the isoproterenol and fenoterol inhalers. The non-selective property of both isoproterenol and fenoterol caused long term and immediate adverse effects than other β-agonists. The regular use of these agonists lead to worsening of asthma and increased risk of death resulted from cardiac effects. Improvement of drug specificity became the focus of drug development in the past 30 years and the β_2-agonist; salbutamol was developed before 1970s[36].

β_2-agonists are bronchodilators. The principal action of a β_2-agonist is to relax airway smooth muscle by stimulating β_2-receptors. The stimulation activates adenyl cyclase and an increase in intracellular cyclic adenosine monophosphate leading to bronchodilatation. The inhalation forms account for almost 80% of the β_2-agonist market. The remaining is contributed by other orally ingested formulations.

Inhaled β_2-agonists have their specific roles in asthma. Short acting β_2-agonists (SABA) such as salbutamol and terbutaline are well recognised as the drugs of choice for the short-term relief of asthma symptoms as well as prevention of exercise-induced asthma due to their rapid onset of action. Inhaled long-acting β_2-agonists (LABA), such as salmeterol and formoterol cause prolonged activation of β_2 receptors in bronchial smooth muscle. The effect produces long lasting bronchodilatation of more than 12 hours, making them a suitable choice for maintenance therapy. The use of these agents on a regular basis however remains a matter of controversy.

One of the concerns with regular use of β_2-agonists is the increased risk of fatal and nonfatal asthma exacerbations. Meta-analysis indicates that LABA without ICS increases the risk for hospitalisation for an asthma exacerbation, life-threatening asthma attacks, and asthma-related deaths in comparison to placebo[37, 38]. One of the studies of salmeterol monotherapy reported a 4-fold increased risk of asthma-related deaths[39]. The risks of LABA are believed to be contributed by the masking of inflammation of asthma by LABA. The bronchodilatation and symptom-relieving effects of LABA use delayed the detection of worsening asthma[40, 41].

At present, LABA is suggested in GINA guideline as the add-on therapy to patients uncontrolled by ICS. Combinations of LABA and ICS have been shown to provide better outcomes. Combination of LABA and ICS has been demonstrated to increase peak expiratory flow (PEF), improve symptoms and reduce corticosteroid dose requirements[42-44].

The combination of LABA and ICS in comparison to higher dose of ICS is also more effective in reducing the risk of exacerbations requiring oral corticosteroids in adults with sub-optimal control on low dose of ICS monotherapy[45]. The combination therapy however has not been proven to

benefit as first line treatment in adults and children with no previous history use of ICS [46].

Due to the combined benefits in asthma control, combination inhalers containing fixed doses of ICS and LABA were developed. These include combined fluticasone/salmeterol (Seretide®) and budesonide/formoterol (Symbicort®) inhalers.

Another evolution of LABA use specifically formoterol, is the single-inhaler maintenance and reliever therapy (SMART) approach. Despite being a LABA, formoterol exhibits a rapid onset of action. The similar or higher intrinsic efficacy of formoterol as compared to SABA, is responsible for this quick onset of action. Formoterol in dry-powder inhaler is showed to have as rapid an onset of action as that of salbutamol [47].

1.3.3 Single-inhaler Maintenance and Reliever Therapy (SMART) Concept

The SMART concept is an approach to asthma management using a single inhaler containing ICS and LABA. The concept applied specifically to single inhaler containing budesonide and formoterol (Symbicort®) is due to a unique property of formoterol. Formoterol being a LABA is suitable for maintenance therapy of asthma, and the rapid onset contributes to the role as a reliever. Studies showed that the SMART approach improves asthma control and reduces asthma exacerbations in mild, moderate and severe persistent asthma patients[48, 49]. The SMART approach is now recommended by GINA guidelines for patients using combined budesonide and formoterol inhaler.

1.3.4 Leukotriene modifier

Leukotriene modifier or Leukotriene Receptor Antagonist (LTRA) such as montelukast has been developed based on the understanding of the pathogenesis of asthma. This class is the first new type of agent with anti-inflammatory properties available since the introduction of corticosteroids for asthma management. Leukotriene modifier acts by inhibiting the effect of cysteinyl leukotriene, a mediator that contributes to inflammation and bronchoconstriction in asthma.

In comparison with ICS, leukotriene modifier is less effective in a persistent mild to moderate asthma[50]. ICS therefore remain as the most important anti-inflammatory agent in asthma management. Leukotriene modifier however has a proven advantage in patients with persistent exercise induced asthma and concomitant rhinitis[51, 52].

Addition of leukotriene modifier to ICS showed modest improvement in peak expiratory flow and a reduction in use of rescue short-acting β_2-agonist[53]. Another Cochrane Collaboration review revealed that the addition of LABA to ICS is superior to LTRA for preventing asthma attacks, improving lung function, reducing asthma symptoms, and use of rescue β_2-agonists[54].

Currently leukotriene modifier is considered as an alternative choice of asthma treatment for patients who remain uncontrolled with use of ICS and LABA.

1.3.5 Theophylline

Theophylline has been used in the treatment of asthma since the 1950s. Its popularity declined with the introduction of β_2-agonists and anti-

inflammatory agents. Addition to that, theophylline has been associated with undesired side effects such as nausea, vomiting, and cardiac arrhythmias.

Theophylline is well accepted as a bronchodilator. Its bronchodilatation is contributed by the non-selective phosphodiesterase inhibition, which results in an increase cyclic AMP and dilatation of airway. There have been increasingly evidences that theophylline has anti-inflammatory effects and a need to review the role of theophylline in asthma management [55].

GINA guidelines recommend theophylline as an add-on treatment to ICS and LABA. This is suggested based on findings indicating greater improvement in lung function, and less need for rescue medication with LABA as compared theophylline [56]. Besides that, side effects are more likely to occur with use of theophylline than LABA.

1.3.6 Stepwise approach to Asthma Management

Guidelines have been developed and implemented to provide decision support in the clinical management and prevention of asthma [2, 26, 57]. The sequence of treatment decisions is within a framework determined by the frequency and chronicity of asthma symptoms. **Appendix 1.1** shows the stepwise approach to asthma management recommended by the GINA guideline [2]. Upon achieving good asthma control, stepping down of asthma medication such as reduction of ICS dose, should be attempted to ensure lowest minimum dose is used long term.

1.4 Malaysia Healthcare System

Chronic diseases such as asthma have contributed significantly to the rise in healthcare costs. It is therefore not surprising to see increasing interest in

consolidation of healthcare system and services to improve the quality of care in many countries including Malaysia. One of the movements in Malaysia under the Malaysian Health Plan is the expansion of human resources, which has significantly increased the role of pharmacists, allowing greater emphasis on the provision of pharmaceutical care[58].

In general, the Malaysia healthcare system is divided into private and public sectors. The public health sector is highly subsidised by the government. The regulation and delivery of the government services are mainly the responsibility of the Malaysia Ministry of Health (MoH).

The Malaysia MoH healthcare system is an integrated network of general hospitals, district hospitals, national institute of health, community and health clinics. Hospitals and government clinics are present in almost all urban, semi-urban and rural areas. The services offered are comprehensive; comprising health promotion, preventive, curative, and rehabilitative care.

Most patients with chronic diseases including asthma received their care at the primary care level. Primary care is provided by both the public and private healthcare sectors. The public primary healthcare sector accounts for 58.4% of the total primary healthcare expenditure in 2004[59] and provided are not only by MoH clinics, but also hospitals. These services operated through 130 hospitals and over 2,700 health and community clinics. The geographical distribution of hospitals varied according to local socio-economic conditions. Mobile health clinics are concentrated mostly in the urban areas.

The private healthcare sector began to expand since the 1980s to offer services to self-paying public. In Malaysia, the private practice take places in hospital, hospice, ambulatory care centre, haemodialysis centre, dental clinics and medical clinics. The private sector is recognised to offer more personalised, faster (less or no waiting time) and possibly more comfortable

and/or luxurious care. In 2009, there were 209 private hospitals licensed for operation in Malaysia. Most of these hospitals are smaller than the MoH hospitals, and a few offered specialist care in areas such as cardiac care, oncology and etc[60]. The numbers of private medical clinic were over 6000; approximately three fold more than MoH health clinics being the main private primary care facilities.

Malaysia MoH lays the policy and the Malaysia Health Plan is prepared to guide the direction of healthcare delivery within the public sector in the country. The pharmaceutical system in Malaysia, which promotes pharmaceutical care activities, is managed by the Pharmaceutical Services Division. Pharmaceutical care management has been one of the main activities of this division. Pharmaceuticals care management emphasises the need for patients managed by MoH facilities to receive 'total pharmaceutical care'; which is further explained as provision of optimum therapy and adequate information on pharmaceutical products[54]. Furthermore, under the 9th Malaysia Health Plan (2006-2010), expansion and standardisation of pharmaceutical care activities by pharmacists (**Table 1.5**) have become the primary objectives of the division.

Table 1.5: 9th Malaysia Health Plan: Pharmaceutical Services Program Objectives[58]

- Increasing the therapeutic success and positive outcomes in pharmaceutical care activities provided by competent pharmacists with specialised training
- Influencing changes in psychosocial-behavioural pattern of the Malaysia population in relation to drug and healthcare products, towards more rational and objective use
- Enhancing and strengthening pharmaceutical care services and drug management towards achieving national health goals in preventive, curative and palliative care
- Increase in equity for quality pharmaceutical services throughout the country.

1.5 Pharmaceutical Care

Pharmaceutical care is a patient-orientated practice, which aims to improve patient outcomes by ensuring effective and safe use of medication. It has helped to explain the potential for growth in the responsibilities of pharmacist and pharmacy services within multidisciplinary co-operation. The concept of pharmaceutical care was first described by Hepler and Strand in 1990 as *"the responsible provision of drug therapy for the purpose of achieving specific outcomes achieving definite outcomes that improve a patient's quality of life. These outcomes are (1) cure of a disease, (2) elimination or reduction of patient's symptomatology, (3) arresting or slowing of a disease process, and (4) preventing a disease or symptomatology* " [61]. The definition was further refined to "*a practice in which the practitioner takes responsibility for a patient's drug related needs and holds him or herself accountable for meeting these needs*" [62].

In Scotland, a guideline to the provision of pharmaceutical care in primary care was published in 1999 [63]. The guideline described pharmaceutical care delivery as a systematic approach that ensures medications are used appropriately to achieve therapeutic goals with minimal or no drug-induced side effects. Three stages of the process were associated with the delivery of care through identification and responding to pharmaceutical care issues - described in the guideline as follows: -

- Assessment of patients for pharmaceutical care issues
- Formulation of a pharmaceutical care plan
- Implementation and monitoring of the care plan

Assessment of patients involved the process of review of a patient's condition and medication. The medical record is a common source of a patient's information. Eliciting information by mean of patient interview is often also conducted to determine the presence of drug related problems and the patient's drug related needs. Upon determination of drug related needs, it is important that medication appropriateness, effectiveness, safety and use in terms of compliance have been addressed systematically.

The identification of pharmaceutical needs lead to formulation of a pharmaceutical care plan, which is meant to address the needs. During this stage of planning, goals need to be established, and a discussion of the patient's therapy must be carried out to resolve the drug related problem and to meet the patient's needs. Due to the continuously changing needs of patients, the identification and meeting of the patient's needs have always been a challenge in pharmacy practice.

The delivery also stresses on the documentation and maintenance of medical information related to the management of patients. Upon carrying out the plan, evaluation should be performed to ensure the issues raised have been resolved. Patients should be continuously re-assessed from time to time to

ensure the emergence of new pharmaceutical needs and drug related problems are addressed and resolved.

Despite common misinterpretation, the delivery of pharmaceutical care is not a practice which works in isolation from other healthcare providers. It requires co-operation and collaborative effort between healthcare professionals and patients. It should not be a concept that is difficult to understand, as meeting patient's needs is the priority of practice in any healthcare profession. In order to achieve better outcomes, healthcare providers need to understand the roles of each member and must develop the levels of trust and confidence in one another. Effective communication between healthcare team members therefore plays an important role in the design and delivery of pharmaceutical care services.

1.5.1 Contribution of Pharmaceutical Care

Pharmaceutical care aims to maximise the contributions of pharmacists in the healthcare system by means of reducing drug-related morbidity and mortality, improving clinical outcomes and decreasing health care costs. As a concept, pharmaceutical care can be delivered to individuals and populations, thus it extends to policy-making levels in some countries such as Scotland [64].

Population or disease orientated pharmaceutical care, which focusses on selected diseases such as hypertension or population subgroups such as the care of the elderly, is considered easier to deliver as compared to the comprehensive care. This approach allows a better defined process of care to be delivered to patients. In some countries such as the UK, this approach is a reflection of the movement of pharmacists into clinical specialisation.

The pharmaceutical care approach has been studied in chronic diseases such as asthma, hypertensive, hypercholesterolaemia, diabetes mellitus and palliative care[65]. Despite variations in the outcomes, the pharmaceutical care approach has been associated with better outcomes. In a pilot study, implementation of a pharmacist-led hypertension clinic in a primary care general practice was shown to improve control of blood pressure control and use of medications such as antiplatelet agents for primary prevention of coronary heart disease and secondary prevention of atherosclerosis [66]. In the management of asthma, pharmaceutical care has significantly improved quality of life, inhalation technique, knowledge and compliance[67]. The study also found improvement in perceived ability to control the condition (self-efficacy). The approaches will be critically reviewed further later in Chapter 5 (Page 102).

1.6 Study Overview

This present study aims to develop a pharmaceutical care model for long-term asthma management in Malaysia. The author wishes to establish a framework in asthma care, which is relevant to Malaysian practice and accepted by health care professionals. An area of interest within this study is to establish the use of an action plan in the delivery asthma self-management in Malaysia. To the author's knowledge, this is the first asthma self-management study in Malaysia.

Appendix 1.2 maps the study components, which intended to meet the aim of the study. In general, the specific aims involved phases of assessment of pharmaceutical care needs, formulation and establishment of a pharmaceutical care model.

Assessment of pharmaceutical needs of patients treated at outpatient clinics is undertaken using a quantitative quality assessment method. A Medication Assessment Tool (MAT_{AST}) for use in Malaysia is validated against a MAT_{AST} developed elsewhere in order to place the tool within the setting of international standards of asthma medication use. Pharmaceutical needs assessment is further extended to a combination of qualitative techniques of focus group and semi-structured interviews in order to expand our understanding of patient factors needing to be addressed in such a care model.

The pharmaceutical care model is formulated based on critical appraisal of assessment of pharmaceutical needs and literature review. Consensus methods are used to establish the multidisciplinary pharmaceutical care model for long-term management of asthma patients treated in outpatient settings. The roles and challenges of the pharmacists in the delivery of the pharmaceutical care model have also been established. In view of the lack of asthma self-management attempts among the asthma population in Malaysia, the research is further extended to a study in the use of an action plan among asthma patients. It is hoped that the research in self-management contributes to the development of a framework for delivery of self-management for Malaysia asthma patients. The concept of self-management will be discussed later in this Chapter 6 (Page 123).

1.7 Study Aim and Objectives

The aim of present study is to develop a pharmaceutical care model for long-term asthma management in Malaysia. The specific aims of the study were:-

- To evaluate the clinical management of asthma patients treated at out-patient clinics using Medication Assessment Tool

- To explore patients' views on clinical management and self-management concept

- To develop and establish a pharmaceutical care model for long term management of asthma

- To establish the roles and challenges of pharmacists in the pharmaceutical care model.

- To establish a framework of self-management by means of an action plan for use of asthma patients in Malaysia.

Chapter 2

2 Evaluation of Medicines Use and associated Clinical Management using an Medication Assessment Tool (MAT_{AST})

2.1 Introduction

This chapter describes a quantitative quality assessment study, which aimed to assess the pharmaceutical care needs of patients treated for asthma at out-patient clinics. The study evaluated the clinical management related to asthma medication use using an asthma medication assessment tool (MAT_{AST}). The study was also undertaken as a preliminary study to demonstrate validation in the use of a method for evaluating quality of chronic asthma medication in a comparative international setting.

Improving quality of care is well-recognised as one of the priorities of many healthcare systems including the Malaysia healthcare system. The struggles to measure quality of healthcare over decades have led to various definitions of quality of care. Donabedian in 1980 defined high quality of care "*that kind of care which is expected to maximise an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its part*" [68]. In 1984, the American Medical Association defined high quality of care as care "which consistently contributes to the improvement or maintenance of quality and/or duration of life" [69]. Quality in healthcare has also been described as the "*degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge*" [70].

Despite variations among the definitions, two aspects are seen to be common ground in the discussion of quality of care. The first aspect of emphasis is the continuity of patient care. The standards of this continuous care determine the degree of quality. The second aspect relates to the components of care. Those components refer to either the technical quality components such as standards of services, tests, procedures or treatments provided to patients for the benefit in achieving good quality of life and to meeting expectations in terms of the patients' satisfaction or preferences.

2.1.1 The Quality Measures

Quality of care can be assessed by evaluating three components of healthcare systems or services; namely the structures (such as staff, equipment and appointment procedures), the processes (such as prescribing, diagnoses, and interaction between healthcare professionals and patients) and the clinical outcomes (such as morbidity, mortality and patient satisfaction) [71, 72].

2.1.1.1 Structural Measures

Structural measures evaluate the availability and characteristics of the health professionals themselves, their facilities, services and the attributes of the healthcare system. The types of information gathered from structural measures may include bed size, type of procedures or tests performed or percentages of certified nurses and doctors. These measures are primarily used for hospital accreditation.

Structural measures are easy to capture and so are inexpensive to obtain. The measures however provide limited indication to the actual quality of care and often are not regarded as very clinically meaningful. There is a lack of evidence that attention to structural measures leads to changes in patients' outcomes [73,74].

2.1.1.2 Process Measures

Process measures reflect what is done to patients. This may include the assessment, procedures and tests carried out to diagnose a disease or treatment provided to patients to manage the condition. Examples of process measures are percentages of patients have blood pressure monitored once every three months or percentages of patients being counselled on their medication.

In comparison to outcome measures, process measures not only would take a smaller sample size and less time for data collection, but also would provide data that were easier to interpret[75]. For example, the more patients with cardiac failure patients that receive the angiotension converting enzyme inhibitor (ACEI), the better the quality of care. Such a process measure is a direct measure of quality as the effective of treatment is proven and the size of effect of the treatment is statistically defined. Consequently, it is also important to highlight that process measures are of little value if they have not been reliably associated with outcome.

Assessment of process allows description of actual practice, thus it has been described as the primary object of quality assessment and improvement[76-79]. It is also recognised as the most sensitive indicator of actual differences in the type of care provided.

2.1.1.3 Outcome Measures

Outcome measures assess the health status after receiving health care intervention from health care intervention or after care have been provided to patients. Outcomes are the ultimate test of effectiveness of medical care. There are five aspects to choose from when selecting outcome measures,

namely death or survival, impairment, disability, quality of life and patient satisfaction with outcome.

The outcome measures are limited as a method for comparing the effects of services on quality of care. Firstly, it has been noted that poor patient outcome may not necessarily be reflected by an inadequate process of care. For example, children who are not immunised may not necessarily die from communicable diseases. This situation might be readily considered as a measure of poor quality of care, but may not be reflected in outcome measures such as mortality rate. Similarly, good quality of care provided, may not be reflected in positive outcome measures. For example, patients unlikely to survive myocardial infarction may do so despite the provision of all proven interventions.

Secondly, it is also important to highlight that outcome measures are influenced by many factors. These factors may not reflect the quality of care, and may not fall within the control of the physician. This is best illustrated with poor health outcomes e.g. incidence of hospitalisation due to non-adherence to asthma medication. The use of outcome measures alone in this situation again does not reflect the quality of care provided.

Other limitations with the use of outcome measures are the time and sample size needed for measurement. For example, conditions such as breast cancer, where 5-year survival rates are a standard measure of outcome. In such circumstances, not only long term follow-up is required, it is also impossible in some circumstances to assess quality of care because the management processes may have changed markedly within the 5-year period[80]. In a study performed to compare the sensitivity of process and outcome measures in detecting differences in quality of care, it was indicated that 3619 patients were needed from each of two hospitals to detect and compare mortality differences of patients treated for myocardial infarction[81]. In a typical UK

hospital, 8 years would be required to complete the data collection. In comparison, it would only require 48 patients in each hospital to detect significant differences in the process of care.

2.2 Study Purpose

Quality improvement has become a central practice in the management of many chronic diseases including asthma. Asthma, globally, is one of the most prevalent chronic diseases. In its acute and chronic forms asthma is a cause of morbidity and mortality that has an impact on public health. Chronic asthma requires long-term medication and asthma usually responds dramatically to treatment. Systematic care in asthma has been proven to reduce morbidity within general practice. The introduction of various guidelines further support the management of asthma by guiding the evidence based approach to asthma management. Published clinical guideline recommendations are directed at improving both the organisation of service delivery and the decisions in individual patient care; consequently they form a good basis for the development of process measures in quality assessment of asthma management.

This study aimed to evaluate the clinical management and related medication use against guideline recommendations for the long-term management of asthma in adults using an asthma medication assessment tool (MAT_{AST}). This tool was specifically designed for use in Malaysia. The present study was also undertaken as a preliminary study to demonstrate the validation in the use of a method for evaluating quality of chronic asthma medication in a comparative international setting.

2.3 Study Aim and Objectives

The aim of study is to assess the quality of clinical management of asthma patients treated at outpatient clinics in Malaysia. The study involved development and validation of a Medication Assessment Tool (MAT_{AST}) and comparison to the development of United Kingdom (UK) MAT_{AST}.

The objectives of this study are:-

1) To develop and validate a MAT_{AST} based on evidence based recommendations and comparison to a MAT_{AST} developed within a UK research team

2) To evaluate the medication use and clinical management of patients treated for asthma at out-patient clinics

2.4 Study Design

2.4.1 Sample Population and Setting

The study was performed within a research group at Negeri Sembilan, Malaysia using a MAT_{AST} designed for use in the local setting. The development and validation was undertaken using a panel review and interview in Malaysia. The UK MAT_{AST} was designed and validated using panel review and interview by using a research group in Glasgow, United Kingdom.

Field-testing of the Malaysia MAT_{AST} was carried out during the delivery of care at two sessions of clinics per week from April 2005 to January 2006. Retrospective case note surveys were carried out on medical records. A brief

interview was carried out using the tool to evaluate the patient educational needs in a subset sample from a population.

Inclusion Criteria

Patients aged 18 and above who are diagnosed with asthma.
Patients prescribed with any form of asthma medication.
Patients who have attended follow up at clinic within the 12-month period from the date of audit

Exclusion Criteria

Patients diagnosed with concomitant chronic respiratory conditions e.g. chronic obstructive airway disease
Patients not attended follow up at clinic within the 12-month period from the date of audit

2.4.2 Ethical considerations

The research project was approved by the International Medical University Research and Ethics Committee. Permission was given by Hospital and Health Clinic Seremban for the use of medical records and consent given by patients to conduct a brief patient interview in the study.

2.4.3 Development of Asthma Medication Assessment Tool (MAT_{AST})

Figure 2.1 summarises the development and validation process of the asthma medication assessment (MAT_{AST}) in UK and Malaysia. The MAT_{AST} was developed based on literature appraisal of Global Initiative for Asthma (GINA) Guidelines and British Thoracic Society and Scottish Intercollegiate

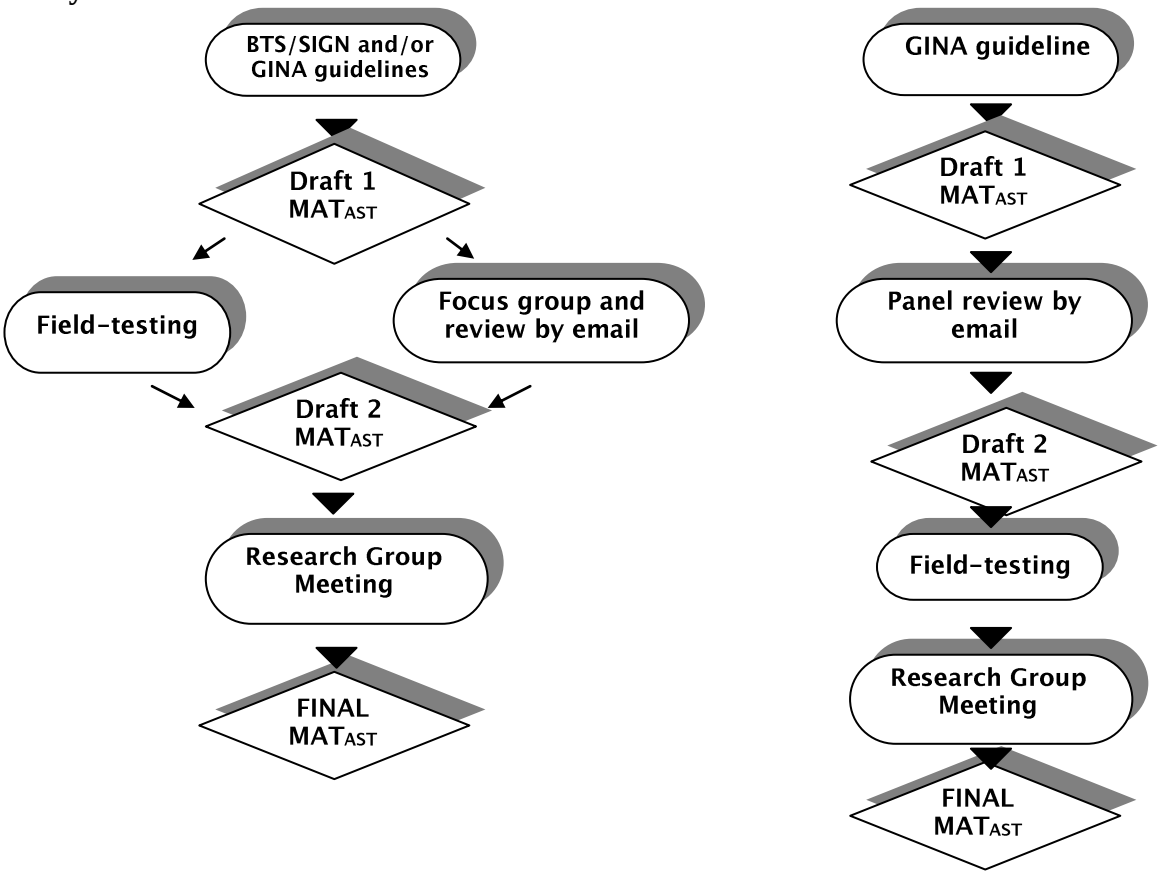
Guideline Network (BTS/SIGN) guidelines for the management of asthma[2, 26]. The development of the asthma MAT_{AST} involved a first stage identification of the medication-related recommendations in each guideline. The selection was later validated by peer group discussion.

The design of MAT_{AST} involved in Malaysia involved 2 stages of peer review. The first draft of MAT_{AST} was reviewed by peer group in Malaysia which consists of eight members, two respiratory consultants and six medical officers from secondary care settings. The review was conducted via interactive process involving peer commenting by email. **Appendix 2.1** shows the review criteria developed in first draft of Malaysia MAT_{AST} and recommendations from Malaysia peer review team.

The draft MAT was then field-tested and further refined after continued iteration with peer group from UK. The peer group from UK consists of expert group which comprised five senior respiratory clinical pharmacists practising mainly in respiratory medicine on a daily basis. **Appendix 2.2** shows the recommendations made on Draft 2 Malaysia MAT_{AST}.

This process was undertaken in a similar way separately in both the Scottish and Malaysian environments and resulted in two MAT_{AST} which reflected some international consensus but which also remained culturally sensitive to the quite different primary care contexts.

Figure 2.1: Method of development and validation of the asthma Medication Assessment Tool (MAT_{AST})



2.4.4 Structure of MAT_{AST} and example of a criterion

Criteria were divided into 5 categories: general care, inhaled steroids use, add-on therapy use, oral steroid use and patient educational needs.

Each criterion was formulated into a format based on an inclusion statement (a clause to qualify those patients or a subgroup to whom the criteria is designed to be applied). The qualifying statement is then coupled with a statement of prescribing/clinical expectations (an explicit standard expressed

in the guideline recommendation). This development method has already been described by our research group in the context of an international co-operation to develop chronic pain management MAT from palliative care guidelines[82] .

Each criterion consisted of two parts: - a qualifier and a standard, as follows:

(Qualifier) "Patient with asthma"

(Standard) *"is prescribed inhaled short-acting β2 agonist"*

Aggregation of individual patient assessments allowed each criterion to be quantified in terms of the numbers of patients to which it was applicable, and also, once applied, the numbers of patients in which the standard was met. Where standards were not met the non-Comparison of levels of applicability and adherence to the 11 criteria common to both the UK and Malaysian MAT_{AST} adherence may or not have been justified or not in the clinical case notes or not ('justified' or 'unjustified). The term justified means any reason recorded in the notes which were used by the clinicians to explain a non-adherence to a guideline recommendation; that is recognising the patient as an 'Exception'. The researcher avoided applying any clinical judgment about whether any justification recorded in the notes was valid or not. The levels of absence of data affecting decisions about applicability or adherence of each criterion were quantified separately and reported as insufficient data to judge applicability (IDq) and to judge adherence (IDs). The structure of the criteria is outlined in **Figure 2.2**.

Figure 2.2: Examples of criteria used in MAT

		N/A	Yes	No	No, but J	ID (q)	ID (s)
1	**Patient with symptomatic asthma** is prescribed inhaled short acting β_2 agonist (SABA)	❑	❑	❑	❑	❑	❑
2	**Patient on asthma treatment** has PEF or FEV_1 measurement at least once in the past 12 months.	❑	❑	❑	❑	❑	❑

N/A – Not applicable; **No, but J** – No, but Justified; **ID(q)/ID(s)** – Insufficient data

The final MAT_{AST} comprised 24 (UK) or 23 (Malaysia) criteria in the form of statements where a qualifying condition ('qualifier', q) is followed by an audit 'standard'. The 'qualifier' represents a statement to determine whether the criterion applies to the patient and so indicates the relevance to the patient and the requirement that the adherence to the standard be tested. The 'standard' is a statement of the guideline recommendation and requires a 'yes' or 'no' response on the basis of evidence that the 'standard' is being met. Lack of applicability, which is when the patient does not meet the qualifying condition(s) is indicated with 'not applicable' (NA). Missing information ('insufficient data', ID) is recorded as affecting the application of the 'qualifier' (IDq) or the 'standard' (IDs). Instructional guidelines on the application of the two MAT_{AST} have been generated to help enable consistent interpretation and application. The MAT_{AST} is intended to be applied to case records and it may be used as a tool to estimate adherence to defined clinical guidelines.

2.4.5 Field testing

The Malaysia study field-testing took place over a period of 6 months between February 2006 to July 2006 in two study sites; a medical outpatient's clinic of an 800-bed state government hospital, Hospital Seremban and a health clinic located next to the hospital. MAT_{AST} developed was applied retrospectively by the investigator using hospital outpatient records and health clinic records. Subset populations of patients who were present during sessions of clinic were invited for a brief interview using MAT_{AST} to evaluate their other component of clinical management specifically delivery of asthma education. Feedback from the panels and results from field-testing produced the final MAT_{AST}.

The evaluation of delivery of asthma education was conducted by brief interview due to lack of documentation of such data in case note. In Malaysia, most of the asthma education is delivered by nurses or pharmacists, and documentation of patient education is not a common practice. Patient interview will provide more of such information. The brief interview conducted was guided by 9 criteria in MAT_{AST}. Eight of the criteria evaluate provision of information about asthma, treatment, and inhaler technique and self-management education. The other criterion is related to the delivery of asthma education which requires demonstration of inhaler technique by patients. The assessment is carried out by author who is a pharmacist with assistance by a nurse.

The UK study took place in a UK general practice in Glasgow. The MAT_{AST} developed was applied in the same way as Malaysia study, using UK general practitioner records. The final MAT_{AST} was also produced based on panels and results from field-testing as Malaysia final MAT_{AST}. **Appendix 2.3** compares the review criteria for final UK and Malaysia $MAT_{AST.}$

2.4.6 Evaluation of medication use and clinical management

The field-testing in Malaysia provides preliminary findings of the quality of medication use in Malaysia. The final MAT_{AST} (**Appendix 2.4**) was re-administered on findings from field-testing to describe the medication use.

2.4.7 Data Handling and Analysis

The Statistical Package for Social Sciences (SPSS v13) was used to report the percentage of applicability and adherence per criterion of both the UK MAT and Malaysian MAT. The applicability of the criteria was determined as the proportion of those criteria tested in all patients that met the qualifying statement. The adherence was reported as the number of "Yes" answers over the number of applicable criteria. As there was no previous study to set as guide, the categorisation was determined in accordance to those agreed by the UK expert group as follows:

≥ 70%	High level of adherence
50-69.9%	Intermediate level of adherence
< 50%	Low level of adherence

2.5 Study Results

2.5.1 Number of criteria in the MAT_{AST}

Based on literature appraisal of the GINA guideline, 31 criteria were proposed by the Malaysian study team, of which 26-criteria were selected after rewording and they went on to be applied in field testing**.** Table 2.1 and Table 2.2 show the modification of criteria and the processes which resulted

in 23 criteria being proposed for the final Malaysia MAT_{AST}. The BTS guideline was taken into consideration for development of 31 criteria but was considered by the expert panel as not directly suited to the Malaysia setting without either selective rewording and or exclusion of certain criteria. The final 23 criteria were decided for inclusion based on their validation in use as criteria that were judged to be both relevant and able to be tested from clinical records. The UK study team proposed 32 criteria based on literature appraisal of BTS/SIGN and GINA guidelines, of which 24 criteria were proposed for final MAT after panel review and field-testing. There were 14 similar criteria in common to both tools.

Table 2.1: Modification in Malaysia Draft 1 and Draft 2 MAT_{AST}

	Draft 1	Draft 2
No of original criteria in draft MAT_{AST}	**31**	**26**
No of criteria removed	7	6
No of criteria added	2	3
No of criteria modified on the criteria standard or qualifier	7	5
No of criteria without modification	17	15
No of review criteria in revised MAT_{AST}	**26**	**23**

Table 2.2: Number of criteria in the MAT_{AST} (Comparison between Malaysian and UK versions)

	Criteria rated valid by research group (Draft 1)	Criteria included in prototype at field testing (Draft 2)	Criteria in the final proposed MAT_{AST}
Malaysia MAT version	31	26 (after panel review)	23 (after field testing and final review)
UK MAT version	32	31 (after panel review & field testing)	24 (after final review)

2.5.2 Level of evidence

Appendix 2.3 shows the level of evidence of review criteria in Malaysia and UK $MAT_{AST.}$ The level of evidence of criteria in final MAT is as in **Table 2.3**. In both $MAT_{AST,}$ about 30% of total criteria are based on Grade A evidence. UK MAT_{AST} has higher percentage (54.2%) of criteria with no grade as compared to Malaysia MAT_{AST} (47.8%)

Table 2.3: Structure and levels of evidence of the final criteria in the Malaysian and UK version of MAT_{AST}

	No of criteria	Grade of criteria		
		Grade A	Grade B	No Grade
Malaysian MAT_{AST}				
General care	4	1	-	3
Inhaled steroids use	3	-	2	1
Add-on therapy use	6	5	1	-
Oral steroid use	5	-	2	3
Patient educational needs (from patient interview)	5	1	-	4
TOTAL	**23**	**7 (30.4%)**	**5 (21.7%)**	**11 (47.8%)**
UK MAT_{AST}				
General care	5	1	1	3
Inhaled steroids use	2	-	1	1
Add-on therapy use	5	4	1	-
Oral steroid use	7	1	-	6
Patient educational needs (from patient interview)	5	2	-	3
TOTAL	**24**	**8 (33.3%)**	**3 (12.5%)**	**13 (54.2%)**

2.5.3 Sample characteristic of Malaysian field-test sample

Table 2.4 describes the basic demographics of Malaysian field-test sample. The mean age of sample population was 49.9 (SD 13.9). More than 60% of the sample was female. The severity of asthma was categorised according to the prescribed medication. 61.7% of the participants were in Step 3 asthma. Less than 40% patients had a record of peak expiratory flow rate (PEFR) within the last 12-month period.

Table 2.4: Demographic characteristics of Malaysian sample population

	n=201
Age	
Mean year(SD)	49.9 (13.9)
Gender	
Male, n (%): Female, n (%)	66 (32.8) : 135 (67.2)
Ethnicity	
Chinese, n (%)	31 (15.4)
Malay, n (%)	83 (41.3)
Indian, n (%)	87 (43.3)
Level of airflow limitation	
Peak Expiratory Flow Rate > 80% predicted, n (%)	22 (10.9)
Peak Expiratory Flow Rate 60-80% predicted, n (%)	41 (20.4)
Peak Expiratory Flow Rate < 60% predicted, n (%)	4 (2.0)
Not recorded, n (%)	134 (66.7)
Level of severity*	
Step 1 (apparent*), n (%)	5 (2.5)
Step 2 (apparent*), n (%)	21 (10.4)
Step 3 (apparent*), n (%)	124 (61.7)
Step 4 or Step 5 (apparent*), n (%)	51 (25.4)
Preventive treatment prescribed	
Inhaled long-acting inhaled β_2 agonist	64 (31.8)
Oral theophylline	72 (35.8)
Oral leukotriene modifier	22 (10.9)
Inhaled Corticosteroids (ICS)	187 (93.0)
Low dose ICS	25 (13.4) [+]
Medium dose ICS	128 (68.4) [+]
High dose ICS	34 (18.2) [+]

** Apparent, as this classification was done according to the prescribed medication.*

[+] *Calculated based on n=187*

2.5.4 Clinical Management Evaluation

2.5.4.1 Level of adherence to medication use, general care of asthma and patient educational needs

General Care

Table 2.5 shows the level of adherence to 23 criteria related to asthma management. The overall mean level of adherence is 58.9% (95% CI 57.0-60.8). The record of inhaler technique assessment was adhered to in 26.4% although 96.1% patients claimed to have had their inhaler technique checked in the past 12 months. The adherence to prescribing of SABA was more than 80%. The monitoring and recording of PEF and FEV_1 was low at only 33.3 % (95% CI 26.8-39.9). None of the participants was prescribed oral steroids.

Medication Use

93% of patients were prescribed ICS. In all cases of patients who were documented to have uncontrolled asthma in the past 12 months and required preventive therapy, ICS was prescribed. The adherence to the requirement to initiate ICS at low dose was complied with in 71.4% (95% CI 52.1-90.8). In 96.8% (95% CI 94.3-99.3) cases, ICS was prescribed not more twice a day. There was a high level of insufficient data to assess the use of LABA as the initial add-on therapy to inhaled corticosteroid prior to use of alternative controllers. All patients who were prescribed LABA were also prescribed ICS. The adherence for use of LABA therapy in those prescribed high dose ICS however was only 55.9% (95% CI 39.2-72.6). Stepping down of therapy in controlled asthma was adhered to by 30.4% (95% CI 21.8-38.9). Oral corticosteroid was not used in any patients as preventive therapy. The dosage regimen of oral corticosteroids prescribed for acute exacerbation was 30mg daily in 65.9% (95% CI 51.3-80.4) and for 5 to 10 days in 97.6% (92.8-100).

Table 2.5: Level of adherence to criteria related to asthma management

	Criterion	Adherence		Applicability	ID
		n	% (95% CI)	n	n
	General care				
1	The record of PEF and FEV_1 in the period of 12 months	67	33.3 (26.8-39.9)	201	0
2	Prescription of SABA as reliever treatment	196	97.5 (95.4-99.7)	201	0
3	The record of assessment of inhaler technique in the past 12 months.	53	26.4 (20.3-32.5)	201	0
4	The record of review by doctor every 3 months.	157	78.1 (72.3-83.8)	201	0
	Use of inhaled corticosteroids (ICS)				
5	Prescription of low-dose ICS as the initial controller treatment (for patients who started on ICS within the past12 months)	21	100	21	0
6	The introductory ICS dose of 200 to 500 ug per day of beclomethasone or equivalent	15	71.4 (52.1-90.8)	21	0
7	Prescription of ICS not more twice daily.	181	96.8 (94.3-99.3)	187	0
8	Attempt to step down therapy in stable asthma	34	30.4 (21.8-38.9)	112	6
	Use of add-on therapy to ICS				
9	Prescription of LABA as add-on therapy to ICS before alternative options	13	8.0 (3.8-12.2)	162	137
10	Prescription of LABA simultaneously with ICS	64	100	64	0
11	Prescription of ICS more than 1000mcg/day with LABA	19	55.9 (39.2-72.6)	34	0
	Use of oral steroids				
12	Appropriate use of continuous oral steroids	0	0	0	0
13	Prescription of prednisolone 30mg for asthma exacerbation in the past 12 months.	27	65.9 (51.3-80.4)	41	0
14	Prescription for 5 to 10 days of prednisolone for asthma exacerbation in the past 12 months.	40	97.6 (92.8-100)	41	0
	Subtotal		**59.7 (57.2.0-62.1)**		
	Patient educational needs				
15	Assessment of inhaler technique by health professional in the past 12 months	148	96.1 (93.0-99.2)	154	1
16	Demonstration of satisfactory inhaler technique	70	45.2 (37.3-53.0)	155	0
17	Information received on triggers of asthma	90	58.1 (50.3-65.8)	155	0
18	Information received on benefits/precautions of treatment.	70	45.2 (37.3-53.0)	155	0
19	Information received on the importance of compliance.	114	73.5 (66.6-80.5)	155	0
20	Information received on follow up visit.	124	80.0 (73.7-86.3)	155	0
21	Information received on smoking cessation.	17	94 (83.9-100)	18	0
22	Self-management education provided to patient.	5	3.2 (0.4-6.0)	155	0
23	Provision of written asthma action plan.	2	40 (0-82.9)	5	0
	Subtotal		**57.8 (54.9-60.7)**		
	Total		**58.9 (57.0-60.8)**		

***SABA**: inhaled short-acting ß$_2$-agonist; **LABA**: inhaled long-acting ß$_2$-agonist; **ICS**: inhaled steroids; **ID**: insufficient data to answer the criterion; **CI**: confidence interval **Stable asthma is concluded based on record of good asthma control for at least 3 months.*

Patient educational needs

Patient educational needs were assessed using a brief patient interview. Despite adherence to inhaler technique assessment claimed by 96.1% patients, only 45.2% (95% CI 37.3-53.0) had satisfactory inhaler technique judged by pharmacist assessment. Adherence to the provision of information on follow up visit and smoking cessation was high. The provision of information about triggers of asthma and medication were both less than 60%. Provision of self-management education was only 3.2% (95% CI 0.4-6.0) and of these, less than 50% had a written asthma action plan.

2.5.4.2 Rank of adherence to asthma management

Table 2.6 shows the rank order level of adherence to 22 out of 23 criteria related to management of asthma. None of the participants was prescribed oral steroids, and so this criterion was excluded from this analysis. Out of 22 criteria, the level of adherence was high (>80%) in 8 criteria. The level of adherence was intermediate (50-79.9%) in 6 criteria (27.3%) and low (<50%) in 8 criteria (36.4%).

Table 2.6: The rank order of level of adherence to criteria

	>80% of adherence to criterion
1	Prescription of low-dose ICS as the initial controller treatment (for patients who started on ICS within the past12 months)
2	Prescription of LABA simultaneously with ICS
3	Prescription for 5 to 10 days of prednisolone for asthma exacerbation in the past 12 months.
4	Prescription of SABA as reliever treatment
5	Prescription of ICS not more twice daily.
6	Assessment of inhaler technique by health professional in the past 12 months (by patient interview)
7	Information received on smoking cessation. (by patient interview)
8	Information received on follow up visit.(by patient interview)
	50-79.9% of adherence to criterion
9	The record of review by doctor at least every 3 months.
10	Information received on the importance of compliance.(by patient interview)
11	The introductory ICS dose of 200 to 500 ug per day of beclomethasone or equivalent
12	Prescription of prednisolone 30mg for asthma exacerbation in the past 12 months.
13	Information received on triggers of asthma. (by patient interview)
14	Prescription of ICS more than 1000mcg/day with LABA
	<**50% of adherence to criterion**
15	Demonstration of satisfactory inhaler technique (by patient)
16	Information received on benefits/precautions of treatment. (by patient interview)
17	Provision of written asthma self-management plan.
18	The record of PEF and FEV_1 in the period of 12 months
19	Attempt to step down therapy in stable asthma
20	The record of assessment of inhaler technique in the past 12 months.
21	Prescription of LABA as add-on therapy to ICS before alternative options
22	Self-management education provided to patient.

***SABA**: inhaled short-acting ß$_2$-agonist; **LABA**: inhaled long-acting ß$_2$-agonist; **ICS**: inhaled steroids; **ID**: insufficient data to answer the criterion; **CI**: confidence interval*

2.5.4.3 Missing data or "insufficient data" (ID)

Malaysia study has 3 criteria in which there was missing information or 'insufficient data' (ID). (**Table 2.7**)

Table 2.7: Criteria with insufficient data (ID)

Malaysia Study	**n (%)**
Patient currently prescribed an inhaled steroid at a dose above 500mcg/day with a documented trial of inhaled LABA	137 (68.2%)
Stable asthma patient with evidence of a step down dose adjustment of 25-50%	6 (3.0%)
Patient with prescription for an inhaled short-acting β2 agonist.	3 (1.5%)

2.5.4.4 Adherence and applicability of common criteria

The draft tools used in field-testing were compared. Table **2.8** shows the adherence and applicability of the 11 criteria common to both tools. In the UK study there was high adherence (≥70%) to 8 out of those 11 criteria. The remaining criteria showed intermediate level of adherence. Only 50% of the patients requiring add-on treatment were prescribed LABA before adding another agent. In the Malaysian study, the level of adherence was high for 5 out of 11 criteria. Only about 3% of patients were provided with self-management plans and only 8% patients requiring add-on were prescribed LABA before adding another agent. In both studies, more than 80% of patients in both studies have

been assessed on inhaler technique by health care professionals e.g. doctor and pharmacist, but only half had been reassessed within the previous 12-months.

Table 2.8: Comparison of levels of applicability and adherence to the 11 criteria common to both the UK and Malaysian MAT_{AST}

	UK study		Malaysia Study	
Criterion	**Adherence (%)**	**Applic--ability (n)**	**Adherence (%)**	**Applic--ability (n)**
1. ICS prescribed no more than twice daily	100	51	97	187
2. Patient with prescription of SABA	96.1	51	97.5	201
3. LABA prescribed simultaneously with ICS	95.6	23	100	64
4. Assessment of inhaler technique by health care professional	82.4	51	96.1	154
5. Patient on high dose ICS with prescription for LABA.	77.0	13	55.9	34
6. Patient provided with a written asthma action plan	76.5	51	40.0	5
7. Patient provided with self-management education	76.5	51	3.2	155
8. ICS started on the dose of 200-800mcg/day*	70.3	41	62.5	24
9. Patient with indications for prescription of ICS	66.7	9	91.0	53
10. Assessment of inhaler technique within the last 12 months	56.9	51	45.5	154
11. Patient with add-on therapy to ICS that was prescribed LABA before adding other agent	50.0	4	8.0	162

2.6 Discussion

The study aimed to establish the quality of clinical management using a validated tool, MAT_{AST}. In order to be valid, criteria, within a MAT, should be evidence based, clear, precise and appropriate for the local setting[83].

2.6.1 MAT_{AST} validation

The evaluation was carried out using a tool, which uses process measures rather than the outcome measures. The process measures are only appropriate if there is evidence of associated improved outcomes[79].

In the UK study, the tool was built based on the recommendations from BTS/SIGN and GINA guidelines. As expected, some of the recommendations from GINA guidelines overlapped with others from BTS/SIGN guidelines. As this tool is meant to be tested for use in the UK, the research group decided that in the case of conflicting information between guidelines, regarding doses or time frames, the BTS/SIGN guidelines would over-ride GINA guidelines. In the Malaysian study, GINA was decided as the main guideline used in the practice of the management of adult asthma. The Malaysian Thoracic Society (MTS) guideline was considered at an early stage of design but was excluded later since the MTS guidelines have not been updated since 2002[57]. Consequently recommendations from GINA guidelines were used to develop the asthma MAT for use in Malaysia.

About 30% of the criteria in both final MAT_{AST} tools were developed from GINA or SIGN/BTS guidelines recommendations with Grade A evidence, which implies that the criteria are based on convincing data from well-designed randomised controlled trials. There were about 50% of the criteria in both tools that were developed from recommendations which are not assigned with a level of

evidence. These criteria were included because they are essential in the management of asthma. An example of a criterion in this category is the assessment of inhaler technique. Although no grading was assigned to this criterion, the panel and research group agreed that it should be included into the tool and a timeframe of 12 months was agreed, as the criterion has a potential to exert a strong impact on asthma outcomes and is seen as an essential part of practice. There was a demonstrable 60% similarity between the tools in terms of the criteria developed.

Findings from this study very much depend on the amount of documentation of information documented and reliability of the information documented. Inaccuracy in documentation or missing information may lead to underestimation or overestimation the standard of practice. Studies in the past have suggested that inconsistency between performances documented in medical record documentation in the outpatient setting and the actual performance of preventive health care services[84]. In our study, missing information is recorded in our tool, allowing poor documentation in practice to be identified. This minimised the underestimation of practice.

Our medication assessment tool (MAT) has been developed based on evidence based recommendations from the GINA guidelines, was validated using a consensus method and produced an audit tool highly comparative with one developed for a UK setting. High adherence to the criteria in the tool is therefore expected to indicate good levels of practice.

2.6.2 Evaluation of asthma management

Data from our study does depend on correct and accurate documentation of the care provided to patients. The current evaluation relied on retrospective data, thus restricting applicable of assessment tool to subset of information available in the case note. The data on drug prescribing is however usually present in case note.

Data from field-testing provided preliminary findings of the quality of medication use in Malaysia. This study has demonstrated an intermediate level of quality of medication use among asthma patients attending outpatient clinics against the GINA guideline.

2.6.3 Use of Inhaled Corticosteroids (ICS)

Inhaled corticosteroids (ICS) are the mainstay treatment of asthma. They are recommended for adult asthmatics who required maintenance therapy with a controller. The field-testing in Malaysia showed intermediate to high levels of adherence in the use of ICS in terms of appropriate indications for ICS initiation, and for the initiating dose of ICS and frequency of ICS use. Short acting β_s agonist (SABA) was also prescribed to almost all patients with asthma according to guidelines.

The use of preventive treatment was high with more than 90% adherence to prescribing inhaled corticosteroids in this current study, despite reports about under-prescribing of ICS in patients with chronic asthma in Malaysia[85]. A recent population-based survey of three large cities in Malaysia, which formed part of a larger study of Asia-Pacific countries, showed that only 10% of all asthmatic patients surveyed and only 17% of the severe persistent asthmatics among them were prescribed an ICS. This perhaps reflects a local higher awareness of preventive medication use in asthma treatment with the growing publications regarding inhaled corticosteroids use. Addition to that, the study site used in our study, Hospital Seremban is an urban teaching hospital. The access to medical resources and dissemination of information among practitioners could lead to the higher awareness of preventive medication use.

Overuse of ICS however could be an issue based on our study. Stepping down of asthma treatment among stable asthma patients is however not commonly done in

patients in our study. Undoubtedly, good control of asthma is difficult to achieve and achievement in control can lead to doctors' and patients' reluctance in modifying treatment. Attempts to adjust ICS dose or other preventive therapy however have been shown to be able to maintain asthma control through appropriate monitoring[86].

2.6.4 Use of Long Acting Beta Agonist (LABA)

LABA was recommended as the first choice of add-on since 2004. Our findings however were not able to establish whether LABA was consistently the first choice of add-on therapy due to the insufficient data. There was however evidence that LABA is underused in Malaysia compared to the UK. Only 8% of applicable patients were prescribed LABA as add-on before addition of other agents as compared to 50% in UK.

In addition to that, the use of LABA among those on high-dose ICS was only below 60%. This is not surprising because LABA is expensive and available mostly for private pay patients. In the MoH hospitals, LABA can also be available for patients, but restricted by specialist prescribing only. In other words, patients would only be receiving LABA if is prescribed by respiratory specialist. With the constrained of budget in MoH, specialists would normally reserve LABA use for selected patients only. LABA is not available in the health clinic due to restricted budget and non-availability of specialist in health clinic. Alternative add-on therapy other than LABA was therefore prescribed in health clinic.

The evaluation however showed that all patients prescribed LABA were prescribed ICS. The adherence to use of LABA in patients with high dose ICS is about 55% indicating need to encourage use of LABA among this group. Despite limitations in availability of LABA in some settings in Malaysia, it is important to note that LABA offers considerable benefits over use of high dose ICS in terms

of safety and effectiveness[87]. The use of LABA should therefore be encouraged especially among patients with high dose ICS to reduce the risks associated with ICS. The high cost and prescribing restriction would still be a barrier of LABA use in asthma treatment as compared to other options for add-on therapy such as oral theophylline and additions to the dose of inhaled corticosteroids.

2.6.5 Inhaler Technique

The assessment of delivery of inhaler technique was evaluated based on brief interview and patient demonstration of inhaler technique. The level of satisfactory inhaler technique is generally poor despite the assessment of patients' inhaler technique once every 12 months. This suggests that assessment of inhaler technique once every 12 months is not adequate. A more regular assessment is necessary along with re-enforcement of inhaler technique training. Furthermore, our findings also indicate the need to enhance asthma education. Patients should be assessed on their educational needs regularly to ensure they have received information that is necessary and important about their condition and medication.

2.6.6 Asthma Self-management

This study suggests a lack of establishment of self-management as part of management in Malaysia, compared to the UK. Self-management appears not to be commonly offered to patients. Similar findings have also been reported by Asthma Insights and Reality in Asia-Pacific (AIRIAP)[88]. It is uncertain whether this is caused by patient's reluctance in accepting self-management or is the result of health professionals' reluctance to promote self-management. Self-management is proven to be beneficial in reducing morbidity. It empowers and prepares patients to manage their condition and is recognised as one of the most important components of chronic care and disease management[89, 90]. It is therefore necessary to establish the barriers to introduce self-management as part of the overall care strategy. This finding suggests a need of further study to understand the reasons

behind poor adoption of training in self-management and to identify the barriers to self-management education in Malaysia.

2.6.7 Record Documentation

Our study depends greatly on the completeness of the medical record. It is noted however that there are about 32% records with documentation of inhaler technique assessment despite that inhaler technique was reported by more than 90% patients to have been undertaken by their health carers . This could indicate a mismatch in documentation and actual performance in care. This is not surprising because studies in the past have suggested mismatch of medical record documentation and actual performance of health care services.[84, 91, 92].Another explanation affecting the mismatch might be a tendency for patients to please the care providers. This mismatch probably included an underestimation of actual performance. This highlights the need to have a standard recording system, which allows systematic documentation. A standard recording system would allow a structured review of a patient's outcome, such as peak expiratory flow rate and asthma control, to be carried out. Such structured review would require and so potentially promote improved documentation[93-95].

2.6.8 Study Limitations

Studies in the past have shown that criteria developed by expert panels could be not be operationalised, were unreliable or not useful. Field-testing should therefore be carried out to obtain good measures of assessment[96]. In our study, peer review group and field-testing were used to validate the tools. In the UK study, field-testing was carried out simultaneously with peer review. Some of the findings (e.g. 12 months as an adequate time-frame for the asthma review and modification to the wording of statement), encountered by the investigator during the field-testing phase were similar to the feedback obtained from the peer review group. Our experience suggests that the design of this study should have included

the field-testing phase after the feedback from the peer group. This would have allowed most of the refining of the MAT to be done before field-testing.

The audit has undertaken patient's demonstration of inhaler technique as one of the evaluation of clinical management of asthma. In current audit, the evaluation of inhaler technique is assessed subjectively without any form of checklist. Although two well-trained assessors (a pharmacist and a nurse) were used in the determination of correct inhaler technique, variation of the level of satisfactory inhaler technique could still be present. Hence, it is recommended that a checklist of inhaler technique to be developed in support of the MAT_{AST} to evaluate inhaler technique.

In the Malaysia study, there remained many modifications, inclusion and exclusion to MAT after field-testing. This is believed to be affected by the composition of the panel included in the study. In the Malaysia study, the members of panel had 8 doctors including 2 specialists. This may have introduced bias as criteria selection may be based on individual practice rather than being objective and according to the guideline. In our study, the biases are minimised by having a separate peer review group from UK consists of senior pharmacists with experiences in asthma management. It is however, recommended that the panel review in future study should also considered a multidisciplinary team in order to minimise the professional bias.

Ideally the evaluation of clinical management to better reflect the asthma management in Malaysia should be carried out on a larger sample and at multiple centres. This was however impossible due to the restriction in access to medical records in other centres. Our field testing was performed on medical records of 201 patients from a hospital outpatient clinic and health clinic in Seremban. Sample size of 200 patients was chosen to allow for rapid data collection within 6 months but large enough to be representative. If the clinical audit time is too long, the data may no longer be credible.

Re-application of final MAT_{AST} on field testing data is used in our study to understand the management of asthma. The reapplication of MAT_{AST} is still possible in our study because the draft MAT_{AST} used in field testing contains most of the criteria that were selected for final MAT_{AST} and alteration of criteria was minimum. The current findings reflect only the management of out-patient clinics in a district area, which may not be extended to the whole of Malaysia. It is however important to note that medication use especially LABA between different out-patient clinics in Malaysia could still be similarly affected by the restriction in prescribing of LABA in the public healthcare system, that is by the Malaysia Ministry of Health. Studies in future could be extended to other institutions and clinical settings to confirm this influence as well as to investigate the variations in quality of management especially medication use between institutions.

The correct application of the tool requires an investigator who understands technical terms (e.g. short-acting β_2-agonist, leukotriene receptor antagonist) and the equivalence of doses between different ICS comparing to beclomethasone. This makes the tool unsuitable for used by untrained persons. Health professionals such as medical practitioners, pharmacists and nurses, who have a good understanding of clinical management, especially medication use and guideline recommendations, will likely face fewer challenges in using the tool. In our study, field-testing was carried out by only one investigator at each site of the study. Inter-rater reliability was therefore not possible to be tested at this stage but needs to be addressed in future studies.

2.7 Conclusion of Chapter 2

The tools developed in this study have been validated using a combination of systematic review of guideline and peer review. Tools developed have

successfully assessed the quality of prescribing, thus allowing identification of potential areas in need of improvement. The tools are also highly compatible and allow comparison against practice at the level of international standards. The preliminary findings in the asthma management in Malaysia outpatient settings found gaps in the management of this condition. The findings have allowed identification of key areas such as self-management education in Malaysia, which require further research.

Chapter 3

3 Malaysian Patients' Views on the Clinical Management and Asthma Self-Management Concept

3.1 Introduction

Asthma causes significant morbidity, mortality and healthcare cost in many countries. Many reasons explain the poor control of asthma. These include inadequate access to support from health professionals, poor asthma education and poor compliance[97, 98]. Good asthma control requires not only the appropriate use of medication, but also co-operation from patients to ensure their medication is used correctly. Patients' inclusion and active participation are critical in quality improvement to ensure efforts in healthcare delivery result in better outcomes and respond to patients' needs.

3.1.1 Values of Patients' Views on Healthcare

The most discussed relationships between patients and healthcare delivery is patient's medication-taking behaviour. Patient's compliance to medication provided by healthcare providers has been a concern for many years in the management of chronic diseases. Despite variation in compliance assessment methods, the compliance rate of long-term therapies has been estimated to be approximately 50%[99]. Compliance among asthmatics was reported to be 17% to 90%[100]. Non-compliance to asthma medication may lead to treatment failure and uncontrolled asthma. Other less common consequences of non-compliance are overuse of medication. Overuse of the asthma medication was estimated in a study to affect 2-7% of patients, which often leads to undesirable side effects[101].

Patients' compliance to their medication has been described as a complex and multifactorial behaviour (**Table 3.1**). Patients' beliefs, experiences and cultural differences are known significantly to influence patients' attitudes to their medication and overall clinical management[102-107]. Exploration of patients' experiences and views on the clinical management and treatment would be valuable information for healthcare providers and planners in the improvement of healthcare delivery.

The concordance initiative is a different model of the patient-prescriber relationship as compared to compliance or adherence. Compliance is defined as 'the extent to which the patient's behaviour matches the prescriber's recommendations'[108]. In contrast, concordance refers to negotiation process between prescribers and patients[109]. The negotiation provides opportunity for discussion of patients' concerns about medication and preferences for management. This two way communication strives for a more equal relationship in therapeutic decision making. The concordance processes which acknowledge the patient's role in the decision-making about their management foster the world wide emphasis on patient centred care[110]. Adherence has been defined as the 'the extent to which the patient's behaviour matches agreed recommendations from the prescriber'[111]. Adherence has been adopted by many as an alternative to compliance, usually refers to the degree to which a patient correctly follows medical advice including medicine taking[111]. Adherence attempts to emphasise that the patient is free to decide whether to adhere to the doctor's recommendations.

3.1.2 Measures of Patients' Views

One of the methods to evaluate patients' views is to obtain measures of patients' preferences[112]. Patients' preferences refer to patients' views about the clinical management and their ideas of what should occur in the healthcare system. Many

terms are used to describe the preferences for healthcare services. The terms include the patients' expectations, needs and priorities. Two distinct meanings have been discussed in relation to patients' preferences. The first concept is "normative expectations" which try to explain patients' beliefs in terms of what should happen in health care[113]. Second, "predicted expectations" are beliefs of what will actually happen irrespective of whether that is what they want from the health care system.

Qualitative and quantitative research methods can be used to evaluate patients' preferences. Qualitative methods such as patient interview and focus groups are useful to explore patients' needs and allow the generation of a range of patient views. Focus groups also encourage sharing and reflection generates patient views and their experiences. Quantitative methods on the other hand, are used when ranking, rating or voting on a range of preferences is needed. Methods used include surveys and consensus methods, with scale responses that range from "extremely important" to "not important" or "most preferred" to "not preferred". These quantitative methods will first require generation of a range of ideas or "options", thus limiting the preference frame.[13] Quantitative methods are only useful if the range of options or preferences are well studied and encompass all the possible options. Quantitative methods benefit from prior generation of preferences from qualitative research.

Table 3.1: Factors affecting Non-Compliance [114]

Category	Factors
Patient-centered factors	Demographic Factors: Age, Ethnicity, Gender, Education, Marriage Status
	Psychosocial factors: Beliefs, Motivation, Attitude
	Patient-prescriber relationship
	Health literacy
	Patient knowledge
	Physical difficulties
	Tobacco smoking or alcohol intake

	Forgetfulness History of good compliance
Therapy-related factors	Route of administration Treatment complexity Duration of the treatment period Medication side effects Degree of behavioural change required Taste of the medication Requirements for drug storage Unhappy clinic visits
Healthcare system factors	Lack of accessibility Long waiting time Difficulty in getting prescriptions filled
Social and economic factors	Inability to take time off work Cost and Income Social support
Disease factors	Disease symptoms Severity of the disease

3.2 Study Purpose

A survey was conducted in 1996 among 100 asthmatics at the medical out-patient clinic of this study hospital. Overall levels of satisfaction with counter services, nursing services, and doctors' services were more than 90%. Despite high satisfaction, little is known of how much these patients value the process of delivery of asthma care. It is possible that patients have clear expectations and preferences about characteristics of the healthcare system. These views on the clinical management may differ between different subgroups of patients. In the planning of provision of pharmaceutical care for asthma patients, insights into patients' experiences and views on the current healthcare service are important. With the increasing focus on patients' self-care in chronic disease, there is also a

need to understand patients' willingness and readiness to participate in self-management schemes.

An exploratory study was thus performed to characterise the types of ideas held by asthma patients towards their clinical management and their views on the concept of a personal plan to guide self-management. The study aimed to establish patients' needs in asthma management, with the use of two qualitative methods; namely patient interviews and focus groups.

3.3 Study Aim and Objectives

The aim of this study is to explore patients' views on the asthma management and the self-management concept.

The objectives of this study are:

1) to develop and validate interview schedules
2) to explore patients' experiences, feelings, behaviours and views on the clinical management of their condition

3) to explore patients' views of the asthma self-management concept

3.4 Study Design

3.4.1 Population Sample and Setting

The study was performed at the hospital out-patient medical department and health clinic at Negeri Sembilan, Malaysia. Two qualitative methods, involving

semi-structured interviews and small focus group discussion were used in the study.

The patient sample was selected from patients diagnosed with asthma who attended the medical out-patient clinic at Hospital Seremban and the Seremban Health Clinic who met the following criteria;

Inclusion criteria

- Patients receiving regular asthma therapy who have attended the medical out-patient clinic at Hospital Seremban and the Seremban Health Clinic for more than 1 year.
- Patients aged 18 years or above.
- Patients who are able to communicate in English, Malay or Chinese (Mandarin and Cantonese)

Exclusion Criteria

- Patients with concomitant conditions affecting airway or breathing difficulties such as chronic obstructive airway disease, tuberculosis, lung cancer, cardiac failure etc.
- Patients with speech or hearing impairment or difficulties

Recruitment to the study was carried out from 3 sessions of the clinic a week for 12 weeks. Eligible subjects were invited for either an interview or focus group.

The study intended to sample 40 patients; 10 patients for semi-structured interviews and 30 patients for 3 focus groups. Focus groups were planned to be done with three ethnic groups; 10 patients in each focus group. The final number

of patients recruited however was only 20 patients, which will be explained later in the chapter.

3.4.2 Ethical considerations

The research project was approved by the International Medical University Research and Ethics Committee. Hospital and Health Clinic Seremban gave approval for the conduct of patient interviews and focus groups in the study. Informed patient consent was obtained beforehand.

3.4.3 Design of the Interview Schedule

Draft 1 interview schedule **(Appendix 3.1)** was developed to guide the interviews and focus groups. The schedule was designed by the author and reviewed by the research team. The research team consisted of a hospital pharmacist, a respiratory consultant and a psychologist. The questions were developed to explore patients' knowledge of asthma disease and medication, their experiences with asthma medication, their management and their views of care provided by the doctors, nurses and other health professionals.

The final interview schedule **(Appendix 3.2**) consists of a list of open-ended questions related to the subjects below: -

- Knowledge about asthma disease and medication
- Experiences, feelings and attitudes towards medication, general management and asthma education

- Views on general management and asthma education
- Attitudes and views towards asthma self-management

A Malay version of the interview schedule was also prepared using back translation technique to guide the interviews and focus groups. The original

questions (English language) were translated to Malay language by the author. Another independent translator was used for back translation of Malay language to English language. **(Appendix 3.3)** The original questions were then compared to back-translated English questions by author and another reviewer. Questions were accepted if both the English questions were deemed to have similar meaning and texts used reaching at least 90% similarity.

3.4.4 Semi-structured interviews

Semi-structured interviews were carried out with eight of the patients recruited by two interviewers. The first interviewer is the author herself who is a pharmacist, while the second interviewer is a clinical psychologist. Both were trained in qualitative study. Second interviewer had experiences in conducting in-depth interviews in the past.

Patients were briefed on the nature of the study and consent was obtained before the patient interviews. Facilitators also explored the participants' awareness of self-management. The interviewer explained to the participants the purpose of self-management and the written action plan. An example of an action plan was shown whenever patients showed difficulty in understanding the self-management concept. The interviewer then explored the views of participants about the self-management concept. Each interview took approximately 30 to 45 minutes. All interviews were audio-taped.

Interviews were conducted using either the English or Malay version of the interview schedule based on the spoken language used by patients. Eight patients undertook semi-structured interviews were conducted (two in English and the remaining six interviews were performed in Malay). Both interviewers had satisfactory command of English and Malay.

3.4.5 Mini focus group discussion

Three focus groups were conducted with three ethnic groups; Chinese, Malay and Indian patients. Each focus group was led by two facilitators and consisted of 4 participants. The author as one of the facilitators raised questions, as outlined in interview schedule that was used for the semi-structured interviews. All participants in the focus groups were encouraged to participate by sharing their experiences and expressing their views about the issues discussed. The second facilitator is a trained respiratory nurse, whose role in focus group was to ensure patient participation in the discussion. Similar methodology and format was used for each focus group. The discussions were video recorded. The focus group discussions with Malay and Indian participants were conducted in Malay. The discussion with Chinese participants was conducted in Chinese dialect, Cantonese. Both facilitators involved in the focus group had good command of Malay and were fluent in Cantonese.

3.4.6 Data Analysis

Semi-structured interviews were transcribed by author. The data analysis was conducted by author and a facilitator of interviews through systematic examination for themes using the framework approach developed by Ritchie and Spencer[115, 116]:-

1) Familiarisation: this stage involves author to read transcripts or notes, in order to familiarise the data collected. During this process, the texts were unitised and concepts were highlighted and labelled. This process allows abstraction and conceptualisation (coding) of data.
2) Developing Coding. Coding took place in s few stages to allow categorisation of information. Based on this initial analysis, coding was developed. Subsequently, coding took place by constantly comparing the current transcript with previous ones to allow the emergence of categories. As the coding proceeded, additional categories of information may emerge. Further

analysis of emergent concepts and themes and their relationships to earlier data was examined.

3) Draw Conclusions from the Coded Data. . This process involves data re-arrangement, grouping and interpretation of categories of information.

Appendix 3.4 presents the transcripts and coding of related data of interviews performed with eight patients.

Focus groups were conducted in Malay and Cantonese. Interviews were not transcribed. Data analysis was conducted using the following steps:

- Familiarisation of interview data via listening and viewing of tapes. At this stage, the author obtained a feel for material as a whole and began the process of analysis.
- Data were analysed and themes were generated based on the descriptive statements or issues raised by participants.
- Relevant data was translated and transcribed into theme categories.

Data from semi-structured interviews and focus groups were interpreted as a whole. It involved the describing of the range of experiences, and establishing the connection between views and experiences.

3.5 Study Results

3.5.1 Participants' Characteristics

Participants demographic are described in **Table 3.2**. From 62 patients attending follow up at the out-patient medical department and health clinic and invited to participate, eight patients agreed to participate in the semi-structured interview and 12 patients agreed to participate in focus group discussion. The participants

consisted of 14 females and six males, with a mean (SD) age of 50 (10) years (range 33-65). Eight of the participants were Indians. Half of the participants had intermittent asthma. One participant owned an action plan (verbal) and four participants (20%) owned a peak flow meter.

3.5.2 Themes and Patients' Responses

A total of 14 categories were identified from interviews and transcripts are presented in **Appendix 3.5**. The categories are *nature of asthma, signs and symptoms of asthma exacerbation, causes and triggers of asthma, impact of asthma, concerns about asthma, sources of asthma information, experiences with medication, views on asthma medication, responses to asthma medication, signs of asthma worsening (signs requiring medical attention), experiences with current management, views on current management, views on asthma education by health professionals* and *views on asthma self-management.*

Table 3.3 to 3.9 shows the interpretation of patients' responses

Table 3.2: Participants' Characteristics (n = 20)

Age, mean (SD) [range]	46.9 (9.8] [range 33-65 years]
30s	6 (30%)
40s	6 (30%)
50s and over	8 (40%)
Gender	
Female	14 (75%)
Male	6 (35%)
Ethnic	
Chinese	4 (20%)
Indian	8 (40%)
Muslim	8 (40%)
Duration of asthma, mean (SD) [range]	15.9 (10.6) [range 3-35 years]
Less than 5 years	2 (10%)
6-20 years	11 (55%)
More than 20 years	7 (35%)
Severity of asthma	
Mild asthma	4 (20%)
Intermittent asthma	10 (50%)
Severe asthma	6 (30%)
Peak flow meter owner	4 (20%)

Table 3.3: Patients' Understanding of Asthma

Interpretation of patients' responses	Description of patients' responses
▪ No indication of misunderstanding of the nature of asthma. ▪ Inflammation basis of asthma was never mentioned by any of the patient in the interview.	*Asthma is a common disease.* *The lung is narrowed when one has asthma.* *Asthma is not contagious* *Asthma control depends on lifestyle* *Asthma management requires self-control.*
▪ Variation of the common signs and symptoms of asthma among patients ▪ Patients in general are able to recognise their own signs and symptoms of asthma	*Wheezing, coughing, difficulty in breathing and increased phlegm production* *Chest discomfort which is described as 'tight' and 'congestion'*
▪ Patients were able to recognise the triggers of asthma. ▪ Ability to recognise triggers or causes are based mostly on previous experiences of asthma attack. ▪ Common triggers are haze, food and daily activity.	*Certain food include fruits and vegetables and drink* *Occupational causes e.g. exposure to certain substances during work* *Dust, Inherited, Haze/ Smoke, Pet e.g. Cat, Weather, Exercise and Activities including household activities* *Stress and anxiety*

Table 3.4: Impact of asthma

Interpretation of patients' responses	Description of patients' responses
▪ Most patients have restricted lifestyle (food habit) and activity is restricted due to asthma. ▪ Minority of patients has to change job due to asthma.	*The need to be very cautious with food and drink and has to stop taking favourite food or drink* *Unable to do exercise and heavy work.* *Unable to enjoy social activities e.g. traveling* *Unable to perform household activities e.g. gardening and cleaning houses* *Job has been affected*
▪ Asthma raised concerns among patients. ▪ Need to look into improve awareness of triggers and signs of asthma exacerbations,	*Recognised that asthma attack can be severe and may lead to hospitalisation and death.* *Failed to prevent asthma due to lack of awareness of the trigger of asthma.* *Failed to recognise the necessity to seek medical care when experiencing a severe episode* *Asthma is inherited by children.*

Table 3.5: Sources of Information

Interpretation of patients' responses	Description of patients' responses
▪ Doctor could be a more common source of information as compared to nurse, pharmacist and media	*Doctor* *Nurse* *Pharmacists* *Newspaper/Television*

Table 3.6: Patients' Experiences with Asthma Medication

Interpretation of patients' responses	Description of patients' responses
▪ Benefits of medication were experienced by patients with minimal complaints of side effects ▪ Compliance to medication is recognised by patients as important for better asthma control. ▪ Some patients have adjusted their own regimen based on their side effect and control. ▪ Patient wants to self-manage with medication. ▪ Patients have preferences for selected type of inhalers.	*Asthma medication comprised of reliever and preventer.* *Asthma attack can be prevented by complying with medication.* *Asthma medication reduced inflammation, cough, sneezing, emergency visit and improved breathing and sleep.* *Asthma medication has caused side effects such as tiredness, tremors, mouth ulcer and dizziness. Side effects occurred when usage of patients' medication i.e. salbutamol is high and when using nebuliser.* *Able to enjoy food e.g. fruits after taking medication.* *Able to resume some social activities and exercise after taking medication.* *Information provided with asthma medication include how much to take and when to take.* *Patient experienced variation between different brands of inhaler containing the same medication.* *Metered dose inhaler is difficult to use due to the breathing coordination.* *Turbohaler works better and faster. It is also easy to use and convenient as* compared to tablet. *Patients adjust prescribed medication or use prednisolone for better asthma control.*

Table 3.7: Patients' Views about Medication

Interpretation of patients' responses	Description of patients' responses
▪ Some patients still found inhaler to be troublesome as compared to tablets. ▪ Some patients have preferences for selected inhalers or brand of inhaler, which contains same medication. ▪ Experiences with medication could lead patient to think that he/she can treat those who have similar signs and symptoms using similar method.	*There is no advance in the treatment of asthma.* *Side effects were of less concerned because medication was effective and occurred when using high dose of medication.* *Medication can be recommended and shared with family member when they have signs and symptoms, which are believed to be asthma.*

Table 3.8: Patients' Responses to Asthma Exacerbation

Interpretation of patients' responses	Description of patients' responses
▪ Patients understood that reliever and medical attention are required for asthma exacerbation.	*Used reliever e.g. β_2 agonist or Symbicort® during asthma exacerbation.* *Used home nebuliser* *Seek medical attention e.g. private clinic doctor or hospital clinic.*

Table 3.9: Signs of asthma worsening (signs requiring medical attention)

Interpretation of patients' responses	Description of patients' responses
▪ Poor recognition of signs and symptoms of asthma worsening (signs which requires medical attention)	*When cough and wheezing have worsened or are severe.* *When peak expiratory flow rate dropped.* *When 2 to 10 times use of reliever failed to control the symptoms*

Table 3.10: Patients' Experiences with the Clinical Management

Interpretation of patients' responses	Description of patients' responses
▪ Patients' satisfaction was associated with access to healthcare services and communication with healthcare provider especially doctor. ▪ Medication use was assessed at periodic interval. ▪ Patients required doctors' feedback and information to increase their confident in their care and medication. ▪ Contact with pharmacists was limited among these patients. ▪ Concerns with information and advice by healthcare provider.	*Patients were satisfied with quick access of healthcare service.* *Patients were satisfied with their asthma management* *Patients were satisfied with doctor who discussed their condition.* *Information given from healthcare provider especially doctor was brief on some occasions. Patient left with uncertainty and may ignore the severity of disease.* *Patients felt that doctors who did not obtain much information from them are not as knowledgeable as the specialist.* *Patient was not aware of the role of pharmacist in asthma management.* *Patients were not confident with health professional's advice or information.* *Inhaler technique was checked occasionally.* *Medicine used (injection) and test done during admission caused fear.*

Table 3.11: Patients' Views on Clinical Management

Interpretation of patients' responses	Description of patients' responses
▪ Patients' preferences correlate strongly to experiences. ▪ Patients would like to have quick access to healthcare service and better communication with doctors.	*Patient preferred doctor to decide their care, due to perception that doctor will be unhappy if patient decide himself.* *Patients did not expect changes in care as management remained similar to patient.* *Patients preferred to be seen by the same doctor at follow up.* *Patients preferred to self-manage because patients know better about themselves.* *Patients preferred doctor to find out more about patient's progress and give feedback about their condition.* *Patients preferred to keep their own medical record* *Patients preferred to have priority of service to be given to asthma patient*

Table 3.12: Patients' Views on Asthma Education

Interpretation of patients' responses	Description of patients' responses
▪ Variation in educational needs among patients. Some patients find group discussion beneficial. ▪ Patients who were well controlled and those who have received education in the past may be less likely to accept education interventions.	*Patients were reluctant to participate in asthma education activities* *Patients did not need asthma education because asthma is well controlled and was taught in the past.* *Group discussion is beneficial because it allows sharing of information.* *Asthma education should include information about exercise, inhaler technique, monitoring of own condition and updates about asthma disease and medication.*

Table 3.13: Patients' Views on Asthma Self-Management *(After description of an example of written asthma self-management plan)*

Interpretation of patients' responses	Description of patients' responses
▪ Experiences with self-management in small group of patients were on use of peak flow for monitoring and adjustment of dosage regimen during exacerbation. ▪ Patients' confidence with self-management requires doctor support and training via education intervention. ▪ Some challenges with delivery of self-management include; ability to understand the action plan,	*Patient has experienced with self-management via verbal instruction, Patient has past experience with peak flow monitoring. Failure to continue the recording of peak flow due to lack of support from health professional* *Does not have knowledge about peak expiratory flow rate (PEFR).* *Prefer to see doctor when unwell* *Would like doctor to decide if self-management is good for them.* *Peak flow monitoring enhanced patient's confidence of their condition.* *Reluctance and lack of confident in asthma self-management because of the complexity and poor reading ability.* *Confident with self-management if training is provided*

3.6 Discussion

In this present study, we were able to elicit patients' views their attitudes on their treatment, healthcare providers and self-management; these are considered separately below:

3.6.1 Medicines Use

All patients recognised that a reliever is needed during asthma attack. Compliance to regular medication is described as 'to *be needed to prevent asthma'*. Most patients recognised that non-compliance to their medication leads to uncontrolled asthma. The concerns and fear associated with uncontrolled asthma is part of the motivation for compliance.

Inhaler devices play an essential role in the management of asthma. Some patients have faced difficulty in using the metered dose inhaler (MDI) and discussed the preference for *Turbohaler*. This is not surprising as the *Turbohaler* has been found to be easy to use and preferred by patients in comparison with MDI[117-120] .The discussion on the inhaler reflects that patients' preferences need to be included in the inhaler device selection. These preferences are very much dependent on the convenience and usability of the preferred inhaler. Although the association of patient device preference with clinical outcomes has not been proven, the correct use of inhaler is important in determining the success of treatment.

3.6.2 General care

The most prominent issue raised by participants with regards to their general care is access to the healthcare service. The delay in treatment that can occur especially during the asthma worsening stage has raised concerns and dissatisfaction among some participants in the study. This is not surprising, as waiting time has been an on-going problem in the Malaysian healthcare system. A

study done in a teaching hospital in Malaysia showed that waiting time influenced customers' satisfaction. The factors that contributed to the long waiting time included the long registration time, insufficient number of counter service staff and insufficient number of doctors[121]. Improvements in waiting time will require policy review and human resource management and is beyond the control of healthcare providers. The importance of asthma management however should not be undermined especially the care during asthma exacerbations. Patient education on self-management, which may reduce immediately the pressure for medical attention may minimise unnecessary hospitalisation and urgent visits to the physician, thus also reducing patients' dissatisfaction of having to wait for the treatment.

3.6.3 Asthma Educational Needs

There are seven important items of information that are recommended to be provided to asthma patients (1) nature of asthma, (2) nature of treatment i.e. differences between "relievers" and "controllers", (3) use of inhaler devices, (4) prevention of asthma exacerbations, (5) signs that suggest asthma is worsening and actions to take, (6) monitoring control of asthma, and (7) recognition of asthma exacerbation [7, 57].In our study, participants had a relatively good understandings of the nature of asthma; the triggers of asthma; and the nature of treatment and symptoms of asthma exacerbation. There were inconsistent ideas about the signs of asthma worsening. Most concerns with asthma morbidity and mortality were associated with the inability to recognise the signs of asthma worsening.

Triggers, causes, signs and symptoms of asthma as well as reactions to asthma attack were described mostly based on patients' previous experiences. This suggests that patients have learned to live with their condition. Information about monitoring of asthma was not discussed; however there were indications that very little was known about spirometric monitoring.

In our study, doctors are seen as the main source of information. The roles of nurse and pharmacist in asthma education are not widely recognised in our study; possibly due to their lack of involvement in the direct asthma care. Although participants did not discuss the expected roles of the nurse and pharmacist, it is crucial to ensure that healthcare members provide consistent information regarding patients' condition and medication.

Multimedia such as television and radio also played a role in asthma education. None of the interviewees however mentioned about reading materials in any form such as leaflets and booklets about asthma. This suggests lack of use of written materials among the health professionals or poor literacy/health literacy among some participants.

3.6.4 Relationships with Healthcare Providers

Participants' experiences with the health professionals suggest poor partnership between healthcare providers and patients. Patient's beliefs and concerns affect patient's compliance. A good relationship between doctor and patient is therefore essential in the asthma management.

Findings reflect the need to improve the communication process between the doctor and patient. Relationships with other healthcare providers are weak due to their limited involvement in asthma care in Malaysia.

Experiences with doctor showed the lack of open communication such as provision of information, promotion of active conversation, provision of encouragement, and identification of patient asthma status and concerns. Some patients would like to participate more in the discussion regarding their management. Studies have shown that patients who are more active in the process of decision making of their management tend to be more committed to

the management plan and to treatment[122]. The positive doctor-patient interaction has also been associated significantly with a higher degree of drug compliance[123].

The communication process should therefore be strengthened to include information on the treatment target, self-management skills, and treatment effects including the perceived side effects, fears and concerns. Educational materials in any form such as booklet, leaflet and action plan should be used to support this process. This process is described as concordance which should take patient's needs into consideration to reach a better understanding and agreement in the management[109, 124].

3.6.5 Views on Self-Management

Patients in our study described asthma as a condition which requires self-control in various aspects of life, including modification in daily activities and lifestyle. Similar behaviour has also been described in another study involving older asthma patients[125].

In asthma studies the process of learning to manage asthma has been described as a lengthy process and has led to confidence in the asthma diagnosis and self-management skills. Self-management is one of the core components of the current standard of care for many chronic diseases include asthma[126-128]. Despite initiatives among some participants, the experiences with self-management programme were limited to monitoring of peak flow at home and a verbal asthma action plan. Participants who had experience with peak flow monitoring showed supportive attitudes towards the self-management. This is not surprising because the ability to interpret peak flow expiratory rate (PEFR) potentially provides them with a sense of control over their disease.

Self-management offers many benefits and its introduction into management improve asthma outcomes[129, 130]. In our study, we explore patients' views on self-management. The views and perceptions of patients of the concept of self-management are limited in general. It is not surprising as patients have no prior knowledge and experience of concept of self-management. On introduction of the concept of self-management, the acceptability and readability to the self-management plan were inconsistent. Reasons of non-supportive attitude towards self-management among the participants were illiteracy, complexity of self-management plan and lack of support from their physician. These reflect the lack of confidence among this group of participants.

Written action plans for asthma are an important component for asthma self-management. Evidence has shown that the presence of an action plan can be a major protective factor against death from asthma[131]. The illiteracy and complexity could be overcome by developing asthma action plans, which are suitable for, and tailored to, a specific population[132].

In promotion of self-care or self-management in chronic illnesses, patient's participation in their own monitoring and management is necessary[90]. It requires initiative and confidence, which is demonstrated by some of the participants in the study through their medication taking attitude, and initiative in getting information from health professionals. Patient's contributions to their own management however can only be optimised if patients have clear understanding of their condition, what to monitor and how to manage (act).

3.6.6 Study Limitations

Our sample of participants was small, but data saturation was used as the guiding principle during the data collection. Recruitment of patients into the study has been difficult due to the reluctance among patients to be subjected to the semi-

structured interviews and focus groups. This has been reported in similar study among an Asian population[133]. It could reflect the lack of exposure of patients to the interview processes.

In our study, there is no formal evaluation of compliance. The reasons for non-compliance however were discussed and linked to the level of patients' understanding of the rationale of treatment. These patients were more likely to comply with their medication. Our study therefore has not been able to elaborate on issues related to non-compliance. This may also reflect that patients who were not compliant or do not believe in their medicines may not be likely to subject themselves to study.

Attitudes or behaviours related to the cultural differences have been suggested to affect patients' attitudes to chronic disease management[105-107]. Themes associated with cultural differences however did not arise from the interviews and focus groups. This could be due to the small sample size or the selection bias affecting the types of patient recruited into this study. Most of the patients recruited in the study have positive attitudes towards their medication. This reflects their trust towards their asthma management to a certain extent, thus making them less likely to have wide differences in attitudes towards medication. Complementary medication was not discussed in our study, which will require investigation in future.

3.7 Conclusion of Chapter 3

Despite a small sample size, the study has provided insights into the patients' experiences and the views of asthmatics treated in out-patient clinics. A majority of these experiences and views are not far from previous studies. The findings from this study allowed identification of some of the current gaps in the management, and establishment of the unmet needs (**Table 3.14**) that would aid

development of a pharmaceutical care model for asthma management in Malaysia.

Table 3.14: The Unmet Needs raised from Interviews and Focus Group

Unmet Needs
Poor access to health service
Lack of information gathered and provided by doctor
Problems with handling inhaler and preferences for selected inhaler
Lack of emphasise on asthma education by other health care providers
Lack of self-management training.
Inadequate support in self-management
Lack of patients' participation in their own management
Lack of supportive use of spirometer in self-monitoring
Low literacy, low health literacy
Concerns with complexity of action plan
Lack of pharmacist and nurse involvement in asthma management and education
Lack of other forms of educational support such as group counseling, brochure
Adjustment of regular medication when asthma is controlled or to reduce side effects

Chapter 4

4 Medication Use and Quality of Care at Out-patient Settings: a Critical Review

4.1 Introduction

The effective management of asthma involves complex processes, which are under the influences of multiple factors. These factors can be clinical, psychological and sociological in nature. Psychological factors are increasingly recognised to be important in the successful management of asthma. These factors are the patient's beliefs and attitudes towards disease, treatment, overall management and healthcare providers. Despite the limited capacity of healthcare providers to intervene on the impact of psychological factors, the factors are important because they have been shown to influence medicines-taking behaviour.

The clinical factors rely on the patients' status of control of their condition i.e. patients' asthma severity and existence of concomitant conditions, and the active roles of clinicians and healthcare team. These factors include the effective use of medication and monitoring of the patient's response to management via subjective and objective monitoring of patient satisfaction and clinical outcomes. Patients have largely played a passive role in the clinical control factors. Clinical outcomes such as asthma control, quality of life, and airway function are by far the most easily measurable parameters describing asthma.

Sociological factors include demographic and socio-demographic variables of the patient, physician and healthcare system that may influence asthma management. These factors are under the control of society at large, the patients, the clinicians and/or the healthcare system. An insight into these factors by means of needs

assessment allows healthcare professionals to design management strategies likely to be the most successful.

4.2 Assessment of Needs

'Need' in general has been described in several ways; normative need, felt need, expressed need and comparative need. Normative needs are the healthcare needs defined by health professionals, administrators or experts in relation to norms or a desirable standard[134]. Felt needs are the perceived needs by individuals in regard to the health services available. The expressed needs arise from the demands of felt needs of demands of felt needs. It is the expression of patient's behaviour in response to their felt needs. Comparative needs refer to the generalisation of needs to a population or characteristics of those who have received a service[135].

Pharmaceutical needs assessment is a systematic approach to identify the gaps in asthma management as well as in the health needs and the care needs of a population. This is often referred to as an evaluation of the "gap" between practice and guidelines and other "unmet needs" of patients including the psychological factors. Guidelines are mostly based on a mix of commonly encountered clinical practice under the principles of evidence based medicine. By definition guideline adherence represents quality of healthcare delivery that is targeted at general common decision-making practice and tends to be limited to those issues that are evidence rich in the clinical trial literature. Much clinical decision-taking has to be in a climate of uncertainty because of patient individuality and the limitation that many specific issues are not informed by good published evidence.

Methods of pharmaceutical needs assessment encompass different research methods in determining health needs namely; audit process, direct observation, questionnaires, consultation with persons in key positions and/or with specific knowledge, review of relevant literature, individual and group interviews.

Clinical audit is defined as "*the systematic and critical analysis of the quality of clinical care. This includes the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient"*[136]. It is a method to establish the extent of actual practice in comparison to best practice.

In the evaluation of pharmaceutical needs described in this thesis, two methods are used; an audit of asthma management and a qualitative assessment of patients' views by mean of semi-structured individual and group interviews. This chapter critically appraises the findings of the audit and qualitative assessment.

4.3 Unmet needs of asthma management at out-patient settings in Malaysia

Despite development of asthma guidelines at national and international level to support the clinical practice, present studies clearly indicate gaps in current asthma management. These gaps highlight the shortcomings of current clinical practices, particularly in medication use, asthma education, communication with doctors, and self-management training. These gaps are summarised in **Table 4.1**.

4.3.1 Patient Satisfaction

None of the patients from audit and qualitative study generally expressed displeasure with the healthcare system although there were preferences in healthcare delivery, most notably on the better communication with doctor and quicker access to healthcare services. No prominent issue was raised around asthma control with medication use. This could reflect patients' acceptance of the incurable nature of the disease and their medication use or it could be explained by lack of critical awareness.

This doctor patient communication is shown to be highly correlated with patient satisfaction with health care services. An effective communication is recognised as requiring two-way communication. It is important to ensure that the communication not only focuses on the need to elicit information from patients, but also on the provision of information and addressing patients' concerns and fears. Studies have shown improvement of health outcomes comes with effective communication processes between doctors and patients[137]. Effective communication may also provide a greater emotional support to the patient; thus achieving higher patient satisfaction.

Accessibility to healthcare raised by patients is an issue, which continues to require careful planning of the structure of the healthcare system. Training of patients in response to asthma exacerbation reduces patients' concerns and fears and improves their confidence in self-management, which may reduce patients' need for immediate medical attention.

Table 4.1: Care Issues arising from Pharmaceutical Needs Assessment identified by Quantitative and Qualitative Evaluation of Asthma Management

Issues raised from audit of asthma management (n=201)	Issues raised from patients from semi-structured and focus group (n=20)	Pharmaceutical needs
Underuse of LABA	Poor access to health service	Review of medication use e.g. high dose ICS
Inadequate review to step down therapy in stable asthma	Lack of information gathered and provided by doctor	Review of medication of patients with stable asthma
Inadequate monitoring and documentation of inhaler technique and objective investigations such as PEFR	Problems with handling inhaler and preferences for selected inhaler	Improve communication process between healthcare providers and patient
Poor inhaler technique	Lack of emphasis on asthma education by other health care providers	Taking patients' preference and ability to use inhaler in consideration of choice of inhalers
Insufficient education on triggers of asthma and medication benefits	Lack of self-management training.	Improvement in the monitoring and documentation of PEFR
Inadequate training in self-management	Inadequate support in self-management	Strengthening of education, assessment and documentation of inhaler technique.
Underuse of asthma action plan	Lack of patients' participation in own management	Improve involvement of other healthcare professional i.e. nurse and pharmacist in asthma education.
	Lack of support in self-monitoring using spirometer	Strengthening provision the educational information on triggers, medication benefits, signs and symptoms of asthma attack, function of asthma monitoring and management of asthma exacerbations.
	Low literacy or low health literacy	Training and support in self-management with support of action plan
	Concerns with complexity of action plan	Simplification of action plan
	Lack of pharmacist and nurse involvement in asthma management and education	Improvement in patients' access to healthcare service especially during asthma exacerbation
	Lack of other forms of educational support such as group counseling, brochure	
	Adjustment of regular medication when asthma is controlled or to reduce side effects	

4.3.2 Misalignment of Asthma Management with GINA guidelines

Findings in relation to medication prescribing by physicians are mostly obtained from the audit. The adherence to prescribing of SABA as reliever is high. Patients' interviews consistently reported the use of reliever during their asthma attack also reflects the routine prescribing of reliever to asthma patients.

The use of ICS was found in almost all patients with persistent asthma; indicating a high level of adherence to first-line preventer in GINA guideline. In comparison to the GAPP survey, our audit showed a higher use of prescribing of anti-inflammatory drugs[138]. This perhaps reflects the improvement in prescribing with the increasing recognition of ICS role as first-line asthma therapy in the GINA guideline.

Underuse of LABA prescribing was found in our audit. Increasing the ICS dose, and addition of sustained release theophylline, were the preferred step-up approaches among patients who were otherwise uncontrolled with the standard dose ICS.

Addressing the adherence to guidelines is an important step to maximising patient outcomes. In a review of 31 surveys, at least 10% of respondents of 28 surveys were not familiar with the guideline recommendations[139]. Many factors were found as barriers to adherence to guideline literature including lack of awareness of the guidelines, a lack of familiarity with the guidelines and a lack of agreement with the guidelines. Various beliefs lead to the disagreement with guidelines e.g. the differences in interpretation of the evidence, lack of applicability of guideline to the practice population and beliefs that guidelines reduced autonomy and do not worth the patient risk, discomfort or cost. In a Malaysia nationwide self-completion survey published in 2007, more than 70% of physicians claimed familiarity with asthma clinical practice guidelines[140].

The familiarity with the guideline could be the reason for high adherence in prescribing of SABA as reliever and ICS to long term prevention in our audit. The underuse of LABA was more likely to be due to the unavailability of LABA in some settings, and limiting the prescribing rights of LABA to specialist only, rather than the lack of awareness. These barriers are common in most Ministry of Health settings in Malaysia due to the control of high cost LABA prescribing. Most clinicians recognise cost as one of the primary constraints in the implementation of clinical guidelines[140].

Although there is clear benefits in terms of clinical outcomes to the use of ICS/LABA combinations in comparison to monotherapy use of moderate to high dose ICS, the cost differences between these approaches have been reported to be highly variable depending upon the type of devices and the required dose[141].

Combinations of ICS/LABA in a single inhaler such as Symbicort® and Seretide ® are available in Malaysia. The use of the ICS/LABA combination in single or separate devices is however not investigated in our audit. The use of LABA and ICS in a single inhaler is known to improve adherence to long-term therapy. The use of a single inhaler also ensures that ICS is not omitted from treatment. There has been reported evidence that a single inhaler can be more cost-effective than separate inhalers[137].

Cost effectiveness and cost-saving data are increasingly available from more developed countries such as the UK. These results are difficult to generalise across countries especially developing countries. The variations in healthcare costs and treatment cost, which contributes to economic evaluation, affected generalisation and comparisons of assessments across borders. An economic evaluation of the asthma medication would be worth investigation, to confirm the cost effectiveness of use of LABA.

In view of need to maximise the clinical benefits of LABA within the current limitations in practice, strategies to improve prescribing should be focused on selected populations of asthmatics who would benefit most from LABA. The use of LABA should be emphasised among patients taking high dose ICS especially with risk factors for complications such as osteoporosis. Patients using a combination of LABA and ICS in separate inhalers should be reviewed to improve compliance by changing into single inhaler whenever possible.

4.3.3 Elements of asthma education

The audit revealed a low to moderate adherence to provision of educational needs particularly benefits and precautions of medication and triggers of asthma. The patients' responses showed patients' understanding about asthma, particularly on asthma triggers, medicines use and drug adverse effects. The common trigger of asthma mentioned by patients was weather related change. This is consistent with a previous study conducted and by observation that hospital admissions are highest at rainy seasons[18, 142]. The levels of patients' understanding were associated with their experiences, which could indicate that patients learn through experiences and that they must just not rely on formal asthma education. However, although knowledge about asthma could be gained from experiences, patient education remains essential to avoid misconception about asthma. Compliance to medication and inhaler technique is also known to improve with patient education[143].

Poor inhaler technique was found in our audit with reported satisfactory inhaler technique among 45% patients. Similar problems were reported in 2004, which found inefficient use of MDI technique among 42% patients[144]. Different levels of inhaler handling skills are required for different types of inhalers. Studies have shown that inhaler technique has been best achieved with breath-actuated inhaler (Easibreathe and Autohaler, followed by Accuhaler). Metered dose inhaler (MDI) was only effectively used in 79% patients, after education and further

reinforcement[145]. Difficulty in handling MDI was expressed by patients in our study. Reinforcement of education from time to time would be needed to improve inhaler technique. Patient's preferences and ability to use inhalers should be carefully considered to help improve the drug delivery.

Compliance was not evaluated in our studies, but the importance of compliance was described by patients as '*necessary to control disease'*. This belief suggests patients' positive attitudes towards medication taking, although there was indication of non-adherence to medication taking upon those achieving asthma controls. Similar non-adherence practice has been reported in a Global Asthma Physician and Patient (GAPP) survey undertaken in 2007. Findings from the GAPP survey reported switching asthma medication or being less compliant, skipping doses and stopping medications entirely.

4.3.4 Incorporation of asthma self-management into asthma education

In our studies, self-management training was consistently shown to be lacking from the remit of patient education interventions. Inclusion of self-management skills into patient education has been shown to improve clinical outcomes and is suggested to be a component of care by GINA guideline[146]. Self-management involves a patient-centred approach which requires the patient's ability to handle the interpretation of asthma symptoms, changes in medication and lifestyle changes. Support of self-management training therefore would need to include knowledge based patient education and skills in recognition of progressive asthma and the management of the clinical signs of changes in the state of control of the condition. Such training would also be beneficial for our patients in this study, who reported inconsistencies in the patients' responses of signs of asthma worsening or signs requiring medical attention.

4.3.5 Format of asthma education

In current asthma care, individual counseling is more commonly offered at hospital out-patient and health clinics. The variety of patients' educational needs clearly indicated the need to expand the formats of asthma education to meet individual patient's style of learning. Group discussion was raised by patients as an option due to perceived benefits of information sharing. This preference was based on their experiences from the study i.e. focus group interview, although it was not the intention of investigator to make the session an educational session. But clearly, some patients found interaction with patients with similar conditions allows much learning to occur from each other's experiences and views. Support of education and training using written materials should also be considered as a means to improve patients' learning.

4.3.6 Multidisciplinary approach in asthma care

Patients reported that doctors are the main source of information and education. This is consistent with findings from the GAPP survey, which reported involvement of physician in education among 86% of participants[138]. In the United Kingdom (UK), asthma nurses now have a more distinctive role in asthma care according to a survey published in 2007[147]. The survey found about 66% of nurses was also involved in autonomous provision of follow-up asthma care and confirmation of diagnosis. The roles of pharmacists are limited to counseling for patient with acute and chronic illness[148, 149]. Randomised trials on the extended role of pharmacists are limited[139].

The greater involvement of the doctor with patients is most likely the reason for their recognition in asthma education. Physicians' involvement in asthma education however is restricted by the limited consultation time. This reflects the need for expansion of roles of other healthcare providers in asthma education. In

current practice, pharmacists' roles are not only poorly recognised by patients in asthma education, but in the general management of asthma.

This finding is not surprising as there was only a limited role for pharmacists in asthma in the study sites in Malaysia. Generally the shortage of pharmacists has been the main challenge for expansion and improvement of pharmaceutical care services in the public sector for many years[150]. The implementation of hospital compulsory service for pharmacy graduates and readjustment of remuneration in 2004 to support staff retention and career development, has significantly improved the pharmacist capacity in healthcare delivery and allowed the expansion of pharmaceutical care services in Malaysia. One of the efforts to improve pharmacists' contribution to medicines management since then was the establishment of Medication Therapy Adherence Clinics (MTAC) in selected Ministry of Health hospitals. The MTAC was developed in 2004 for areas including diabetes mellitus, renal transplant, human immunodeficiency virus/ acquired immunodeficiency syndrome and warfarin with the need to deliver pharmaceutical care to patients in critical areas of treatment[150]. The MTAC for respiratory patients was initiated in 2007 to one hospital, Hospital Malacca.

In view of the likely expansion of the pharmacists' contributions into asthma management in the near future, focus has to be placed on forming a framework which would guide the delivery of pharmaceutical care and help establish the roles of pharmacists in the multidisciplinary care framework.

4.4 Challenges in addressing pharmaceutical needs

4.4.1 Health professionals acceptability and readiness to deliver the concept of self-management

There are number of foreseeable barriers to the delivery of self-management as a component of asthma care. Although there were increasingly convincing items of evidences of self-care or self-management, there is lack of implementation of such a model in Malaysia. The lack of generic chronic disease self-management model would mean such development and implementation would be the first of its kind in Malaysia and certainly in asthma care.

Based on the experiences in self-management in other countries, the successful implementation leading to positive patient outcomes depends on several factors. Self-management relies on information given by clinicians, thus the acceptability is very much dependent upon the clinicians' perceptions, knowledge and skills with self-management. A study performed in the United Kingdom based on views from general practitioners, nurses and patients on the concept of self-management concluded that health professionals were unenthusiastic with the concept. Most concerns from clinicians were associated with patients' ability and capacity to self-manage[151]. Clinicians were not convinced that patients would be able to make appropriate choices in their own management. Additionally, the amount of consultation time was probably too limited to support self-management services. There was also concern that self-management may create an impression of "overconfidence" among patients that they can rely on self-management plan and not return for regular review by professionals[151].

Undoubtedly, the lack of self-management practice and research in Malaysia indicates that guided self-management plans were seen as a low priority in asthma management. The priorities of asthma management could be more focussed on detection or diagnosis of asthma, treatment, education and monitoring to ensure

asthma is well controlled. Furthermore, the limited experience in not only asthma self-management, but also self-care practice in chronic disease management generally will mean that there is continuing lack of experience in the self-management concept. There is no existing model of care including supporting educational materials, which can be used as a generic framework development of a formal self-management education in Malaysia. Development and implementation of self-management in Malaysia at this point would therefore be seen as the first of its kind and certainly the first in asthma care.

The success of self-management also relies very much on patients' motivation to be involved in such practice. Although there is evidence of patients' acceptance upon knowledge of the beneficial effect of self-management, their ability and capability remain to be questioned. Much more work such as simplification of action plan has to be done by healthcare providers to ensure that education intervention is designed to cater for the patients' needs across multi-ethnic and multi-linguistic communities.

4.4.2 Recognition of relevance by other healthcare providers in asthma management

To address the difficulties of preventing and managing chronic disease, a collaborative multidisciplinary approach has been recognised as a possible approach to better health outcomes. The roles of the nurse in asthma management in very well established in developed countries such as UK.

The involvement of pharmacists in clinical pharmacy services began in the 1990s. As other developed countries such as UK and USA, the patient-centred clinical services began in hospital sectors with patient counseling and therapeutic drug monitoring (TDM) and total parenteral nutrition (TPN) services[152]. Despite less than 20 years since the development of clinical pharmacy practice, pharmaceutical care has now dominated the picture of professional pharmacy

practice in Malaysia. The practice has now expanded at ward and ambulatory care levels and focusing on direct patient care.

Although pharmacists are capable of implementing services which deemed to be important in the practice and beneficial for patients' health outcomes, the provision of care requires clinical pharmacy skills and sufficient training in the relevant medical specialties. Additionally, a clear framework for advancement of pharmacy practice is essential as a basis of care and is needed to ensure the practice meets the minimum standard of care that would be of benefits to the patient outcomes.

Although a multidisciplinary approach is discussed in most models of chronic disease management, there has been variation of doctors' acceptability of the roles of pharmacists in the management of patient care. Literature evidence that although physicians appeared to be comfortable with pharmacists providing a broad range of services, they would prefer pharmacists not to be involved in direct patient care[153]. The roles of pharmacists could vary between countries and also healthcare systems, and certainly worth investigation before implementation of any pharmaceutical care model.

Pharmacist' attitudes could be another barrier to overcome. It should not be a surprise to see reluctance among some pharmacists to accept the changes in the profession. When there are pharmacists who are enthusiastic with the paradigm shift of the pharmacy profession, there could always be pharmacists who prefer to work within their "comfort zone", thus the reluctance to change. The lack of confidence and experience in the new areas of practice could partly explain this professional response to new opportunities.

4.5 Conclusion of Chapter 4

The high healthcare burden of asthma indicates the need to investigate the gaps in current asthma management. Needs assessment has been used to identify the gaps in asthma management, and thus to identify areas of care for improvement. Current attempts at improving the management of asthma should focus on increasing roles of other health professionals including pharmacists, improving communication between doctor and patient, and increasing patients' as active participants in their own self-management via self-management training.

It is important to note that needs assessment in our studies were done using a clinical audit and patient interviews. Other needs assessment method such as direct observation may add ideas to care needs. This method is not possible due to limited access to healthcare system.

Chapter 5

5 Development and validation of a pharmaceutical care model for long term management of asthma

5.1 Introduction

An effective asthma management plan requires safe and appropriate use of the asthma medication, frequent monitoring of the patient's condition as well as the patients' participation in their own treatment. The success of a management plan greatly depends on the healthcare professionals' effort. Pharmaceutical care models have been developed in many countries to describe the expanding roles of health professionals, particularly the pharmacists', in patient centred care[154]. Those models developed have been shown to improve objective and subjective outcome measures in populations with chronic conditions such as hypertension, cancer, asthma and hypercholesterolaemia and population groups such as geriatric patients[155-157].

5.2 Pharmacists' Roles in Asthma Management

Pharmacist can play many roles in the management of asthma. Studies of pharmaceutical care services delivered by pharmacists in asthma management have mostly been performed in the community setting. In Indiana, a non-controlled study conducted by an independent pharmacy reported improvement in the quality of life and a decrease in the usage of urgent health care services at one-year post-intervention[158]. There was a reduction of the number of hospital admissions and visits to the emergency department by 77% and 78% respectively.

Positive impacts on the quality of life, peak flow, clinical symptoms and asthma severity have also been reported at 12 months in studies of community pharmacy based pharmaceutical services conducted in Germany[67, 159]. A significant improvement was also observed in humanistic outcomes i.e. self-efficacy, patient knowledge, adherence to medication and inhalation technique following pharmaceutical care services being involved. In another study performed in New Zealand involving 100 asthma patients, a community pharmacy asthma management programme was reported to identify 431 drug related problems with an average of 4.3 per patient[160]. Some 66% (285 out of 431 problems) of those drug related problems were compliance-related, while 19.3% (n=83) of the problems were medication choice, dosage or dosage form related, 10.7% related to inappropriate or incorrect choice or use of device and 2.6% (n = 11) related to documented or suspected adverse drug reactions or drug interactions. Pharmacist interventions within 6 months of consultation including revision of asthma action plans, referral to health professional with pharmacists' recommendations and medication counseling have estimated to resolve between one-quarter and three-quarters of their medication-related problems. Consistent with studies in Germany, there was also improvement in the quality of life among the intervention group.

In Finland, the therapeutic outcomes monitoring (TOM) programme concept was tested in a study conducted in 2000[161]. The training of self-management through pharmacists' regular review in this study was found to improve asthma symptom measures i.e. mucus excretion and daytime wheeze. Close to 80% of patients reported improvement in one or more asthma symptom at 12-month post intervention. There were significant improvement in the symptom scores of daytime wheeze ($P < 0.001$) and mucus excretion ($P < 0.05$). Change in their daily asthma medication was reported in 57% (n=16) patients during the intervention. The findings consistently showed positive effect through pharmacist interventions.

The TOM programme concept was also published in 2001 in a study conducted in Denmark. In Denmark, the community pharmacy based TOM programme was reported to improve asthma symptom status, days of sickness, and quality of life[162]. The TOM programme was implemented using a structured, systematic outcome improvement processes based on the principles of pharmaceutical care and co-operation between pharmacists, patients, and physicians. There were improvements in asthma symptom scores ($p = 0.024$) and inhalation technique ($p = 0.0001$) from baseline at 6 months of study. At 12 months of study, means asthma symptom scores for TOM patients significantly improved from baseline by 0.47 (23%; $p = 0.004$). The increase of peak expiratory flow rate by 1% at 12 months however was not significant (0.098). The study supported the value of collaboration between health care professionals in primary care to improve the quality of care for patients with asthma.

The impact of a community pharmacy based asthma management scheme was also evaluated in Australia[163]. The findings of this study reported significant reduction in the proportion of intervention patients who were classified as having severe asthma from 87.9% to 52.7% ($p<0.001$). The proportion of patients using combination of reliever and preventer medications with or without a LABA as opposed to reliever only improved by 7.5% (95% CI 1.8% to 9.5%; $p = 0.02$). There were also significant improvements in the intervention group as compared to the control group in relation to adherence to preventer medication (OR 1.89, 95% CI 1.08 to 3.30; $p = 0.03$), quality of life (difference -0.23, 95% CI -0.46 to 0.00; $p = 0.05$) and asthma knowledge (difference 1.18, 95% CI 0.73 to 1.63; $p<0.01$). The proportion of intervention patient with correct inhaler technique increased significantly by 48.6% (95% CI 39.2% to 58.0%; $p < 0.001$). There was no significant change in spirometric values in both control and intervention groups.

Review of these studies allows description of processes of patient care necessary to formulate, plan, and implement a model of asthma care. There is no consistent

definition of "model of care". In general, it is described as a multifaceted concept, which defines the way health services are delivered by a unit or to a population of patients[164]. A model of care should be developed using multidisciplinary effort, incorporating the best available evidence from patient-centred research with the needs and preferences of individuals, communities and health professionals.

5.1.2 Consensus Methods

Consensus methods are structured facilitation techniques that explore consensus among a group of experts to generate plausible views on a particular topic. They are increasingly used in practice and in surveys to formulate clinical guidelines, to establish priorities in service provision and to select desirable characteristics of review criteria. Several consensus techniques exist, including the nominal group technique, consensus development panel, Delphi technique, RAND appropriateness method, and iterated consensus rating procedures[72].

The nominal group technique involves a structure interaction of a group of experts. It usually involves participants in expressing or discussing their individual views on a topic. In the process of discussion, differences of views are explored before individual rates or ranks of agreement are obtained. The outcomes of the rating and ranking processes are fed back to the participant group. Consensus techniques have been used to establish appropriateness of clinical guidelines, to develop quality indicators and to identify priorities.

The Consensus Development Panel involves a group of participants, normally experts by certain definitions, to discuss evidence of the topic of discussion[72]. This method collates the judgments of individuals based on majority voting. A Consensus Development Panel provides opportunities for debate and discussion.

The Delphi technique is defined as "a method of systematic solicitation and collation of the informed judgments on a particular topic" [165]. It is a structured process which involves the collection of expert opinions or responses in two or more formal rounds or cycles to achieve a group consensus. The questionnaires used in Delphi survey are used to obtain ideas or opinions of participants, who are mainly experts of issues. At the second and further rounds of the survey, feedback is provided to participants for expression of their agreement to the new or revised statements. Therefore, the participants' expression from the second round is exposed to the influence from their colleagues' opinions. Traditional Delphi uses open-ended questions to collect information in the initial round. A modified Delphi technique can be administered using a structured instrument[166]. The use of structured instrument at initial round serves as a platform for future questionnaire development used in subsequent iterations.

The RAND appropriateness method combines the Delphi and nominal group techniques. The RAND method is commonly discussed as a consensus approach for selection or prioritisation of review criteria of interventions or guidelines. The approach requires a systematic literature review of the condition to be assessed, the generation of indicators based on this literature review, and the selection of expert panels. Participants are asked to read the evidence found from literature review, rate the indicators generated, discuss and re-rate the indicators in a face to face discussion. The consensus findings thus comprise a mixture of expert views and evidence. The use of 'non-experts' or naïve participants in Delphi technique is possible. But it is not possible for our survey because the uncertainties and lack of experiences in the context of consensus may affect the findings.

The Delphi technique which was chosen for use in our study is widely used to develop diagnostic criteria, prioritise quality indicators, gather opinions and develop research agendas[167]. It has the advantage of reaching participants from disparate geographical areas and different healthcare professionals within the healthcare system. It does not need participants to meet up, yet it allows collection

of a large response by mail. Increasingly nowadays, electronic communication is used to facilitate the collection and compilation of survey findings. Use of electronic data collection in Delphi surveys is also a flexible means to support changes of statements and suggestions to be reported to participants. The anonymity of the method also provides free will in the process of feedback and rating[168, 169].

5.3 Study Purpose

The aims of the research were to develop a validated model of care for long term management of patients with asthma in out-patient setting, and to establish the agreed roles of pharmacists in the asthma management.

5.3.1 Study Aim and Objectives

The objectives of this study are:

1) To develop a validated multidisciplinary model of care for asthma management based on our previous quantitative and qualitative works as well as a literature review

2) To establish the agreed roles of pharmacists using a consensus method

5.4 Study Design

5.4.1 Ethical Considerations

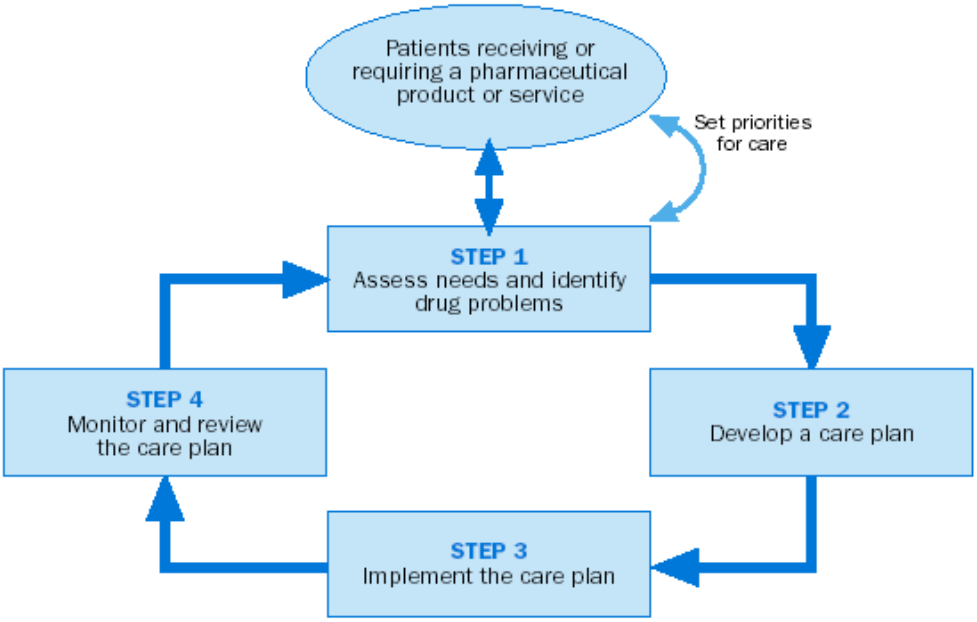
Approval to undertake the survey was granted from the International Medical University Research and Ethic Committee (**Appendix 5.1**).

5.4.2 Identification of activities within multidisciplinary model care and pharmacists 'contribution in the asthma management

A search was performed using MEDLINE and Embase databases from 1994 to 2007 to identify published papers related to the development of models in asthma care. Combined keywords used include "asthma and pharmacist interventions", "asthma and care model" and "asthma and pharmaceutical care model". The search identified 41 published papers, of which 11 were found to be useful[161, 170-179]. The papers were reviewed by author based on overall quality, control group used, health outcomes reported and relevance to pharmacy practice. The relevance to pharmacy practice was determined by descriptions of the pharmaceutical care service or interventions in the published papers.

The systematic review approach to delivery of pharmaceutical care was used as the prototype model for the designing of our pharmaceutical care model. Based on the published work, previous work on pharmaceutical needs, and international guidelines of long term management of asthma, a draft pharmaceutical care model for asthma management (**Figure 5.1**) was developed. Evidence of pharmacists' contribution in asthma management was also documented (**Appendix 5.2**). **Table 5.1** summarises the pharmacists' contributions in asthma management derived from the review.

Figure 5.1: The systematic review approach to delivery of pharmaceutical care



5.4.3 Questionnaire Design

A questionnaire to obtain consensus on the pharmaceutical care delivery processes in a multidisciplinary asthma care model was developed and the potential roles of pharmacists within the model were identified. Face and content validity of the questionnaire were established through email discussion by a panel comprising three pharmacists and a respiratory consultant. The questionnaire was piloted and refined in a field-testing involving 5 pharmacists and 5 medical practitioners. The refined questionnaire (**Appendix 5.3**) was used for validation.

The refined final questionnaire consists of 57 items. Thirty two (32) of the items relate to assessment, management, patient education and monitoring activities within the model of asthma care. The remaining twenty-five (25) items comprise potential pharmacists' activities in asthma management. Seven point Likert scales were used where appropriate (1=''strongly disagree'' and 7=''strongly disagree'').

5.4.4 Delphi Surveys

This research adopted maximum of three rounds of Delphi surveys. For fast and convenient data collection, the surveys were hosted on a web-based survey platform (www.surveymonkey.com). Each item is attached to a seven point Likert scale. Empty columns were provided in the web-based surveys to allow participants to provide opinions on the items generated.

Participants for survey were selected from a broad range of expertise. A total of 93 pharmacists and medical consultants from 9 institutions were invited into the survey. The panel was selected to represent both geographic diversity and a broad range of expertise on the basis of their area of specialisation, prior experiences with asthma patients and clinical work with asthma patients. Medical consultants panel were respiratory specialists, family medicine consultants and senior medical officers with experiences in treatment of asthma patients. Pharmacists invited were clinical pharmacists working in general medicine wards and pharmacists with at least 3 years experiences in managing asthma patients. All participants were invited through an email invitation letter with an attached URL link to the web-based survey.

The surveys took about 9 weeks from mailing date of round one to receipt of all responses from round three. Each round was opened for a pre-specified time of 2 weeks to permit time for responses.

The Delphi rounds may take as many as six rounds before a consensus is achieved[180]. The number of Delphi rounds in our survey was fixed at three at the outset. Although more than three rounds can be offered, too many rounds can be time consuming and may lead to fatigue among respondents[181].

A total forty (40) participants; 19 pharmacists and 21 medical consultants responded to the first round of Delphi survey (Delphi 1). Items, which failed to achieve consensus, were reviewed by the author, refined and rated in the next round of the Delphi survey. Feedback percentage and median as well as responses were sent together with the revised items. The number of Delphi rounds was therefore kept to minimum of three rounds to obtain a high response rate. The number of rounds was predefined before survey so that experts knew from the very beginning how many rounds the survey consisted of.

5.4.5 Data analysis

Demographic data and response rates were analysed using descriptive statistics. Percentage of consensus achieved by each item was presented. Consensus to an item was achieved if 80% or more of participants scored the item 6 or 7 on the Likert scale. Items which failed to reach consensus at 1st round of survey, were revised and subjected to regarding in the next round. The process was repeated for a maximum of three rounds.

5.5 Study Results

Response rates between Delphi rounds were 29/40 (73%; Delphi D2) and 19/29 (66%; Delphi D3). **Table 5.2** shows the characteristics of the participants involved in all three rounds of the Delphi process. The average years of practice among the participants in the first, second and last round of surveys were 10.7 (SD 6.3), 10.6 (SD 5.8) and 9.4 (SD 5.4) with median between of 7 to 8 years.

Table 5.2: Characteristics of participants in the Delphi round one (D1), round 2 (D2) and round 3 (D3)

	Delphi Round 1 – 3 (D1-D3)		
	D1	**D2**	**D3**
Response Rate, Count (%)	40	29 (73%)	19 (66%)
Median of years of practice	8	8	7
Range of years of practice	3 – 29	3– 24	5 – 18
Mean (SD) years of practice	10.7(6.3)	10.6(5.8)	9.4(5.4)
Pharmacists, Count	19	13	10
Medical Consultants / Specialists, Count	9	6	3
Medical Officers, Count	12	10	6

Table 5.3 shows the consensus collated for 32 activities within multidisciplinary care model for long term management of asthma. After Delphi survey rounds 1, 2 and 3, 28 items (88%) achieved consensus. Five activities (12%) did not reach consensus after three rounds of Delphi survey.

Table 5.4 shows the consensus collated for the 25 pharmacists' activities in the asthma care in Twenty (20) activities achieved consensus at Delphi 1, 2 and 3 surveys. Five activities failed to achieve consensus at the end of round 3 of Delphi survey.

Table 5.3: Consensus on Activities within Pharmaceutical Care Model of Asthma

		%D1 n=40	% D2 n=29	% D3 n=19	Consensus achieved?
1.	Patient assessment and documentation on				
	• past medical history, past drug history and history of asthma	93			Y
	• factors triggering the asthma	100			Y
	• asthma control and severity based on subjective and objective measures e.g. PEF and symptoms	90			Y
	• patients' expectations and concerns of their treatment	85			Y
	• patient educational needs	88			Y
	• patient's ability and motivation to self-manage	75	69	74	N
2.	Management plan includes				
	• an individualised treatment plan	95			Y
	• an individualised goal of therapy	95			Y
	• an asthma self-management training if determined to be beneficial for patients	78	76	74	N
	• patient education	93			Y
3.	Patient prescribes with reliever and preventive treatment.	88			Y
4.	Patient provides with printed asthma action plan after asthma self-management training.	70	69	63	N
5.	Patient's concerns and expectations address accordingly.	75	86		Y
6.	Patient provides with educational materials if necessary.	90			Y
7.	Patient provides with advice or education on				
	• the asthma pathology (nature of asthma) and factors triggering the asthma	93			Y
	• the signs and symptoms of asthma exacerbation	100			Y
	• action to be taken during asthma attack	93			Y
	• the medication dosage regimen, benefits and precautions	100			Y
	• the goals of treatment	98			Y
	• inhaler technique	98			Y
	• asthma self-management skills which involves stepping up of treatment during attack	75	76	68	N
	• the patient's concerns e.g. fears with medication use, concerns about asthma morbidity	98			Y
8.	On follow up/review, patient assessment and documentation on				
	• their control of asthma using daytime & nocturnal symptoms, limitations of activities, frequency of use of reliever & exacerbation in a week	100			Y
	• patient's peak expiratory flow rate (PEFR)	85			Y
	• patient's adherence to medication	100			Y
	• patient's needs to adjust medication (step up and down) based on asthma control	95			Y
	• drug related problems e.g. side effects, cognitive skills in using inhaler	98			Y
	• patient's concerns e.g. fears with medication use, concerns about asthma morbidity	98			Y
	• individualised goal of therapy e.g. best PEFR	83			Y
	• inhaler technique	100			Y
	• patient educational needs	95			Y
	• compliance to printed asthma self-management plan instructions	73	76	68	N

Table 5.4: Consensus on Contribution of Pharmacists on Asthma Care

	% R1 n=40	% R2 n=29	% R3 n=19	Consensus
Assessment				
1. Assessment of asthma control and severity	23	-	-	N
2. Confirming patient's past medical history, past drug history and history of asthma	63	83		Y
3. Assessment of patient's medication related concerns or fears	53	83		Y
4. Assessment of patient's educational needs	53	89		Y
5. Assessment of patient's expectations	43	41	47	N
Management Plan				
6. Plan & recommend changes to type of inhaler based on patients' ability to use inhaler	75	83	-	N
7. Plan & recommend changes in the medication regimen based on the patient's assessment	63	83	-	Y
8. Plan & recommend cost-saving interventions	45	41	63	N
Provision of Asthma Education				
9. Provide education on inhaler technique	93	-	-	Y
10. Provide education on nature of asthma and the asthma triggers	83	-	-	Y
11. Provide education on signs and symptoms of asthma exacerbation	83	-	-	Y
12. Provide education on asthma self-management which is initiated by physician	70	83	-	Y
13. Provide education on medication dosage regimen, benefits and precautions	95	-	-	Y
14. Provide education on the use of spirometer	60	62	74	N
15. Address patient's medication related concerns or fears	83	-	-	Y
16. Provide written information e.g. educational materials and asthma action plan to patient if necessary	90	-	-	Y
Monitor and Review				
17. Monitoring of subjective measures e.g. asthma control test scores, use of SABA	53	76	74	N
18. Monitoring of objective measures e.g. peak flow rate	53	66	68	N
19. Assessment of patient's needs for medication in accordance to clinical guideline or protocol	73	76	75	N
20. Assessment of patient's adherence to medication	83	-	-	Y
21. Assessment of patient's compliance to preventive measure i.e. avoidance of asthma triggers	43	86	-	N
22. Assessment of patient's inhaler technique	93	-	-	Y
23. Assessment of drug therapy problems e.g. adverse effects, drug interactions, duplication therapy	83	-	-	Y
24. Referral to doctor when identified drug therapy problems	63	83	-	Y
25. Document outcomes of the patient's interventions	68	83	-	Y

5.6 Discussion

5.6.1 Consensus on activities within multidisciplinary care model for long term asthma care

The findings from the Delphi surveys outline the activities within a multidisciplinary care model for the long term management of asthma. The majority of the activities had reached consensus at the first round of Delphi survey. These activities are uncontroversial core activities delivered to patients with asthma (**Figure 5.2**).

There was early consensus for assessment of patient's past medical history, past drug history, asthma triggers, patients' expectations and concerns, patient educational needs and monitoring of asthma control. These findings demonstrate familiarity and capabilities at early detection and monitoring of patient's progress. There was also agreement that the management plan should be individualised. This includes the treatment plan, goals of therapy and patient education support.

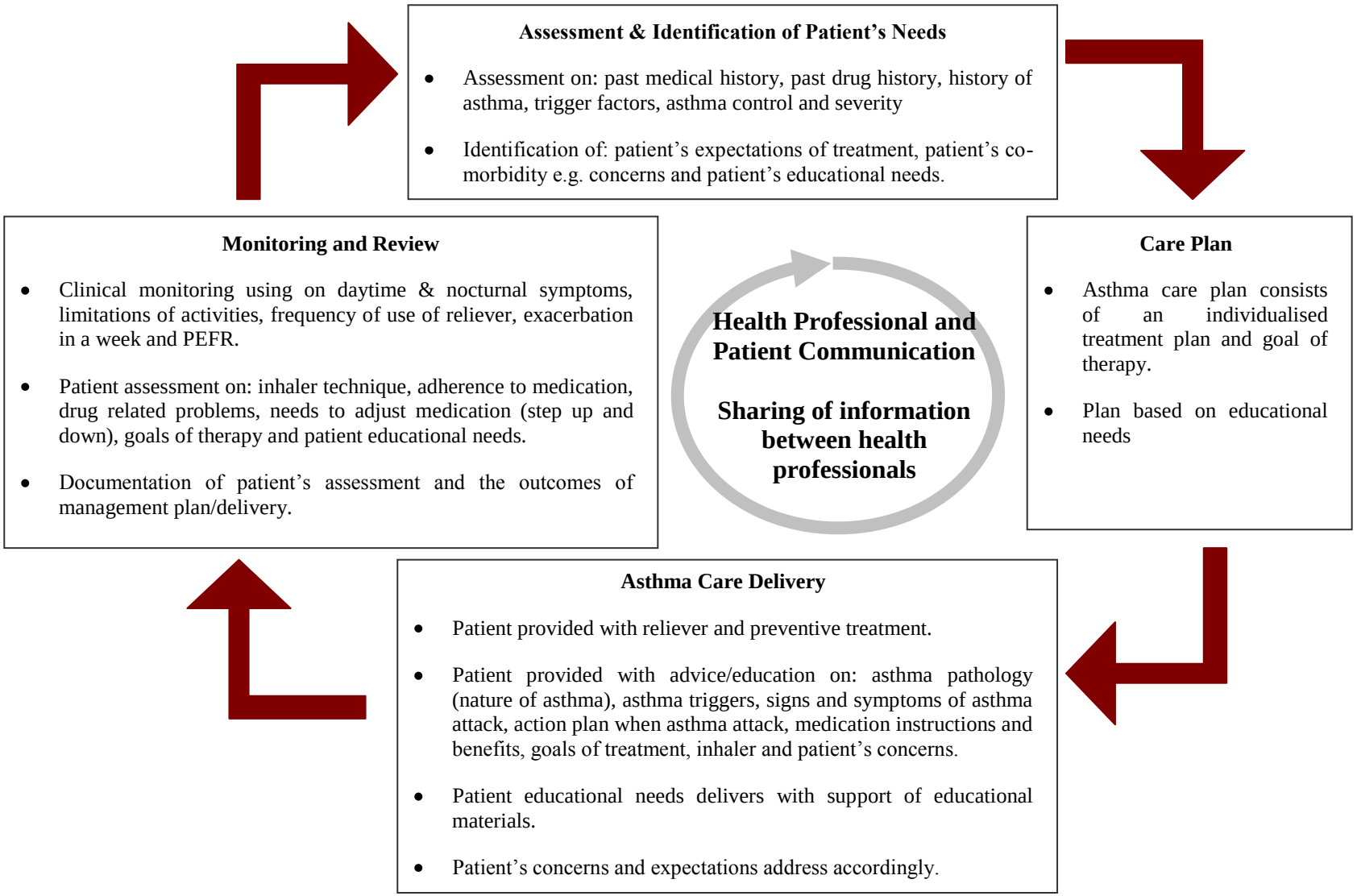
Patient education on asthma was generally accepted to include nature of asthma, signs and symptoms of asthma attack, medication use, and goals of therapy, inhaler technique and the patient's concerns. These educational needs were consistently highlighted in guidelines, thus it is no surprise that the consensus was achieved in the first round of the Delphi survey. On follow up, there was no reluctance among participants to agree on the perform of comprehensive assessment and documentation on patient's asthma control i.e. the daily signs and symptoms, lung performance, adherence to medication, drug-related problems, patient concerns, inhaler technique and education needs.

Five of the 32 activities (12%) which failed to reach consensus after three Delphi rounds are self-management activities. Health care professionals play an important role in supporting self-management and determining the clinical

outcomes. The low priority given to guided self-management indicates the lack of acceptability and support by health professionals to include self-management as a core component of asthma management.

Self-management training was consistently shown to be lacking from patient education interventions despite its proven positive effect on clinical outcomes[146, 182].Qualitative studies have shown that some health care professionals were unenthusiastic about self-management. The attitude is generally rooted from the limited experiences with self-management and lack of confidence in patients' capabilities in self-care. Patients need on-going self-management support from their healthcare providers. Training and encouragement on self-management should help to improve confidence in educating them to undertake self-management.

Figure 5.2: Multidisciplinary Care Model for the Long-Term Management of Asthma



5.6.2 Consensus on pharmacists' contribution in asthma management

Figure 5.3 outlines the findings from Delphi on the agreed pharmacists' activities and contribution to the asthma management.

Figure 5.3: Agreed Pharmacists' Contributions in the Long term Management of Asthma in the Out-Patient Setting

Patients' Assessment

- Confirms patient's past medical history, past drug history and history of asthma
- Assesses patient's medication related concerns or fears
- Assesses patient's educational needs

Delivery of Management Plan

- Recommend changes in the medication regimen based on the patient's assessment
- Provide education on: inhaler technique, nature of asthma and the asthma triggers, signs and symptoms of asthma exacerbation, asthma self-management which is initiated by physician, medication dosage regimen, benefits and precautions,
- Address patient's medication related concerns or fears
- Provide written information e.g. educational materials and asthma action plan to patient if necessary

Monitor and Review

- Assessment of patient's adherence to medication, patient's inhaler technique, drug therapy problems e.g. adverse effects, drug interactions, duplication therapy
- Referral of drug therapy problems to doctors
- Document outcomes of the patient's interventions

Activities for rating through consensus were selected based on patients' needs and the sources of evidence of delivery of pharmaceutical care. Early consensus was achieved on pharmacists' contribution to assessment of patient's medication related concerns, patients' past medical history, past drug history and history of asthma, and the educational needs. The participants showed agreement for pharmacists to assess patient's adherence to medication, compliance to preventive measures, inhaler technique and drug therapy problems on follow up. These demonstrated confidence in pharmacist's ability to gather sources of information to assess and address drug therapy needs and problems.

The reasons for participants failing to achieve agreement on activities related to assessment of asthma control, or using spirometer are not known. A study done in Malaysia in 2009 revealed that less than 40% of medical practitioners agreed that pharmacists should be involved in performing glucose and cholesterol tests[183]. This is not surprising because there was little involvement of pharmacist in direct patient care in the past due to shortage of pharmacists. The limited opportunity for multidisciplinary collaborative care may contribute to the lack of trust and confidence in expansion of pharmacists′ direct patient care.

5.6.3 Quantitative definition of Consensus

Consensus in the Delphi method has no clear statistical definition. The determination of consensus varies from study to study. The methods include percentage of agreement to criterion; mean rankings, standard deviation of responses to a criterion, pre-determined number of items, median and interquartile deviation (IQD) of responses[184, 185]. Nor is there clear consensus in the literature of which is the best method of data analysis and interpretation for the Delphi process. In our study, 80% participants' agreement was considered as a consensus, in line with a few previous studies[186, 187]. In some other studies,

consensus has been described as low as 50% of agreement to items[169, 188].We chose a higher of cut-off percentage before the start of survey to ensure that findings remained valid and robust despite small numbers in terms of response rates in the later rounds of Delphi.

5.6.4 Study Limitations

The Delphi method used was structured, systematic, and transparent, and reflects the opinion of participants who were interested and motivated in the care model, rather than a few influential individuals. Despite its usefulness, the Delphi method has limitations. There was potential researcher bias to maintain survey questions to its original intent during the process of designing and revising of questionnaire.

Survey findings highly depend on the composition and active participation of the panel. Due to the unavailability of a register of "experts", we include both pharmacists and clinicians through available contacts from 9 hospitals within Malaysia to balance the insight to pharmaceutical care activities. Inevitably, participants are known to bring their personal views and agendas to the consensus method which could lead to arbitrary decisions in the consensus process[189]. By inviting experienced pharmacists and clinicians from different institutions, we sought to ensure that the findings would be meaningful, relevant and acceptable to health professionals from different geographical areas and different backgrounds. The eventual composition of our expert panel has average years of practice between 9 to 10 years with 50% of them practices for at least 7 years in all 3 rounds. The panel however was marginally biased towards pharmacists' perspective as slightly more "pharmacists" than "clinicians" participated in last round of Delphi survey.

One of the other difficulties was keeping the participants to respond to the timeline determined. Response rates in our Delphi survey are low and they decreased as the rounds progressed which is consistent with Delphi surveys

previously reported[190, 191]. Although researchers have minimised the workload for the Delphi participants by making completion of questionnaire as simple as possible, a full response has yet to be achieved. At round 2 and 3 of our Delphi surveys, the attrition rates were 27% (11 out of 40 failed to respond) and 34 % (10 out of 29 failed to respond) respectively. The contact by investigators usually through telephone and email was recognised as an important element to sustain response to the survey.

5.6.5 Implications of findings

Although the weaknesses associated with the nature of consensus and the composition of our participants should be acknowledged, the ideas generated from this consensus survey represents a considerable advance in our understanding of the activities acceptable in the management of asthma. The positive attitudes in consensus however do not necessarily lead to behaviour change in practice; but useful as a model that can be adapted to by all those involved in the developing asthma care.

The consensus showed apparent lack of consensus in some of the activities such as self-management. It is certainly worth to further investigate why such activities which have offered evidences in clinical outcomes did not achieve consensus.

5.7 Conclusion of Chapter 5

The formulation of a pharmaceutical care model and pharmacists' roles in the care of the patient with asthma requires active partnership between health professionals. In our survey, we demonstrate a method to formulate activities which are highly evidence-based and with consent across clinicians and

pharmacists. Patients' needs and opinions were considered in the process of designing the questionnaire.

The framework that was developed not only spells out the pharmacists' responsibilities, but also identifies priorities for continued professional development in this field of asthma education. Further exploration and promotion of the practicality of consensus will be required for future implementation.

Chapter 6

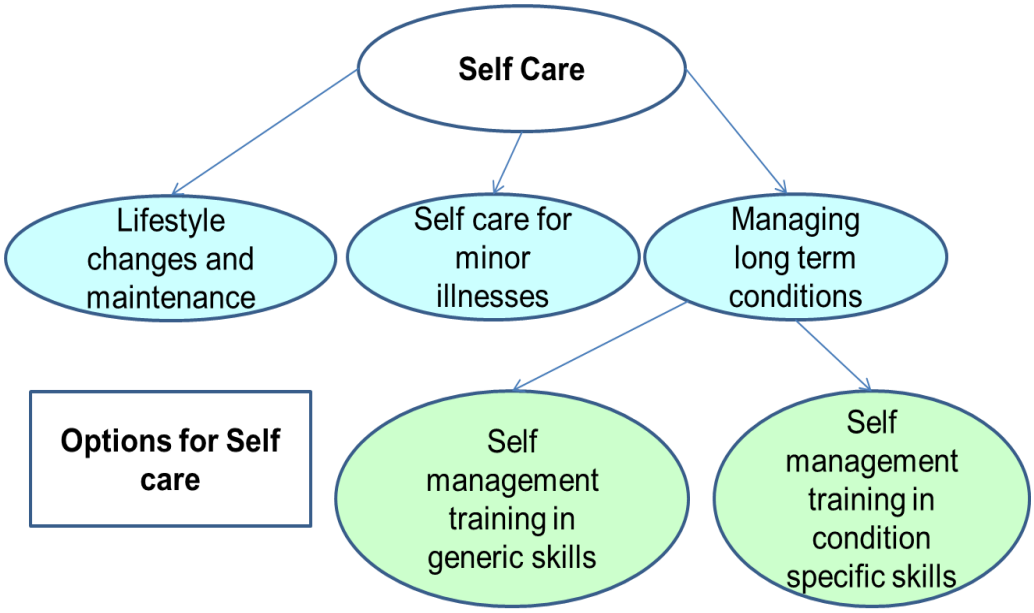
6 Development and Validation of a Pictorial and Written Asthma Action Plan in supporting self-management training via educational intervention

6.1 Introduction

6.1.1 Self-Management

The history of the concept of self-management in asthma can be traced back to the 1980s, due to the high incidence of asthma associated mortality and morbidity. The exact reasons for this trend towards worsening outcomes in former times were not fully understood, but poor self-care was raised as an important risk of asthma mortality and morbidity[192]. Self-care is described as a concept, which aid individual empowerment in health or disease management. It encourages individual behaviour in taking the choice of a healthy lifestyle, meeting their social, emotional and psychological needs, caring for their condition and preventing further illness or accidents. It was distinguished from self-management, a term which is commonly used for interventions used by patients managing long term or chronic condition such as diabetes, congestive heart failure or asthma[193]. Self-management is hence considered a component of self-care as illustrated in **Figure 6.1**[194]. The underlying theory of self-management focuses on patient's self-efficacy to accomplish a specific behavior or achieve a reduction in symptoms, leads to improved clinical outcomes[195].

Figure 6.1: Components of Self-Care[194]



6.1.2 Self-Management in Asthma Management

Asthma self-management refers to behaviours based on appropriate knowledge about asthma and its provoking factors, compliance with inhaled medication, self-monitoring of changes in severity of the disease, recognition of symptoms, adequate inhalation technique, and correct use of self-monitoring using a peak flow meter. To date, there are more than 40 published sources of evidence in self-management in various settings including, hospital outpatient, emergency room and community. The sources of evidence strongly supported the use of asthma self-management. Incorporation of written action plan, into regular monitoring and appropriate education has been found to reduce visits to the emergency room, hospital admissions, asthma symptoms and used of rescue medication as well as improve lung function[196, 197].

Most international and national asthma guidelines now stress the importance of patient self-management in asthma management. The United Kingdom's National Asthma campaign has also indicated that, “equipping people with asthma with the

tools they need to manage their condition is as important as writing the correct prescription".

A tailored asthma self-management education is required to maximise the benefits of self-management[198]. The key feature of self-management involves extensive "self-treatment" behaviour, which requires patients to adjust or initiate medical therapy based on the changes in their asthma severity. The act of medical therapy adjustment or initiation is usually guided by a written guide, which is called an action plan.

An asthma action plan to support asthma self-management lays down stepwise information on the self-managing steps during stable, progressive and life threatening asthma. Despite the clear benefits of uptake of an action plan to develop patients' self-management, the plans are not always well received[199-201]. The problem of poorly received self-management among patients may be contributed to by poor dissemination of guideline recommendations on education, clinicians doubts of patients' ability to self-manage, lack of suitable or inadequate printed information, to support the implementation of the action plan and lack of a patient's confidence to take control of their condition.

With the increased demand to include self-management as a component of asthma management, the current forms of written information are no longer sufficient. Self-management requires patients' participation in monitoring and management. An asthma action plan which contains extensive information on the signs of uncontrolled asthma and action taken during asthma attack will be required to support self-management. Studies have shown that adults with inadequate literacy skills however have less ability to manage medication[202]. An effective literacy level is essential to ensure that written information provided is comprehended correctly.

6.1.3 Written medical and health information: Problems and Challenges

Medical and health information can be misinterpreted or misunderstood easily by patients[203]. This is no surprise as health professionals have the tendency to use medical terminology and complex sentences, which patients might not understand easily. Furthermore, stress due to health status or environment could affect patients' acceptance of information. The fear to appear stupid or patients not trusting the doctor may also cause hesitation to admit or raise concerns with the instructions or reasons for medical therapy. Another problem in comprehension is the presence of low literacy skills. It is estimated that even in developed countries such as the United States and some European countries, low literacy skills are reported in between 10% to 20% of population.

Health literacy is defined as the degree to which individuals have the capacity to process and understand basic health information and services needed to make appropriate health decisions[204]. Data from the United States (US) suggest that impairment is common and is frequently overlooked especially amongst African Americans and white non-Hispanics[205]. In the UK 15% of patients with rheumatoid arthritis in one study were reported to be functionally illiterate[206] and this figure was similar to that found in a US study specifically looking at those with asthma[207].

Language used in the provision of information is an important determinant, yet may not achieve good comprehension of information. Prevalence of 23% of English speaking and 34% Spanish-speaking respondents could not read and understand their spoken languages were revealed by a study in USA[208]. Reading skills level of the average adult citizen in USA is estimated to be between the 8th and 9th grade level. Comprehension of half of the health and medical information has been shown to require a readability level of 10th grade or higher[209, 210]. In

other words, a comprehension gap in health information could exist among average adults of USA with reading skills.

The difficulty level of the comprehension of information also depends on the type of information studied. Some of the information is beyond patients' understanding due to either the complex nature of the concept or terminology used. In asthma information this is especially true when it involved a series of steps such as inhaler technique. Simplification of language used in written medical information is an important step in addressing the problem. The addition of pictures to illustrate information was significantly more likely to be remembered than information provided in text. Studies have shown that pictograms enhance comprehension in medicine-related instructions such as the techniques in the use of medical devices and the understanding of dosage regimens of medicines[211-215]. Pictorial representations have been shown to improve recall of medical instructions in a clinical setting[216] own to be an effective tool, enhancing consultations and aiding understanding[214]. It also markedly increase attention to and recall of medical and health information. Although the use of medical pictograms can be useful in patient education, pictograms can also be misinterpreted[217].

6.2 Study Background

Despite great effort in dissemination of self-management as part of asthma management at international and regional level, uptake of self-management among clinicians and patients remained lacking. The action plan is essential to support this training of self-management. The complexity of self-management information requires higher levels of literacy for interpretation. Incorporation of pictures or pictograms into medical or health information may improve comprehension and recall of information. The implementation of self-management training using an action plan is a complex process and requires

consideration of limitations or barriers in the population receiving delivery of the service. It is therefore essential to evaluate the patients' understanding of an action plan before it can be reliably used in patient education.

The present study was aimed to examine the feasibility of a self-management among Malaysian population, focussing on development and validation of a printed asthma action plan in the form of pictorial and written.. Our study was undertaken in three phases; assessment of patients' interpretation of pictograms related to asthma self-management, development of asthma self-management schedule via literature appraisal and panel review, and evaluation of self-management training with support of asthma action plan via an educational intervention among asthma patients.

6.3 Assessment of patients' interpretation of pictograms related to asthma self-management

Effective communication is essential to the success of healthcare consultations. One method of communicating medication information to patients with low health literacy is to use pictograms as an alternative means of illustrating instructions or concepts. If a pictogram/symbol is neither guessable nor based on logical relationships with its meaning, the message has the risk to be misinterpreted. The development of clear, culturally acceptable symbols or pictograms to aid communication is essential and can be determined by comprehensive design and testing

6.3.1 Pictograms/Symbols Assessment Methods

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Structured methodologies to evaluate the appropriateness of pictograms or symbols in certain groups of patients are used in augmentative and alternative

communication (AAC), pharmaceutical research, and public safety pictogram research. These methods include **iconicity, translucency** and **guessability** tests.

Iconicity refers to the visual relationships between a symbol and its meaning. There are two dimensions of iconicity; transparency and translucency. Transparency test reflects to the strong resemble of a symbol to its meaning while translucency reflects the learnability of a symbol once its meaning is provided. The iconicity test was further developed by Haupt and Alant in 2002 to evaluate the distinctiveness or uniqueness of symbols. In the study, participants were presented with 36 copies of a test grid[218]. Participants were provided with 36 word labels, and asked to select the word label which best matches the symbols in test grid. The findings provided measure of the degree to which a symbol is selected only in response to its word label.

The **translucency test** is used widely in AAC researches to assess participants' from a range of cultures perceived the relationships between symbols and its' meaning[219]. Translucency test assesses how closely respondents rated the relationship between a pictogram and its given word label. Previous study has involved rating of the relationships on a 7-point scale[220]. A rating of 1 indicates little or no relationship between symbol and the given meaning, while 7 indicates a very strong relationship. A symbol with high translucency represents symbol strongly resemble its meaning, and more likely to be learnt and remembered.

For patient education, it is best that pictograms in medical information are able to be interpreted even without patients training. The first impression of symbols influenced the interpretation. **Guessability test** determines the initial or naive participants' ability to recognise and interpret the pictograms. It has been used to evaluate the pharmaceutical pictograms in the United State Pharmacopeia Dispensing Information (USP-DI) in a low literate South African population[213, 217]. It involves the naive respondents to guess the meaning of pictograms presented to them.

In our current study, pictograms have been designed for a pictorial asthma action plan to be used in self-management training. Guessability and translucency methods were selected to evaluate these pictograms due to the potential of misinterpretation. These methods evaluate different aspects of how individual interpret the pictograms, with and without their given meanings. The study also provides valuable insight into the types of pictograms which are acceptable and understandable to the local population and evaluate patients' comprehension of pictorial asthma action plan.

6.3.2 Study Aim and Objectives

The aim of this study was to assess patients' comprehension of an asthma action plan to support asthma self-management.

The objectives of the study are:

1) To evaluate patients' interpretations of pictograms related asthma self-management.

2) To evaluate patients' comprehension of pictorial asthma action plan

The first phase of study was a study performed in collaboration with Prof Dr Martyn R. Partrigde and the team from London Charing Cross Hospital, United Kingdom and findings have been published collectively with a sample of other populations from the United Kingdom[132].

6.3.3 Study Design

6.3.3.1 Subjects and Setting

The evaluation of patients' interpretations of pictograms was undertaken at the asthma out-patient clinic of Hospital Seremban, Malaysia. The study protocol was initiated by Prof Martyn R Partridge and team at Charing Cross Hospital, London and adopted in collaboration by the author as a contributory study for the development and validation of an asthma action plan for use in Malaysia setting.

Patients identified after the application of the inclusion and exclusion criteria were recruited via convenience sampling. The inclusion criteria included patients aged 18 or above with a confirmed diagnosis of asthma and receiving any inhaled form of preventive asthma medication. The exclusion criteria included patients prescribed with only reliever in inhaled or oral form, those not able to communicate in English, Malay or Chinese (Mandarin or Cantonese), those with visual or auditory impairment, those with known psychiatric illnesses and degenerative conditions which affect memory, behavior, learning or communication.

6.3.3.2 Questionnaire Design

Eligible patients from Hospital Seremban were invited to participate by informed consent. Patients were informed of the nature of study and processes involved in the study. Consenting patients were included into the study. The study involved self-completion of two questionnaires and a brief face to face interview.

Three questionnaire tests were used in the study namely guessability, translucency and comprehension tests. Guessability and translucency tests are performed via self-completion or with support from the investigator. Face to face interview was conducted to administer the comprehension test.

The guessability and translucency tests (**Appendix 6.2 & Appendix 6.3**) consist of 27 similar pictograms, which are associated with self-management. In the guessability test, participants were asked to provide their interpretation of each pictogram using one or two words. The interpretation can be repeated for different pictograms. Correct and incorrect interpretations of the actual meaning of each pictogram were provided in the translucency questionnaire. A 7 point Likert scale was attached to the possible interpretations of each pictogram in the questionnaire. Participants were asked to grade between a score of 1 to 7 their level of agreement with each pictogram interpretation. A rating of 1 indicated no relationship between the pictogram and the specific interpretation, and a rating of 7 indicated a very strong relationship.

After guessability and translucency tests, participants were provided with a pictorial asthma action plan (**Figure 6.2**). The use of the pictorial asthma action plan as strictly for the purpose of study was emphasised to patients. The description of the action plan was provided to patients. Patients' ability to comprehend the asthma action plan was assessed using a series of questions related to action points in the action plan (**Table 6.1**). Opinions of the pictorial asthma action plan were also gathered at the end of the assessment.

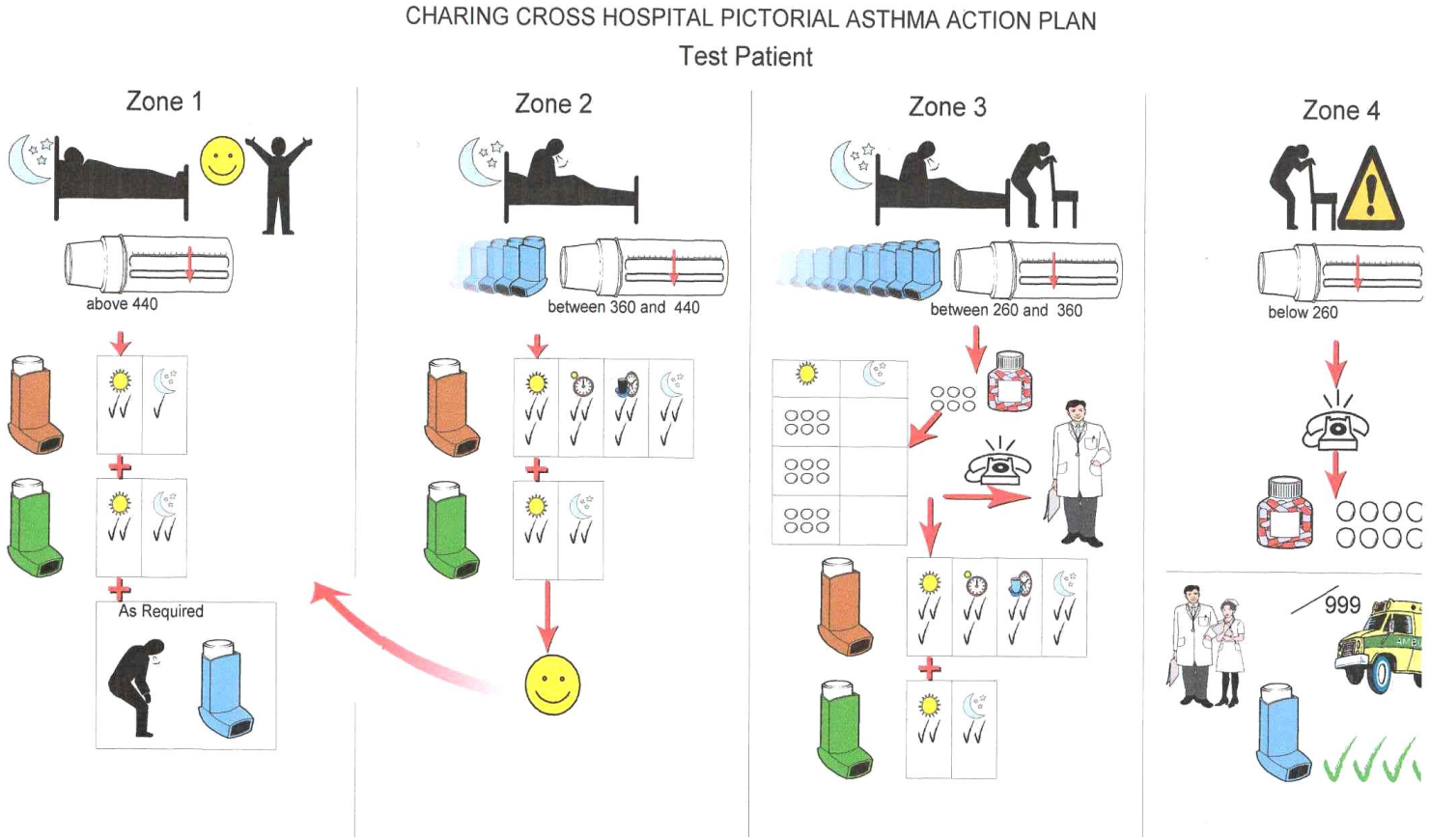
Table 6.1: Assessment of comprehensibility of pictorial asthma action plan

• What should you take when your asthma is controlled? • When should you increase the dose of your brown inhaler to four times day? • When should you be using prednisolone tablets? • How should you be taking the tablets according to Zone 3? • What should you do after completion of the prednisolone tablets? • When should you be seeking for medical attention?

6.3.4 Data handling and analysis

Findings on patients' interpretations of pictograms were entered into spreadsheets and analysed using SPSS (v11). For guessability test and comprehensibility, numbers and percentages of patients who have provided the correct answer to each pictogram or question were calculated. The data from the translucency test were analysed to present the mean, standard deviation, and median of scores as well as number and percentage of participants providing scores of 6 to 7. The mean of scores report the average score of responses while median summarises the central tendency of responses from a Likert scale. In this study, patient agreement between a pictogram and an interpretation was defined as 85% or more participants providing scores of 6 or 7.

Figure 6.2: Example of Pictorial Asthma Action Plan



6.3.5 Study Results

6.3.5.1 Patients' Characteristics

Table 6.2 shows the characteristics of the19 patients studied. The mean age of study group was 49.2 years (SD 10.8). Thirteen (68.4%) were female. The group consisted of patients of Malay (42.1%), Indian (31.6%) and Chinese (26.3%). The mean school leaving age was 15 (SD 3.25).

Table 6.2: Patients' Characteristics

Age ; year (SD)	49.2 (10.8)
Gender; Count (%)	
Female	13 (68.4)
Male	6 (31.6)
Ethnic; Count (%)	
Malay	8 (42.1)
Indian	6 (31.6)
Chinese	5 (26.3)
Educational Level; Count (%)	
Left school age 14	7 (37)
Left school at 15-16 years	2 (10.5)
Left school at 17-20 years	9 (47.4)
College/Diploma	1 (5.3)

6.3.5.2 Patients' Interpretation of Pictograms related to Self-Management

Based on translucency findings, twenty-six (26) out of 27 pictograms achieved satisfactory agreement with its correct meaning (**Table 6.3**). Sixteen of these pictograms were interpreted correctly (via guessability test) by more than 80%. The high median of 7 reflected that 50% of the patients have provided correct meanings to all the pictograms. Pictograms representing "caution" and "using extra doses of reliever medication" were identified correctly by 53% and 6% respectively. Pictogram "spacer" achieved 82% agreement (translucency test) with its interpretation. None of the patient could guess the similar pictogram (spacer) correctly.

Table 6.3: Patients' Interpretation of Pictograms related to Self-Management

		 Nighttime	 Daytime	 Caution	 Sleeping	 Breathless at night	 Very breathless	 Breathless	 Very breathless	 Fit & Well
Guessability	**Correct n (%)**	19 (100)	19 (100)	10 (53)	19 (100)	16 (84)	15 (79)	19 (100)	15 (79)	19 (100)
	Blank n (%)	0	0	9 (47)	0	0	0	0	4 (21)	0
	Wrong n (%)	0	0	0	0	3 (16)	4 (21)	0	0	0
Translucency	**Mean Score**	7	7	6.7	7	7	7	6.7	7	7
	Median Score	7	7	7	7	7	7	7	7	7
	Count	19	19	19	19	19	19	19	12	19
	Score 6-7 (%)	100%	100%	100%	100%	100%	100%	100%	100%	100%
		 Fit & Well	 Walking	 "Well"	 Tablets	 Telephone	 Doctor	 Doctor & nurse	 Ambulance	 Spacer
Guessability	**Correct n (%)**	18 (95)	19 (100)	15 (79)	19 (100)	19 (100)	19 (100)	19 (100)	19 (100)	0
	Blank n (%)	0	0	4 (21)	0	0	0	0	0	8 (42)
	Wrong n (%)	1 (5)	0	0	0	0	0	0	0	11 (58)
Translucency	**Mean Score**	7	7	7	7	7	7	7	7	6.3
	Median Score	7	7	7	7	7	7	7	7	7
	Count	19	19	19	19	19	19	19	19	17
	Score 6-7 (%)	100%	100%	100%	100%	100%	100%	100%	100%	82%
		 Turbohaler	 Inhaler	 Using extra doses of reliever medication	 Peak Flow Meter	 Accuhaler	 "Everyday"	 Take inhaler	 Take one dose of medication daytime and nighttime	 Take two doses of medication daytime and nighttime
Guessability	**Correct n (%)**	13 (68)	19 (100)	3 (16)	15 (79)	4 (21)	15 (79)	14 (74)	17 (90)	16 (84)
	Blank n (%)	6 (32)	0	0	4 (21)	15 (79)	0	0	0	0
	Wrong n (%)	0	0	16 (84)	0	0	4 (21)	5 (26)	2 (10)	3 (16)
Translucency	**Mean Score**	7	7	7	7	7	6.6	7	7	7
	Median Score	7	7	7	7	7	7	7	7	7
	Count	12	19	19	19	11	19	19	19	19
	Score 6-7 (%)	100%	100%	100%	100%	100%	90%	100%	100%	100%

6.3.5.3 Patients' Comprehension of Pictorial Asthma Action Plan

The correct and wrong responses to questions assessing comprehension of the pictorial asthma action plan are presented in **Table 6.4.** All patients suggested their regular medication for daily use at Zone 1 and take oral prednisolone as well as contact doctor at Zone 3. Less than 60% patients suggested increase of inhalers in Zone 2. The majority (>70%) suggested that they would contact the doctor or seek immediate medical attention when oral prednisolone is needed or when asthma is uncontrolled after oral prednisolone.

Table 6.4: Patients' Comprehension of Composite Pictorial Asthma Action Plan

	Correct Responses Count(%)	**Wrong Responses** Count(%)
1. (Zone 1) What medication do you take everyday?	19 (100%)	0
2. (Zone 2) What medication should you take if you feel breathless, during a day and night?	11 (58%)	8 (42%)
3. (Zone 3) What should you do if you still feel breathless after increasing your inhalers?	19 (100%)	0
4. (Zone 2 & Zone 3) Give one example when you should contact the doctor	14 (74%)	5 (26%)
5. (Zone 2 & Zone 3) When should you get emergency/urgent treatment?	14 (74%)	5 (26%)

6.3.6 Discussion

Comprehension in this study reflects the process of interpreting the meaning of words or pictures to understanding their collective meaning. Most pictograms were well understood at first interpretation. Some pictograms were less easily understood but achieved a satisfactory level of agreement in the translucency test, which reflects improvement in understanding of pictograms upon prompting. These include images suggesting ‘‘use of extra doses of reliever medication’’, “very breathless “, “peak flow meter”, “take one dose of medication daytime and nighttime”,” take two doses of medication daytime and nighttime”, “everyday” and “take inhaler”. Some patients were not able to recognise the images of “accuhaler” and “turbohaler“. On the other hand, imagine of “metered dose inhaler” is well recognised and understood by all patients. This is not surprised because metered dose inhaler is the most frequently use inhalers as compared to turbohaler and accuhaler. “Spacer” is also not recognised by some patients. Spacer is not frequently used in Ministry of Health hospital due to high cost of device.

None of the patient has seen asthma action plan before this study, and majority has never been introduced on the concept of self-management. Despite these, most were able to recite the action points based on the pictorial action plan. Patients find most difficulty in reciting the Zone 2 action point of self-management plan which required patients to identify the correct increase of inhaled corticosteroids dose and frequency.

Our study only evaluates the interpretation of pictograms and comprehension of action plan after short briefing. This has not proved that the pictorial asthma plan is possible to be used to replace or add to a written asthma plan. Written asthma plan usually provided to patients and patients are expected to recall the plan when they encounter the key signs and symptoms presented in action plan. Assessment

of patients' recall is thus important to understand how much patients can recall after self-management education.

6.3.7 Conclusion of Chapter 6.3

The existence and understandability of an asthma action plan is important as a guide to patient's self-treatment. A pictorial asthma action plan may offer an educational material for patient self-management especially for patients with literacy difficulty. Our study has identified pictograms from an established action plan, which are less easily interpreted or recognised. Special attention to the meaning of these pictograms would be required in future counseling involving an asthma management plan which contained pictograms.

6.4 Development of Pictorial and Self-Management Training via Educational Intervention

6.4.1 Study Aim and Objectives

The aim of this part of study is to develop asthma action plans for use in self-management training.

The objectives are:

1) To develop a self-management schedule

2) To develop pictorial and written forms of asthma action plan suitable for use by asthmatics in Malaysia.

6.4.2 Study Design

6.4.2.1 Ethics Consideration

This component of study does not involve patients, thus no ethical consideration was required.

6.4.2.2 Literature Review

Guidelines and a literature search were performed to identify the action points involved in asthma self-management (**Appendix 6.4**) and examples of an asthma action plan (**Appendix 6.5)**. A draft 1 self-management schedule was developed and validated by panel review. The panel consisted of 3 senior respiratory specialists and 2 medical officers involved in asthma clinic of study site, Hospital

Penang. Feedback was used to revise the self-management schedule (**Appendix 6.6**).

Using the self-management schedule, pictorial and written asthma action plans were developed. The same panel of clinicians reviewed the action plans and feedback was used to revise the asthma action plans.

6.4.3 Study Results

6.4.3.1 Asthma Patient Self-Management Schedule: Action Points

The final self-management schedule consisted of 3 stages of asthma status and 3 series of action points (**Appendix 6.7**). At stable asthma, regular medication should be used with reliever when required for asthma attack. At progressive asthma attack (Zone 2), patients are required to perform one of the 3 action points as according to their regular inhaled corticosteroids (ICS) type and dose. The action point could involve steps to increase ICS dose and duration, initiate a standard dose of prednisolone or use Symbicort® when required. The use of other regular medication is required to be continued. Monitoring is to be performed after 1st-day to assess improvement. Patients who showed improvement were to continue for 7-days. Those who could not observe improvement would be required to seek medical attention immediately. At life threatening stage (Zone 3), patients would be required to seek medical attention immediately.

6.4.3.2 Pictorial Action Plan

The self-management schedule was used to build pictorial action plan for educational intervention in Malaysia. A total of 17 pictorial action plans (**Appendix 6.8**) with various possible combinations of regimen was developed using pictograms that were tested in the early phase of the study and with

reference to the pictorial asthma action plan developed by Prof Dr Martyn R Partridge and team at Charing Cross Hospital, London.

6.4.3.3 Written Action Plan

Six (6) written asthma action plans (**Appendix 6.9**) were created by the author. The English version asthma action plans were developed for patients who will require oral prednisolone, increase of ICS dose and duration and Symbicort Maintenance and Reliever Therapy (SMART). Each of these action plans was also constructed in the Malay language.

6.4.4 Discussion

A typical written individualised management plan for asthma contains four self-management action points. These include; (1) taking regular inhaled steroid medication, (2) doubling the dose of inhaled steroid medication in response to deterioration, (3) taking oral corticosteroids and (4) seeking medical aid in response to a further deterioration in either symptoms or peak flow.

Of these four key action points of asthma self-management, the recommendation for the second stage has the weakest level of evidence, although well-established for asthma self-management plan such as in UK personalised asthma action plan. Studies have shown that doubling of ICS dose failed to achieve good control or did not change the outcomes of asthma during asthma exacerbation[221, 222]. Thus, a set of 3 key action points were developed in our study. The first action point is at stable asthma (Zone 1) in which an individual is expected to use regular asthma medication and reliever when necessary for acute attack. At the progressive asthma attack (Zone 2), the individual is required to self-administer a course of oral prednisolone, increase dose of ICS or administer Symbicort® as reliever. The life threatening stage (Zone 3) will involve seeking medical help.

Three action points at progressive asthma attack (Zone 2) were created in view of the requirement of patients using different types and dosage of maintenance inhaled corticosteroids. The first action point involves use of systemic corticosteroids, which are standard therapy for patients with asthma exacerbations. It allowed faster resolution of exacerbations for all severity except mildest exacerbations[13]. In view raising of the concerns about the misuse of prednisolone tablets and the benefits of high dose ICS, increasing the dose of ICS was added as an alternative action point for patients with low maintenance ICS. For patient with low maintenance ICS, their action point within written or pictorial action plan in response to progressive asthma exacerbation will be to increase ICS dose by four-fold instead of use of prednisolone tablet.

In contrast to a two–fold increase of ICS, a higher dose of ICS has been shown to provide better outcomes during asthma exacerbation. A study has found quadruple normal maintenance dose of ICS to be effective in reducing the risk of asthma exacerbations[223]. Foresi et al. revealed that increasing dose of the ICS at the earliest indication of asthma worsening was as effective as a high maintenance dose in reducing number of exacerbations and need for oral corticosteroids[224]. This dose increase was found to be beneficial for patients on low maintenance doses of ICS. At a dose of 2,400 µg/day, inhaled budesonide was as effective as systemic corticosteroids (40 to 60 mg oral prednisolone or 125 mg methylprednisolone) to prevent relapse of asthma exacerbation. No significant differences improvement of $FEV_{1,}$ PEF and clinical symptoms were observed in groups taking high dose ICS or systemic corticosteroids[225]. A higher dose of budesonide up to 3,200 µg daily was also found to have similar efficacy[226]. These two studies involved use of high dose of ICS for at least 7 days.

The third action point for Zone 2 caters to patients taking Symbicort®. Symbicort® as maintenance and reliever therapy (SMART) is shown to significantly reduce asthma exacerbations and improve asthma control. Addition

to that, GINA guideline has indicated the use of SMART approach for patients prescribed with the inhaler. Self-monitoring of progress is important.

All action points required patients to be able to interpret the key asthma signs and symptoms or peak flow measurement to determine the severity of asthma, in order to respond with the appropriate action point. Studies have revealed no significant differences between patients using PEF and a symptom self-management plan[227]. In Malaysia, self-monitoring of peak flow meter measurements usually is uncommon and very few patients owned a peak flow meter. In Malaysia, a unit of peak flow meter may costs up to RM150 and is not easily available from community pharmacies. Peak flow based self-management will therefore currently be less likely to be used in comparison to symptoms based self-management.

6.4.4 Conclusion of Chapter 6.4

Patient self-management offers benefit in asthma management. Although the asthma action plan is easily found from resources, it is not known whether the asthma action plan would be suitable for the Malaysian local setting. The present study has generated multilingual written as well as pictorial asthma action plans, which would potentially cater for most of the needs of patients who require self-management training. This requires confirmation in future studies.

6.5 Evaluation of asthma self-management training using asthma action plans at out-patient setting.

6.5.1 Study Aim and Objectives

The aim of this part of the study was to evaluate the asthma self-management training using asthma action plans at out-patient setting.

The objectives were:

1) to evaluate the reported attempt of patient self-management
2) to evaluate patients' recall of action points for patient self-management
3) to evaluate the effect of education and self-management on clinical outcomes, namely; admissions, unscheduled visits to doctors/emergency rooms, days off work, lung function test and asthma control.
4) to make recommendations for the delivery and documentation of a systematic clinical intervention.

6.5.2 Study Design

6.5.2.1 Subjects and Setting

The study was conducted at the asthma out-patient clinic of Penang Hospital, Malaysia. Penang Hospital is a 1000-bed state government hospital. The study population were recuited from adults attending regular follow up at an out-patient clinic from February to December 2009. The inclusion criteria included adults aged 18 to 65 years old, with a confirmed diagnosis of asthma and prescribed inhaled corticosteroids as maintenance therapy with a satisfactory level of compliance. Patients were excluded if they had documented or observed signs of other respiratory conditions such as chronic obstructive airway disease, received self-management training previously in any form, those with visual and auditory

impairment and those with known psychiatric and memory degenerative condition, which may affect memory, learning or communication. .

6.5.2.2 Ethics Considerations

This research was approved and funded by International Medical University, Malaysia (Appendix 6.1). Permission for the study was given by the head of the Respiratory Department of the hospital for the recruitment of patients and access to patient medical records. Patient informed consent was obtained before recruitment to the study.

6.5.2.3 Study Procedure

The study was carried out at asthma out-patient clinic which run from 8.30 am to 1.00pm every Tuesday at Penang Hospital. The average number of asthma patients attending the clinic is 15 patients per day. Potential subjects were identified a day before the clinic session from the list of patients registered for follow up. At the day of clinic session, the first pre-identified patient to arrive and every second patient thereafter were selected and invited to join the study.

The patients were first assigned at random to receive either a written or pictorial asthma action. Patients who reported difficulty in reading and understanding of the written action plan however were re-assigned into the pictorial asthma action plan. The nature of study was described to the patients. Consenting patients were provided with approximately 20 to 30 minutes self-management plan training. Assessment was performed at enrolment and at 2 successive outpatient clinics during follow up at intervals of 4 months.

The study targeted for a sample size of 80 patients based on an anticipated population proportion of 4.6% asthma prevalence in Malaysia, and a precision (d) of 0.05 at 95% confidence interval[228]. In our study, one hundred and eleven (111)

patients were identified and ninety six (96) were invited over a 3 months from asthma out-patient clinic to participate in this study. A total of 62 (64.6%) of patients invited gave consent for participation in the study.

6.5.2.4 The asthma self-management plan

The self-management plan training consisted of counseling on the nature and common signs of asthma. Counseling on self-management using a written and pictorial asthma action plan was provided. The asthma action plan consisted of three zones. For each zone of self-management plan, key signs and symptoms were presented with the respective action points. At zone 1 (stable asthma), patients are expected to use asthma medication regularly, with use of reliever at acute asthma attack. At progressive asthma attack (Zone 2), step required include increase ICS to quadruple dose, initiate oral prednisolone or use of Symbicort® as maintenance and reliever therapy. Patients who need to initiate oral prednisolone at Zone 2 will receive a prescription for a course of prednisolone from doctor. At worsening and life threatening asthma attack (Zone 3), the key action point is to seek medical attention immediately or call ambulance.

6.5.2.5 Assessments

Assessment of self-management knowledge (at enrolment) and recall (at 1st and 2nd follow visits) was tested using 3 hypothetical short scenarios (**Table 6.5**). These scenarios had been scenarios tested in a previous study for assessment of practical knowledge of self-management by Kolbe et al[229]. At follow up visits; patients were allowed to refer to their personal asthma action plan if carried by patients. The correct response to a scenario reflects the action point to the presentation of asthma exacerbation at each zone within the plan.

Other measures obtained include history of hospital admission, days off from work, emergency visits and degree of asthma control measured using asthma control test (ACT**) (Appendix 6.10).** ACT is a well validated 5-question simple tool to evaluate the degree of asthma control. The tool provides a total score of 25. An ACT score less than 19 indicates poorly controlled asthma[230, 231].The tool has been translated into different languages. In our study, ACT in Malay, English and Chinese were used.

Patients were also asked of their attempt at self-management at 1st and 2nd follow visits. PEF and FEV_1 were also recorded at enrolment, 1st follow up and 2nd follow up assessments. Data collection form was designed to collect all information obtained. (**Appendix 6.11)**

Table 6.5: Hypothetical Scenarios

You woke this morning feeling perfectly well and spent the day doing your usual activities. At 7 o'clock in the evening you sit down to relax and you notice you are feeling a little wheezy and breathless. What would you do?
Over the next half-hour the wheezing and breathlessness get worse and you find it a little difficult to walk to the kitchen for a drink. What would you do?
It has now been about one hour and your breathing continues to get worse and by 8 o'clock you are so wheezy and breathless that you find it difficult to speak or get up from your chair. What would you do

6.5.2.6 Outcome Measures

The primary outcome measure of this study was "recall" of knowledge of self-management action points after education at each follow up visits. Number of self-management action point attempts by patients was also recorded.

Clinical outcome measures used in this study were effects on hospital admissions, days off from work, emergency visits, level of asthma control, PEF and FEV_1. These measures were commonly reported in studies of asthma self-management.

6.5.2.7 Data analysis

Data analysis was performed using SPSS v16. Percentages of each before-and-after analysis were performed on all participants at each follow-up. The before-and-after comparisons at enrolment, 1st follow up assessment and 2nd follow up assessment were carried out using McNemars test with continuity correction for paired nonparametric data. Chi square was used to assess comparison of non-parametric data and t-test for continuous data.

6.5.3 Study Results

6.5.3.1 Participants

Of the 62 patients who were initially enrolled into the study, all participated in the 1st follow up assessments at 4 months, and 51 patients participated in the final (second) follow up asssessment at 8 months. Six declined to participate in the study at 8-months primarily due to lack of interest in self-management plan and five were lost to follow-up. **Table 6.6** shows the patients' characteristics of 62 patients first enrolled into the study. The majority of patients of study was female (>70%). The mean age for participants in pictorial action plan and written asthma plan was 49 years (SD 11.4) and 43 years (SD 14.9) respectively. The written asthma action plan group comprised a higher proportion of patients with mild persistent asthma (31.3%) than the pictorial asthma action plan group (16.7%).

More than 80% of patients in both groups had attained an education level above primary school.

Table 6.6: Patients' Characteristics

	Pictorial AP Group (n=30)	**Written AP Group** (n=32)	**Total** (n-62)
Age, years, mean(SD)	49.03 (11.44)	43.41 (14.87)	46.13 (13.51)
Gender		Count (%)	
Male	5 (16.7)	9 (28.1)	14 (22.6)
Female	25 (83.3)	23 (71.9)	48 (77.4)
Ethnicity			
Chinese	10 (33.3)	7 (21.9)	17 (27.4)
Indian	13 (43.3)	12 (37.5)	25 (40.3)
Malay	7 (23.3)	13 (40.6)	20 (32.3)
*Severity of asthma**			
Mild persistent	5 (16.7)	10 (31.3)	15 (24.2)
Moderate persistent	15 (50.0)	16 (50.0)	31 (50.0)
Severe persistent	10 (33.3)	6 (18.8)	16 (25.8)
Duration of asthma			
<6 years,	3 (10.0)	6 (18.8)	9 (14.5)
6-10 years	6 (20.0)	6 (18.8)	12 (19.4)
10-15 years	10 (33.3)	5 (15.6)	15 (24.2)
>15 years	11 (36.7)	15 (46.9)	26 (41.9)
Education level above primary	20 (83.3)	25 (92.6)	45 (88.2)

**Severity of asthma assessed by apparent drug use*

6.5.3.2 Responses to Rapid Onset Attack Scenarios

11.3% (n=7) and 21.6% (n=11) of patients had reported attempt of self-management action plans at 1st follow up and 2nd follow up assessments respectively (**Table 6.7**). All patients provided correct response (use of beta agonist) to onset of asthma attack at enrolment, 1st and 2nd follow up assessments. At assessment of a progressive asthma attack, 53.2% (n=33) and 62.7% (n=32) of patients responded with increasing ICS dose or initiation of oral prednisolone at 1st follow up and 2nd follow up assessments respectively. Only 24.2 %(n=15)

however, provided correct increase in dosage and duration of Zone 2 action point at 1st follow assessment. This improved to 47% (n=24) at 2nd follow up assessment. In response to a life threatening attack scenario, all patients responded correctly to "seek medical help or call ambulance" at enrolment, 1st follow up and 2nd follow up assessments.

6.5.3.3 Response to Progressive Asthma Attack based on Type of Action Plan

At both assessments, there were no significant differences between pictorial and written action plan groups in the proportion of patients who responded correctly to progressive asthma attack (**Table 6.8**). The proportion of correct responses for pictorial AP improved from 23.3% to 45.8%, while written AP improved from 25% to 48.1%.

There were significant differences in the response to progressive asthma attack scenario at 1st follow up ($p=0.009$) and 2nd follow up ($p<0.01$) between groups receiving "SMART approach", "increase ICS" and "initiate oral prednisolone" (**Table 6.9**). At 1st follow up assessment, higher proportions of patients receiving the SMART action plan (53.3%) provided correct responses compared to those receiving the "increase ICS" plan (15.4%) or the "initiate oral prednisolone" plan (14.3%). At 2nd follow up assessment, all patients in the SMART action plan group provided a correct response.

Table 6.7: Responses to Rapid Onset Attack Scenarios

	Enrolment	1st follow up	2nd follow up
	n=62	n=62	n=51
	Count (%)	Count (%)	Count (%)
At Onset of Asthma Attack			
Use of beta agonist	**62 (100)**	**62 (100)**	**62 (100)**
At Progressive Asthma Attack			
Increase use of beta agonist	**8(12.9)**	**9 (14.5)**	**16 (31.4)**
Increase ICS or take oral prednisolone	-	33 (53.2)	32 (62.7)
Correct response to dose and duration	-	**15 (24.2)**	**24 (47.0)**
Incorrect response to dose and duration	-	18 (29.0)	8 (15.7)
Seek medical help (GP or A&E)	55 (88.7)	29 (46.8)	19 (37.3)
At Life Threatening Stage			
Seek medical help (GP or A&E)	**53 (85.5)**	**53 (85.5)**	**43 (84.3)**
Call ambulance	**9 (14.5)**	**9 (14.5)**	**8 (15.7)**
Reported attempt of action points	-	7 (11.3)	11 (21.6)

ICS = Inhaled Corticosteroids; GP=General Practitioner; A&E= Accident and Emergency
P=value for baseline (enrolment) versus 1st follow up; P**=value for baseline (enrolment) versus 2nd follow up*
Underlined action points represent the correct responses.

Table 6.8: Written and Pictorial Asthma Action Plan Comparison of Correct Responses to Progressive Asthma Attack Scenario

		n	Correct response Count (%)	
1st follow up	**Total Participants**	**62**	**15 (24.2)**	
	Pictorial AP	30	7 (23.3)	p>0.05
	Written AP	32	8 (25.0)	
2nd follow up	**Total Participants**	**51**	**24 (47.1)**	
	Pictorial AP	24	11 (45.8)	p>0.05
	Written AP	27	13 (48.1)	

ICS = Inhaled Corticosteroids
AP=Action Plan

Table 6.9: "SMART approach", "Increase ICS" and "Initiate Oral Prednislone" Action Plans Comparison of Correct Response to Progressive Asthma Attack

		n	Correct response Count (%)	
1st follow up	**Total Participants**	**62**	**15 (24.2)**	
	Increase ICS	26	4 (15.4)	
	Initiate oral prednisolone	21	3 (14.3)	p=0.009
	SMART	15	8 (53.3)	
2nd follow up	**Total Participants**	**51**	**24 (47.1)**	
	Increase ICS	20	6 (30.0)	
	Initiate oral prednisolone	19	6 (31.6)	p=0.000
	SMART	12	12 (100)	

ICS = Inhaled Corticosteroids
AP=Action Plan

6.5.3.4 Clinical Outcomes

No changes in lung function and asthma control were observed at 1st follow up assessment in comparison to baseline measures. (**Table 6.10)** Asthma control significantly improved at the 2nd follow up assessment among written asthma action plan group (p=0.001). Comparisons between pictorial and written action plans at 2nd follow up showed significantly higher in the asthma control test in the written action plan group than in the pictorial action plan group (20.0 [SD 1.9] versus 18.0 [SD 2.0], p=0.02) (**Table 6.11**). A higher although not significant FEV_1 was found in the pictorial action plan group than the written action plan group at 2nd follow (1.6 litres [SD 0.5] versus 1.4 litres [SD 0.5], p=0.09). No differences were found in the lung function between the two groups of patients. No significance differences in markers of asthma morbidity were present (**Table 6.12**).

Table 6.10: Asthma Control and Lung Function Tests at Enrolment, 1st and 2nd follow up assessments.

	Baseline	1st follow up	2nd follow up	p*	p**
Pictorial Asthma Action Plan Group (n=24)					
Peak Expiratory Flow Rate (PEF [SD])	293 (105)	305 (95)	298 (87)	>0.05	>0.05
Forced Expiratory Volume in 1 second (FEV_1)	1.44 (0.49)	1.44 (0.45)	1.41 (0.45)	>0.05	>0.05
Asthma Control Test Scores (SD)	17.9 (2.1)	19.0 (2.0)	18.2 (2.1)	>0.05	>0.05
Written Asthma Action Plan Group (n=27)					
Peak Expiratory Flow Rate (PEF [SD])	318 (86)	310 (80)	327 (80)	>0.05	>0.05
Forced Expiratory Volume in 1 second (FEV_1)	1.6 (0.64)	1.55 (0.56)	1.64 (0.51)	>0.05	>0.05
Asthma Control Test Scores (SD)	18.9 (2.2)	19.1 (2.1)	20.0 (1.9)	>0.05	0.01

P=value for baseline (enrolment) versus 1st follow up; P**=value for baseline (enrolment) versus 2nd follow up*

Table 6.11: Written and Pictorial Asthma Action Plan Comparisons of Asthma Control and Lung Function Tests

	Written AP	Pictorial AP	*p*
Asthma Control Test Scores			
Baseline	18.9 ± 2.2	18.1 ± 2.0	>0.05
1st follow up	18.9 ± 2.2	19.0 ± 1.9	>0.05
2nd follow up	20.0 ± 1.9	18.3 ± 2.0	0.02
Forced Expiratory Volume in 1 second (FEV_1)			
Baseline	1.7 ± 0.7	1.5 ± 0.50	>0.05
1st follow up	1.6 ± 0.6	1.5 ± 0.5	>0.05
2nd follow up	1.4± 0.5	1.6 ± 0.5	0.09
Peak Expiratory Flow Rate (PEFR) ; L/min			
Baseline	316± 85	289± 101	>0.05
1st follow up	310± 80	302± 92	>0.05
2nd follow up	327± 80	298± 87	>0.05

Table 6.12: Written and Pictorial Asthma Action Plan Comparisons of Asthma Morbidity Markers

	Written AP	Pictorial AP
Hospital Admissions; Count (%)		
Baseline	1 (3.3)	1 (3.1)
1st follow up	0	1 (3.1)
2nd follow up	0	1 (3.1)
Emergency Hospital Visits; Count (%)		
Baseline	1 (3.3)	2 (6.3)
1st follow up	1 (3.3)	2 (6.3)
2nd follow up	0	1 (3.1)
Day off from work; Count (%)		
Baseline	2 (6.7)	3 (9.4)
1st follow up	1 (3.3)	2 (6.3)
2nd follow up	0	2 (6.3)

Values are presented as number of subjects, and percentages of the total subjects in parenthesis.

6.5.4 Validation of the procedure

The key feature of self-management involves “self-treatment" behaviour, which required patients to adjust or initiate medical therapy based on the changes in their asthma severity. This practical knowledge needs patients to first recognise the characteristics of their asthma status. Although, the recall of this practical knowledge may not necessarily lead to change in self-management behaviour and outcomes, it would offer validation of the self-management training and tool; and the asthma action plan.

6.5.4.1 Patients’ recall of self-management plan

Recall is the process of retrieving words or picture elements from memory. Most people read or see material only once, and depend on their memories when taking health actions. When reference to original materials is used, most must first recall or remember the type of information available[217]. Improving recall of health or medical information is important to help patients to cope with their condition.

In our study, most patients had their asthma action plan with them or were provided an example of asthma action plan during the recall assessment. Despite education and reinforcement, less than 50% patients were able to recall the self-management plan correctly at final assessment. Our study showed patients have no difficulty in recalling the action points for onset and worsening of asthma attack. This also showed ability to recognise the early signs of asthma attack as well as the signs and symptoms of potentially life threatening signs.

The steps which presented most difficulty in recollection is the progressive asthma attack (Zone 2) which requires patients to act according to one of the three action points; initiate a course of oral prednisolone, increase ICS to quadruple dose or SMART approach. The SMART approach group has a smaller sample

size due to less frequent use as compared to other single corticosteroids inhaler. Despite small sample size, SMART approach has consistently showed to be easier to recall compared to the two other action points. This is not surprising, as SMART approach is probably the easiest action point among the three action points as it does not involved use of additional medication and complicated dosage regimen. Most patients' recall improved from 1st follow-up to 2nd follow-up.

Minority of patients has recalled the wrong dose, reflecting possibility of misinterpretation of Zone 2 action point. The complexity of some dosage regimen explained the reason of misinterpretation. Besides that pictogram as sole communication sources can be easily misinterpreted[232, 233]. Thus, requires support with verbal instructions to ensure proper comprehension of pharmaceutical information.

6.5.4.2 Clinical Outcomes

Our present study did not show conclusive improvement in asthma morbidity measures and lung function tests at both assessments. The probable reason that our study has failed to show consistent clinical outcomes is likely to be due to the patients recruited. Patients recruited were relatively well-controlled patients. The inherent stable nature of asthma in most patients may have prevented the further improvement of their health outcomes upon intervention.

Well-controlled asthma patients may also be less motivated to learn and attempt to apply such a self-management plan. This can be shown by the small drop-out due to lack of interest in self-management. Further studies should be performed with uncontrolled asthma patients to establish the true clinical benefits of our approach.

A significant improvement in asthma control however was found in the written asthma action plan group at final assessment. Asthma control was also significantly higher than the patients in this group compared with patients receiving the pictorial asthma action plan.

6.5.4.3 Study Limitations

This present study may have several limitations. The sample size was limited: the study targeted 80 patients but was only able to recruit 62 patients within 3 months of recruitment. A few observations made during the study may explain the reasons for this. There was lack of support by medical practitioners in clinic for patient self-management. The study was generally accepted by a few senior consultants within the clinic, but not well received by some other medical practitioners. They were lack of support from medical practitioners to help in recruitment. Some patients were reluctant in joining the study due to the commitment to "learn" the self-management skills. Despite explanation and clarification on objectives of study and patients' roles, some patients were still not confident to join the study.

The second limitation of the study is that it is a single-centre study, which restricts the generalisation of this result. As with any other intervention, the experience of the service providers would affect the outcomes. The results from this study suggest that well-structured training, educational materials and on-going follow up should not be prohibitive to an effective self-management training programme.

The other limitation is the 8 months study period. The short study period does not allow any interpretation of long term efficacy of the action plans and self-management training. Future study which extended the study period over a 1 year period after the patients' initial training would be useful to understand changes in health behaviour, specifically self-management attitude. Study to examine patient

perceptions of benefits and limitations related to self-management measures could also provide insight into the attitude and behaviours around self-management.

Level of health literacy of sample populations was not considered in this study. Health literacy is known to have impact on understanding of health information. It is not known how the level of health literacy would impact the understanding and uptake of asthma action plan, will worth investigate in future study.

6.5.5 Conclusion of Chapter 6.5

The implementation and effectiveness of the self-management programme has been addressed in randomised trials in Western populations. To the author's knowledge, this is the first study done in Asian subgroup population and certainly in Malaysia to test the implementation of self-management training supported with an asthma action plan. The asthma action plan used in this study was developed systematically to ensure that it is well understood by the majority of patients before its use in formal education programme.

Chapter 7

7 Implications for Practice and Education

7.1 The Multidisciplinary Pharmaceutical Asthma Care Model

The healthcare and financial burden of asthma have been rising steadily over the years. It is essential that healthcare professionals work together to ensure that a suitable healthcare service is put in place to address patients' complex needs effectively.

Findings from our consensus survey (Chapter 5) yields a series of pharmaceutical care activities in a multidisciplinary care model for management of asthma in out-patient setting. Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.[59] It involves cooperation between pharmacists and other professionals in 1) assessment and identification of patient's needs, 2) formulation of management plan, 3) implementation of asthma care and 4) monitoring and review of patient therapeutic outcomes[64].

Patient assessment is arguably the most important activity in the components of asthma care. A comprehensive and systematic patient assessment is essential to establish patient needs in asthma management and education. Patient assessment should include evaluation of past medical history, past drug history, history of asthma, trigger factors, asthma control and severity and patient's co-morbidity. Patient knowledge and understanding can be evaluated to determine a patient's educational needs.

A pharmaceutical care plan should be designed to outline the individualised care provided to a patient. The plan aims to resolve patient needs identified via patient assessment, and guides the provision of pharmaceutical care.

Pharmacotherapy is an essential component of asthma management. Asthma patient should be prescribed with reliever and preventive treatment according to their severity of asthma[2, 26]. Medication delivery, specifically inhalers or spacers, should be selected according to patients' capability[117, 145]. Asthma education should also be provided. Components of education should include asthma pathology (nature of asthma), asthma triggers, signs and symptoms of asthma attack and action plan when asthma attacks[26]. Patients should also be educated on their medication and provided with the direction of use, benefits and goals of treatment. Patient's concerns such as side effects of medication should be addressed appropriately. Education should be supported with educational materials if necessary[234].

Delivery of asthma self-management is known to improve clinical outcomes[196,197], but has failed to achieve adequate support in our consensus study. Health professionals who play a key role in providing self-management support were not enthusiastic about guided asthma self-management.

Most studies in self-management focused on the clinical improvement with use of self-management with little focus on the process of self-management learning. Self-management involves complicated activities, and many challenges in its implementation have been described[151]. Complexity of asthma self-management plan may be a barrier to its acceptance. Our preliminary study showed use of a pictorial asthma guide as an alternative asthma action plan for patients who have reading difficulty.

Periodic monitoring is required to determine patient's asthma control and needs for adjustment of medication. Clinical monitoring should include subjective and objective parameters including daytime & nocturnal symptoms, limitations of activities, frequency of use of reliever, exacerbation in a week and peak expiratory flow rate. Patient should be fully evaluated on their inhaler technique, adherence to medication, drug related problems and related educational needs. Initial and ongoing patient assessment as well as patient's outcomes should be documented. A common tool for documentation can be used to improve communication and sharing of information between health professionals, as well as reducing replication of patient's evaluation.

7.2 The Roles and Responsibilities of Pharmacists within the Model

The important role of pharmacists in the conceptual asthma care model is explored in support for the delivery of the services. Our consensus process clearly articulated 10 agreed pharmacists' roles. In general, the consensus among pharmacists and medical practitioners favours activities of pharmacists in patient counseling but not activities related to the patient assessment and monitoring. It was agreeable that the pharmacists are responsible to educate patients on inhaler technique, nature of asthma and the asthma triggers, signs and symptoms of asthma exacerbation and use of medication. Patient training should be supported with educational materials whenever necessary. Pharmacists are also responsible for the review of patients' adherence to their medication, inhaler technique and concerns about the therapy. The roles of pharmacists in recommending medication adjustment should be based on issues related to the asthma therapy such as side effects and difficulty in handling an inhaler.

The establishment of pharmacists' roles in the model, guides ways for participation in the asthma care team. It also creates opportunities beyond the routine roles of pharmacists. In the long term, the model has the potential to

improve the credibility of the public health care services via partnerships between patients and healthcare professionals.

7.3 Implications for Practice and Education

Although the asthma care model is well developed as a conceptual framework, there are no specific steps, methods, or existing framework to guide the health care team to the implementation of the model. The framework however guides the design of successful intervention for pharmaceutical care implementation by providing direction and review points for healthcare team.

The key factors for the successful implementation of care model require adequate resources and planning to ensure successful adaptation and integration. Five important elements are important to support the pharmacists' roles and implementation of the care model; (1) pharmacists' attitudes towards pharmaceutical care, (2) workforce training and education, (3) reorientation of existing pharmacists' roles, and (4) manpower needs.

7.3.1 Understanding and attitudes towards pharmaceutical care concept

Pharmaceutical care is a crucial principle of pharmacy practice[235]. This does not imply that pharmaceutical care is solely a pharmacist-driven practice. The pharmaceutical care concept describes the means of improving patient management via continuous processes of assessment and monitoring of drug effectiveness and adverse reactions as well as patient education. It reflects what the patient should receive and should be delivered as according to clinical settings by health professionals involved in the management of the patient[235]. The understanding and knowledge of the principles of pharmaceutical care is essential for health professionals to implement it effectively.

In a study carried out in New Zealand involving 377 community pharmacists, over 60% of the pharmacists surveyed had a correct understanding and knowledge of the pharmaceutical care process[236]. Lack of understanding of pharmaceutical care was reported by 42.7% pharmacists to be one of the factors influencing their decisions to implement pharmaceutical care. Other factors include lack of motivation (35.9% pharmacists) and lack of confidence (41.7% pharmacists). Close to 16% pharmacists agreed that fear of change as one of the barrier to implementation of pharmaceutical care. System-related factors e.g. lack of reimbursement system, lack of access to patient medical records, etc also affect the implementation of pharmaceutical care.

Pharmaceutical care encompasses a continuum of care processes which begins from identification of drug therapy problems and ends with therapy outcomes assessment. The consented traditional activities of pharmacists in patient education and counseling in our consensus study do not alone constitute pharmaceutical care and this may reflect some resistance in adoption of new roles by pharmacists.

7.3.2 Workforce education and training in pharmaceutical care

It is essential that patient care is delivered by competent pharmacists. The establishment of pharmacists' responsibilities prepares pharmacists and pharmacy departments for involvement in the development and implementation pharmaceutical care.

In our consensus survey, the consented activities of pharmacists focus on the assessment and monitoring of drug adverse effects as well as patient education. There was lack of acceptance of pharmacists' roles in assessment and monitoring of therapy outcomes.

In the Malaysian context, individual and group patient education i.e. drug counselling, is routinely performed by pharmacists to achieve better compliance and health outcomes. In Malaysia, various studies have demonstrated positive outcomes of patients' intervention in counseling. Study has shown improvement of patients' insulin injection technique after counselling by pharmacists. The counseling significantly improved insulin technique score from 7.17 ± 1.53 to post counseling score 10.27 ± 1.19 ($p = 0.003$)[237]. Counselling by pharmacists also significantly changes patients' negative perceptions of insulin therapy. Pharmacists also showed ability to improve knowledge of osteoporosis in postmenopausal women. Patients' levels of knowledge were significantly higher in the intervention group at 12 month of study (77.6 ± 11.7% versus 65.2 ± 17.2%, $p<0.001$)[238].

Despite the above, there is very limited evidence of pharmacists' involvement in activities related to assessment and monitoring of patients progress. In one of the studies performed in 2005 in a teaching hospital, a total of 298 pharmaceutical care issues with an average of 9.6 ± 2.67 issues per patient were identified. The common pharmaceutical care issues were related to therapeutic drug choice (27.8%), predisposing patient factors (12.8%) and adverse drug reaction/interactions (11.1%)[239]. In another small scale study performed among 38 patients with diabetes mellitus, 540 pharmaceutical care issues were identified[240]. More than 20% of subjects required monitoring of patients' progress and therapy. The findings found noncompliance to medications among 97% of the participants. These studies are done hugely in the hospital setting, in which pharmacists working under MoH hospitals, enjoy complete control over the supply of medicines. A study in community pharmacy showed that pharmacists offered activities such as dispensing and patient counselling as part of their daily practice[241]. Patient-orientated practice is partly restricted by the level of legal control of medicine. Lack of ability and willingness to perform the patients' orientated activities beyond these routine activities was one of the significant barriers[242]. These studies reflected pharmacists' ability to identify pharmaceutical

care issues. The ability of pharmacists to address the issues is not known. Pharmacists' contribution to activities beyond counseling is important and opportunities for pharmacists to make a much greater contribution in asthma care. Professional training and education of pharmacists and students would be useful in addressing this.

Training is also essential to prepare pharmacists for other potential roles within the multidisciplinary care model and to reduce variability of content of the asthma education material. The application of training of pharmacists is frequently addressed through continuing education programme.

In some countries, continuing professional development (CPD) is essential to maintain pharmacists' registration or license to practice. In Malaysia, participation in CPD activities is mostly voluntary. For pharmacists in public sector, the provision of the update and training of pharmacists is the responsibility of the MoH. In 2008, a total of 467 courses, conventions and workshops were conducted for the pharmacists by government departments[243]. It is not known how many of these CPD sessions were asthma related.

A comprehensive training package seeking to upgrade the professional development of the pharmacists in term of skills and knowledge is essential to support and develop pharmacists' responsibilities in asthma care. The training should promote standardisation across the levels of care to consistent clinical practice and passing on of inconsistent messages to the patients.

One of the training needs essential in asthma care is self-management education. Despite the lack of acceptance among practitioners, training is needed to improve the understanding and consistency of the content of self-management education. CPD in asthma self-management is also needed to improve the acceptance of asthma self-management.

The schools of pharmacy also hold the responsibilities to equip the profession with the competency in terms of knowledge and skills to practice. Experiential training has been provided by many schools to provide practical experiences to students. Continued expansion of experiential learning in all areas of pharmacy practice is necessary to meet future needs for clinically trained pharmacists.

In order to train practitioners effectively, pharmacy educators and the practitioners need to work collaboratively to develop new patient-centred practice models, and better experiential education. Pharmacy educators need to strengthen their efforts to develop students' inter-professional relationships and understanding of practice. Inter-professional learning should also be encouraged within medical and pharmacy curriculum to improve understanding of collaborative effort.

Multidisciplinary education at a relatively early phase of professional development is seen as one way of equipping these professionals to provide a service which is to all intents and purposes 'seamless'[244]. It defines as bringing various professions together to understand a particular problem or experience. It should increase emphasis overlapping skills and competences as well as the collaborative practice. Such programme developed at undergraduate level may benefits by improving team working attitudes and communication skills.

7.3.3 Reorientation of existing Pharmacists' Roles

Multidisciplinary practice teams are the key towards implementation of pharmaceutical care model. This requires substantial redesign and reorientation of the existing care roles. The Crown report published in 1999 on prescribing, supply and administration of medicines recommended extending prescribing rights to other professional groups[245]. It extends the roles of pharmacists as dependent or supplementary prescribers. The dependent or supplementary prescribing expands pharmacists' roles in prescribing medicine within a clinical management plan

after diagnosis by a doctor. This responsibility also develops opportunity for pharmacists in patients' monitoring and assessment. This requires more formal integration of pharmacists into health care and the development of partnerships with other healthcare professionals and patients at the level of primary, secondary and tertiary care. Such movements of roles not only involve changes to legislation, but also practice models.

Pharmacists in Malaysia practise under two different legal frameworks. Ministry of Health (MoH) employed pharmacists enjoy full control over the supply of medicines. Exemptions from many pharmacy regulations apply to the practice in MoH[246]. On the other hand, pharmacists in the private healthcare sectors do not have full control over the supply of medicines. Private care settings such as private clinics and private hospitals dispense medicines to their own patients.

There are challenges for pharmacists in Malaysia to become players in the prescribing process, as well as being involved in patients' monitoring of therapy. In a survey among doctors, nurses and pharmacy personnel, prescription related inquiries were the main reason for their interaction with pharmacists[247]. Nurses agreed that pharmacy services such as drug counseling, drug compounding, and therapeutic drug monitoring are important activities, but there were lack of patients' contribution in these activities. Health care professionals in Malaysia are not prepared for community pharmacists to diagnose minor ailments, write prescriptions or to conduct screening tests[183]. There is strong disagreement for community pharmacists to make changes to prescriptions. More than 40% of the respondents disagreed that community pharmacists are well educated in or well trained to perform clinical therapeutics, diagnosis of minor illnesses based on the patient's signs and symptoms and; screening tests such as glucose and cholesterol tests[183].

This practice should change in the near future to support a level of patient care that genuinely affects patients' drug therapy outcomes. This requires health

professionals to work hand in hand patiently, honestly, and meaningfully to support a level of patient care at the level of primary, secondary and tertiary care that genuinely affects patients' drug therapy outcomes.

7.3.4 Manpower Needs

Due to the shortage of pharmacists in Malaysia, mandatory service for new pharmacy graduates was introduced in 2002. Before 2002, MoH preregistration pharmacy graduates were given a training pay allowance. With the initiation of 3 years of mandatory service, pharmacists are now entitled to a full junior-grade pharmacist salary. This upward revision of pharmacist salary scale attracted retention of more pharmacists in MoH after completion of the 3 years of compulsory service.

MoH supports a pharmacist-to-population ratio of approximately 1:2000, the standard suggested by the World Health Organisation (WHO) and estimated to achieve the ratio by 2020. This translates into a need for approximately 18,000 registered pharmacists.

In December 2009, approximately 7000 pharmacists were registered with the Malaysian Pharmacy Board, giving a pharmacist-to-general population ratio of about 1: 6000. Despite this positive enforcement to improve pharmacy workforce in MoH, the number of pharmacists remained insufficient. Vacancies for pharmacists still exist at some levels of the MoH e.g. state, district and others. In the effort to increase pharmacy workforce, there is also a growth in pharmacy schools especially private education in Malaysia to train more pharmacy graduates.

The increase of pharmacy workforce is critical for expansion of pharmacists' roles into patients' orientated activities. To allow this development effectively,

adequate remuneration is crucial to support the retention of pharmacists. Besides that, the working relationships between pharmacists and pharmacy technicians should also be optimised. Pharmacy technicians can be trained to handle some of the pharmacy services freeing up the pharmacists' time. The provision of pharmacy services can also be further facilitated using information and technology systems.

7.4 Future studies

From the series of our studies, the priority for future research should focus to continue building of a successful framework in asthma management. The studies should focus on:-

- evaluation of translation of model into action or practice
- exploration of barriers encountered by pharmacists in developing roles in patients assessment and monitoring
- exploration of the barriers to the uptake of the self-management training and feasibility of self-management training among asthma patients

Our studies set off to focus on model for chronic asthma patients monitored at out-patients clinics. Future studies should also considered patients who are unstable or at acute stages of asthma. The care needed could be different as of patients discussed in these studies.

In order to survive as a profession, pharmacy must also be willing to recognise the rapidly occurring changes in health care and patients' needs. Pharmacists must accept the reality that traditional roles are no longer adequate in the current system and be more proactive to step into all critical activities important in the care. Important objectives of such a study would include:

- assessment of pharmacists' understanding and attitudes towards pharmaceutical care concept;

- assessment of the extent and nature of current pharmacists' roles;
- identification the gaps of skills and knowledge of pharmacists required to fully implement the roles of pharmacists;
- evaluation of specific implementation strategies to facilitate the roles of pharmacists;
- identification of important factors which influences pharmacists' role implementation in a variety of settings;
- investigation of the views and experiences of pharmacists during the implementation; and
- evaluation of the impact and outcomes of pharmacists' roles.

Medical Research Council (MRC) Framework for the Development and Evaluation of Randomised Controlled Trials (RCTs) for Complex Interventions to Improve Health should be considered in guiding the future development, evaluation and implementation of interventions to improve health. The framework was first published in 2000 [248, 249] and updated following review in 2006. The framework guides researchers to select and implement the appropriate methods of their intended interventions through systematic considerations of development, evaluation and implementation processes[250]. Part of the approaches involve critical appraisal of existing evidences. The processes will also allow enhance recognition of limitations on study design.

7.5 Conclusion

This thesis presents a series of studies designed to help the understanding of the needs of patients in the development a pharmaceutical care model for the long-term management of asthma in Malaysia and, from these, elucidation of pharmacists' roles in the model and evaluation of self-management training.

The findings show limited acceptability of the roles of pharmacists in patient assessment and monitoring as well as a certain lack of support among the medical community in the implementation of asthma self-management. These are greatly associated with local challenges and limitations of suitable workforce at national level.

APPENDICES

Appendix 1.1: Stepwise Management Based on Asthma Control

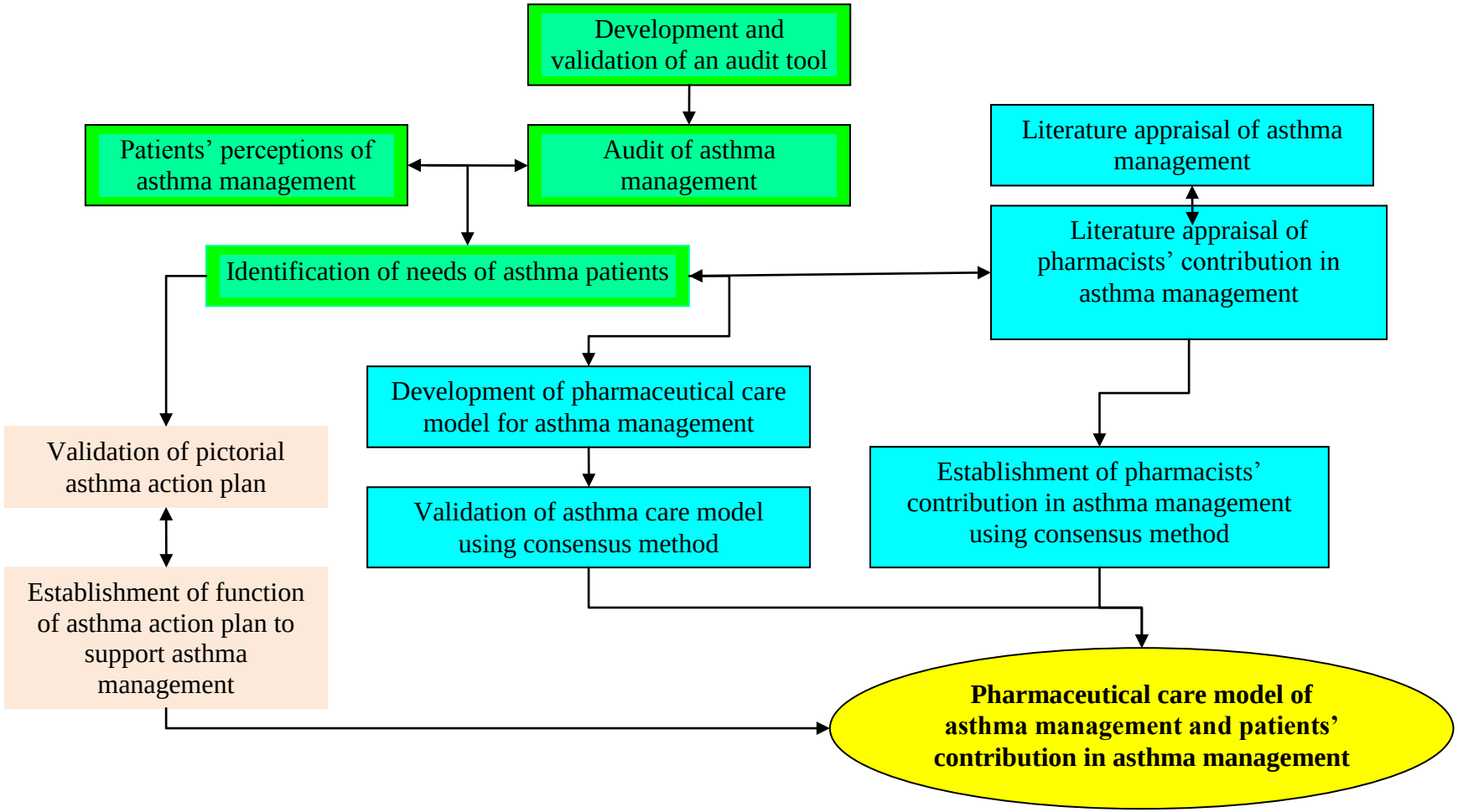
Stepwise Management Based on Asthma Control

Step 1	Step 2	Step 3	Step 4	Step 5
As needed rapid-acting β_2-agonist				
Controller options	Select one	Select one	Add one or more	Add one or both
	Low-dose inhaled ICS*	Low-dose inhaled ICS* plus long-acting β_2-agonist	Medium-or high-dose ICS* plus long-acting β_2-agonist	Oral glucocorticosteroid (lowest dose)
	Leukotriene modifier	Medium-or high-dose ICS	Leukotriene modifier	Anti-IgE treatment
		Low-dose inhaled ICS plus leukotriene modifier	Sustained release theophylline	
		Low-dose inhaled ICS plus sustained release Theophylline		

ICS = Inhaled Corticosteroids

Appendix 1.2: The development of a pharmaceutical care model for asthma management in Malaysia

The development of a pharmaceutical care model for asthma management in Malaysia



Appendix 2.1: Draft 1 Malaysia Asthma Medication Assessment Tool (MAT_{AST})-Review Criteria and Panel Recommendations

Panel Review Recommendations of Draft 1 Malaysia Asthma Medication Assessment Tool (MAT_{AST})

Review Criteria for Draft 1 Malaysia MAT_{AST}	Panel Review Recommendations	Outcomes (Review Criteria for Draft 2 Malaysia MAT_{AST})
GENERAL CARE		
1. **Patient with symptomatic asthma** is prescribed inhaled short acting β_2 agonist (SABA)	No comment	1. No change in original criterion
2. **Patient with one or more of the following finding is** prescribed with inhaled steroid □ experiences symptoms at least once a week over a 3–month period □ use of inhaled SABA more than once a week over a 3-month period □ experiences nocturnal asthma symptoms more than twice a month	No comment	2. No change in original criterion
3. **Patient on asthma treatment** has PEF or FEV_1 above 80%.	This is measuring clinical outcome. To be collected as part of sample characteristic rather than as a criterion.	*Criterion to be removed from MAT.* *A new review criterion is added:-*

	PEF or FEV monitoring is important part of management. The frequent of monitoring reflect the quality of care.	3. **Patient on asthma treatment** has PEF or FEV_1 measurement at least once in the past 12 months.
4. **Patient on asthma treatment** has had difficulty sleeping because of asthma symptoms (including cough) in the past one-month period	These criteria are outcome measures. Achievement of standard can be influenced by many factors. Thus, criteria could not reflect the standards of quality care and are not reliable as measures of quality.	*Criterion to be removed from MAT.*
5. **Patient on asthma treatment** has had asthma symptoms during the day (cough, wheeze, chest tightness, or breathlessness) in the past one-month period.		*Criterion to be removed from MAT.*
6. **Patient on asthma treatment** has had usual activities (e.g. work, housework, school, etc) affected by asthma symptoms in the past one-month period .		*Criterion to be removed from MAT.*
INHALED STEROIDS USE		
7. **Patient started on inhaled steroid in past 6 months** was initiated in a dose of 200–500ug mcg/day beclomethasone or equivalent.	No comment	4. No change in original criterion
8. **Patient prescribed an inhaled**	No comment	5. No change in original criterion

steroid is prescribed once or twice daily inhaled steroid.		
9. **Patient prescribed with inhaled steroid** is prescribed pressurised meter dose inhaler with spacer.	It is not a practice to prescribed spacer unless patient has problem using MDI. Other types of inhaler e.g. turbohaler can also be prescribe depending of patient's preferences and available of type of medication. This step is to be decided by patient's ability of using MDI and necessity of aerochamber.	*Criterion to be removed from MAT.*
10. **Patient prescribed an inhaled steroid** is reviewed at least every three months	No comment	6. No change in original criterion
11. **Patient with stable asthma and prescribed an inhaled steroid** has evidence documented of a step-down dose adjustment of 25-50%.	No comment	7. No change in original criterion
ADD-ON THERAPY USE		
12. **Patient poorly controlled on medium-dose inhaled steroid,** has one of the following steps taken: □ addition of long-acting inhaled β_2 agonist □ addition of sustained-release	Require specification of medium dose of ICS.	8. **Patient inadequately controlled* on 200-500 ug/day beclomethasone or equivalent inhaled steroid,** has one of the following steps taken: □ addition of long-acting inhaled β_2 agonist

theophylline - addition of leukotriene modifier - increase of inhaled steroid up to 2000mcg/day - additional of slow release β_2 agonist tablet.		- addition of sustained-release theophylline - addition of leukotriene modifier - increase of inhaled steroid up to 2000mcg/day - additional of slow release β_2 agonist tablet.
	Assessment of inhaler technique is important and should be documented in follow up visit.	A new criterion is to be added to assess the assessment and documentation of within the 1st year of 1st visit. 9. **Patient prescribed an inhaler** has had inhaler technique assessed on follow-up visit and documented for one year from the 1st visit.
13. **Patient prescribed an inhaled steroid requiring an add-on therapy** has had inhaler technique assessed and documented.	No comment	10. **No change in original criterion**
14. **Patient prescribed an inhaled steroid requiring an add-on therapy** has a documented use of more than 3 times of SABA in a day.	This is a signs and symptoms of inadequate control of asthma. Many other signs and symptoms could indicate inadequate control e.g. cough at night etc. This criterion is to be removed.	*Criterion to be removed from MAT.*
15. **Patient on an inhaled long acting β_2 agonist (LABA)** is maintained on an inhaled steroid.	No comment	11. No change in original criterion

16. **Patient prescribed higher doses of steroid (> 1000 ug/day of beclomethosone,** is prescribed an inhaled LABA.	No comment	12. No change in original criterion
17. **Patient poorly controlled on higher doses of steroid and inhaled LABA,** has one of the following steps taken: □ addition of sustained-release theophylline □ addition of leukotriene modifier □ addition of long acting oral β_2 agonist □ addition of oral steroid	Compliance and inhaler technique should be documented before following steps taken.	Standards on compliance and inhaler technique checked taken to be added. 13. **Patient inadequately controlled on higher doses of steroid and inhaled LABA,** has the following steps taken: □ compliance issue discussed □ inhaler technique checked □ addition of sustained-release theophylline □ addition of leukotriene modifier □ addition of oral steroid
ORAL STEROID USE		
18. **Patient prescribed oral steroid** is prescribed with prednisolone or methylprednisolone.	Prednisolone is the most important oral steroid in asthma. So, it is more important to know whether prednisolone is the 1st choice.	Methylprednisolone is to be removed from standard. 14. **Patient prescribed oral steroid** is prescribed with prednisolone.
19. **Patient prescribed daily oral steroid** is prescribed once every day or	Recommend qualifier to be rephrased. Qualifier needs to define appropriately to	Add ">3 months" into qualifier. 15. **Patient with asthma on long term**

alternate day.	reflect patient prescribed on long term oral steroids as criterion 21.	**oral steroid (>3 months)** is prescribed once every day or alternate day.
20. **Patient prescribed daily oral steroid** has appropriate action taken to ensure the lowest possible dose is used (i.e. dose adjusted as according to response).		Add ">3 months" into qualifier. 16. **Patient with asthma on long term oral steroid (>3 months)** has appropriate action taken to ensure the lowest possible dose is used (i.e. dose adjusted as according to response).
21. **Patient with asthma on long term oral steroid (>3 months)** has prescribed with preventive treatment for osteoporosis.	No comment	17. No change in original criterion
22. **Patient with exacerbation of asthma and prescribed with oral steroid** is prescribed with a dose of 30-40 mg prednisolone.	No comment	18. No change in original criterion
23. **Patient prescribed a short course of steroid** is prescribed prednisolone for at least 5 days.	No comment	19. No change in original criterion
PATIENT EDUCATION NEEDS		
24. **Patient with stable asthma who is receiving inhalers** has had inhaler technique checked.	No comment	20. No change in original criterion

25. **Patient prescribed an inhaler** demonstrates a satisfactory inhaler technique.	No comment	21. No change in original criterion
26. **Patient prescribed an inhaler** has reassessment of inhaler technique performed as part of clinical review.	Standard of criterion needs to be more specific. A reasonable timeline has to be included to ensure it reflects the recent quality of care.	22. **Patient prescribed an inhaler** has had inhaler technique assessed at least once in the past 12-month period.
27. **Patient with exercise–induced asthma** is advised to take inhaled SABA prior to exercise.	No comment	23. No change in original criterion
28. Patient on asthma treatment **has had their education** needs met on □ benefit /precautions of treatment □ importance of compliance □ regular monitoring	Triggers of asthma and smoking cessation are also important aspect of education and should be assessed. Standard being modified to include these two components of education.	24. Patient on asthma treatment **has had their education needs met on** □ triggers of asthma □ benefit /precautions of treatment □ importance of compliance □ regular monitoring □ smoking cessation
29. Patient on asthma treatment **has monitored their own PEFR and can recognise signs of acute attack.**	No a common practice in Malaysia for patient to monitor using PEFR unless patient educated on self management.	*Criterion to be removed from MAT.*

30. Patient on asthma treatment **has a written management plan** □ presented by patient □ available at home	***Standard is ambiguous.*** ***Requires simplification of standards.***	25. Patient guided on self-management **has a written management plan.**
31. Patient on asthma treatment **has had guidance on self-management**	***"What guidance do you mean?" The guidance needed should be specified.***	26. Patient with a written self-management plan **has had the following information written:** □ **Signs and symptoms of attack** □ **Dose regimen** □ **Duration of medication** □ **When to seek medical advice** □ **Use of PEFR**

Summary

No of original criteria in Draft 1 MAT_{AST} = 31

No of review criteria Draft 2 MAT_{AST} (after panel review) = 26

No of criteria removed = 7

No of criteria added = 2

No of criteria modified on the criteria standard or qualifier = 7

No of criteria without medication = 17

Appendix 2.2: Review Criteria of Draft 2 MAT_{AST} - Recommendations after Field Testing

Review of Draft 2 MAT_{AST} (after Field Testing):- Applicability & Practicality of Criteria

Review Criteria for Draft 2 MAT_{AST}	*Recommendations after Field Testing*	*Outcomes (Review Criteria for Final MAT_{AST})*
GENERAL CARE		
1. **Patient with symptomatic asthma** is prescribed inhaled short acting β_2 agonist (SABA)	The word 'symptomatic' in qualifier has limited the applicability of criteria to patients with symptomatic asthma. Evidence recommended that all patients with asthma have received a reliever (SABA). **Recommendation:** Remove the word "symptomatic" in qualifier.	1 **Patient with asthma** is prescribed inhaled short acting β_2 agonist (SABA)
2. **Patient with one or more of the following finding is** prescribed with inhaled steroid • experiences symptoms at least once a week over a 3–month period • use of inhaled SABA more than once a week over a 3-month period • experiences nocturnal asthma symptoms more than twice a month	In more than 50% of the case, there were insufficient data to assess the criterion. Most patients were prescribed inhaled steroids when symptoms mentioned started and most record no longer in record. **Recommendation:** Criterion is rephrased to assess the availability of record of clinical review in the past 12 months.	2 **Patient with asthma** has a record of a review of their clinical condition in the past 12 months
3. **Patient on asthma treatment** has PEF or FEV_1 measurement at least once in the past 12 months.	Qualifier limited the applicability of criteria to patients on asthma treatment. Spirometry is a monitoring tool that should be applied to all	3 **Patient with asthma** has PEF or FEV_1 measurement at least once in the past 12 months.

	asthma patients. **Recommendation:** Rephrase qualifier to "Patient with asthma"	
INHALED STEROIDS USE		
4. **Patient with asthma and prescribed an inhaled steroid in the past 6 months** has a record of being initially started at the dose of 200-500mcg/day.*	This criterion is easy to audit. Timeframe is plausible. **Recommendation:** No change to original criterion	4 **Patient with asthma and prescribed an inhaled steroid in the past 6 months** has a record of being initially started at the dose of 200-500mcg/day.*
5. **Patient with asthma and currently prescribed an inhaled steroid** is prescribed once or twice daily inhaled steroid.	This criterion was easy to audit. **Recommendation:** No change to original criterion	5 **Patient currently prescribed an inhaled steroid** is prescribed the steroid inhaler either once or twice daily.
6. **Patient with asthma and currently prescribed an inhaled steroid** is reviewed at least every three months	Medication use review is done as part of clinical review. Criterion 2 (revised version) has include assessment of clinical review. **Recommendation:** Criterion to be removed from MAT_{AST}.	
7. **Patient with stable asthma and prescribed an inhaled steroid** has evidence documented of a step-down dose adjustment of 25-50%.	This criterion was easy to audit. **Recommendation:** No change to original criterion	6 **Patient with stable asthma and prescribed an inhaled steroid** has evidence documented of a step-down dose adjustment of 25-50%.
ADD-ON THERAPY USE		

8. **Patient inadequately controlled* on 200-500 ug/day beclomethasone or equivalent inhaled steroid,** has one of the following steps taken:- ☐ addition of long-acting inhaled β_2 agonist ☐ addition of sustained-release theophylline ☐ addition of leukotriene modifier ☐ increase of inhaled steroid up to 2000mcg/day ☐ additional of slow release β_2 agonist tablet.	The MAT was first designed using GINA 2004. With reference to GINA 2005, LABA has been recommended as preferred choice of add-on therapy (Grade A). Patient not prescribed with LABA as 1st LABA but with other add-on should have a trial of LABA. **Recommendation:** The criterion will be removed. 3 new review criteria are added to reflect the GINA recommendations.	7 **Patient with asthma and currently prescribed an inhaled steroid at a dose above 500mcg/day** has a documented trial of inhaled LABA **8 Patient with asthma currently prescribed an inhaled steroid plus additional 'preventer' which is not a long-acting β_1 agonist** has a record of a therapeutic trial with a long-acting β_1 agonist. **9 Patient with uncontrolled asthma after addition of LABA therapy to ICS (<1000 mcg)** has had the following steps taken ☐ addition of sustained-release theophylline ☐ addition of leukotriene modifier ☐ addition of long acting anti-cholinergic ☐ increase of inhaled steroid up to 1000mcg/day
9. Patient prescribed an inhaler has had **inhaler technique assessed on follow-up visit and documented**	Insufficient data to assess the applicability to criterion standard because 1st visit record does not only necessary means 1st time diagnose of asthma/use of inhaler. Inhaler assessment	10 **Patient with asthma and receiving inhaler** has a record of the demonstration of satisfactory technique in the past 12 months by a competent health care

for one year from the 1st visit.	should be done for all patients on inhalers at least once a year. Timeframe of 1 year is agreed by research group. **Recommendation:** Rephrased to "Patient with asthma and receiving inhaler has a record of the demonstration of satisfactory technique in the past 12 months by a competent health care professional." This criterion will be placed under general care.	professional.
10. **Patient prescribed an inhaled steroid requiring an add-on therapy** has had inhaler technique assessed and documented.	Easy to apply and applicable to most of the patient records. But it will be very similar to the revised criterion 10 above. **Recommendation.** Criterion to be removed from MAT_{AST}.	
11. **Patient with asthma and currently prescribed long-acting inhaled β_2-agonists** is also on an inhaled steroid.	This criterion was easy to audit. **Recommendation:** No change to original criterion	11 **Patient with asthma and currently prescribed long-acting inhaled β_2-agonists** is also on an inhaled steroid.
12. **Patient prescribed higher doses of steroid (> 1000 ug/day of beclomethosone,** is prescribed an inhaled LABA.	This criterion was easy to audit. **Recommendation:** No change to original criterion	12 **Patient prescribed higher doses of steroid (> 1000 ug/day of beclomethosone,** is prescribed an inhaled LABA.
13. **Patient inadequately controlled* on higher doses of steroid and inhaled LABA,** has the following	This criterion was easy to audit.	**13 Patient inadequately controlled* on higher doses of steroid and inhaled**

steps taken:- □ addition of sustained-release theophylline □ addition of leukotriene modifier □ addition of oral steroid	**Recommendation:** No change to original criterion	**LABA,** has the following steps taken:- □ addition of sustained-release theophylline □ addition of leukotriene modifier □ addition of oral steroid
ORAL STEROIDS USE		
14. **Patient prescribed oral steroid** is prescribed with prednisolone.	This criterion is not needed because in all cases, prednisolone is used when oral steroids is used. **Recommendation.** Criterion to be removed from MAT_{AST}.	
15. **Patient with asthma on long term oral steroid (>3 months)** is prescribed once every day or alternate day.	This criterion was easy to audit. Although the prevalence (applicability) of criterion is less than 1%, the appropriate use of oral steroids is important in asthma management. The criterion should therefore still be included into MAT_{AST}. **Recommendation:** No change to original criterion	14 **Patient with asthma on long term oral steroid (>3 months)** is prescribed once every day or alternate day.
16. **Patient with asthma on long term oral steroid (>3 months)** has appropriate action taken to ensure the lowest possible dose is used (i.e. dose adjusted as according to response).	It is very difficult to assess the appropriateness of action taken based on the limited record available in most cases. Timeframe will be required. Some patients do not have record in the past if seen in other clinic although dose adjustment may have been done. Although the prevalence (applicability) of criterion is less than 1%, the	**15 Patient on long-term oral steroid tablets (longer than 3 months)** has had the dose reviewed at least twice in the past 12 months

	appropriate use of oral steroids is important in asthma management. The criterion should therefore still be included into MAT_{AST}. **Recommendation** To rephrase the criterion to assess frequency of dose review. Timeframe is the past 12 months.	
17. **Patient with asthma on long term oral steroid (>3 months)** has prescribed with preventive treatment for osteoporosis.	This criterion was easy to audit. Although the prevalence (applicability) of criterion is less than 1%, the appropriate use of oral steroids is important in asthma management. **Recommendation:** No change to original criterion	16 **Patient with asthma on long term oral steroid (>3 months)** is prescribed with preventive treatment for osteoporosis (calcium supplement, biphosphonates, HRT, vitamin D or related).
18. **Patient with exacerbation of asthma and prescribed with oral steroid** is prescribed with a dose of 30-40 mg prednisolone.	This criterion was easy to audit. **Recommendation:** No change to original criterion	17 **Patient with exacerbation of asthma and prescribed with oral steroid** is prescribed with a dose of 30-40 mg prednisolone.
19. **Patient prescribed a short course of steroid** is prescribed prednisolone for at least 5 days.	This criterion was easy to audit. **Recommendation:** No change to original criterion	**18 Patient prescribed a short course of steroid** is prescribed prednisolone for at least 5 days.
PATIENT EDUCATIONAL NEEDS (PATIENT INTERVIEW)		
20. **Patient with asthma and receiving inhalers** has had inhaler technique checked.	This criterion is the similar to criterion no 22. Criterion 22 is appropriate as the time frame is not realistic and practical.	

	Recommendation: Criterion to be removed from MAT_{AST}.	
21. **Patient with asthma and receiving inhalers** demonstrates a satisfactory inhaler technique.	This criterion was easy to assess. **Recommendation:** No change to original criterion	19 **Patient with asthma and receiving inhalers** demonstrates a satisfactory inhaler technique.
22. **Patient with asthma and receiving inhalers** has had inhaler technique assessed at least once in the past 12-month period.	This was easy to audit. **Recommendation:** No change to original criterion	20 **Patient with asthma and receiving inhalers** has had inhaler technique assessed at least once in the past 12-month period.
23. **Patient with exercise–induced asthma** is advised to take inhaled SABA prior to exercise.	It is rare to have exercise-induced asthma. Besides that, majority of the patients are not sure themselves whether they have exercise-induced asthma. Therefore, insufficient data to conclude applicability to criterion in most patients (99.4%). **Recommendation:** Criterion to be removed from MAT_{AST}.	

24. Patient on asthma treatment **has had their education needs met on** ☐ **triggers of asthma** ☐ **benefit /precautions of treatment** ☐ **importance of compliance** ☐ **regular monitoring** ☐ **smoking cessation**	**Standards to be rephrased to reflect the information requested from patients.** **Recommendation:** Rephrased of standard from "has had education needs met on" to "has received information on".	21 Patient with asthma **has received information on:** ☐ **triggers of asthma** ☐ **benefit /precautions of treatment** ☐ **importance of compliance** ☐ **regular monitoring** ☐ **smoking cessation**

25. Patient guided on self-management **has a written management plan.**	This was easy to audit. **Recommendation:** No change to original criterion	**22** Patient guided on self-management **has a written management plan.**
26. Patient with a written self-management plan **has had the following information written:-** □ **Signs and symptoms of attack** □ **Dose regimen** □ **Duration of medication** □ **When to seek medical advice** □ **Use of PEFR**	***This was easy to audit.*** **Recommendation:** No change to original criterion	**23** Patient with a written self-management plan **has had the following information written:-** □ **Signs and symptoms of attack** □ **Dose regimen** □ **Duration of medication** □ **When to seek medical advice** □ **Use of PEFR**

Summary

No of original criteria in Draft 2 MAT_{AST} = 26

No of review criteria in Draft 3 MAT_{AST} (after field testing) = 23

No of criteria removed = 6

No of criteria added = 3

No of criteria modified on the criteria standard or qualifier = 5

No of criteria without modification= 15

Appendix 2.3: Comparison of review criteria between UK MAT_{AST} and Revised MAT_{AST} (Draft 2)

Medication Assessment Tools Review: Final UK versus Proposed final Malaysia study

Malaysia Final MAT$_{AST}$	GRADING	UK Final MAT$_{AST}$	GRADING
GENERAL CARE			
2 **Patient with asthma** is prescribed inhaled short acting β_2 agonist (SABA)	**A**	1 **Patient with asthma** is prescribed inhaled short-acting β2 agonist.	**A**
24 **Patient with asthma** has a record of a review of their clinical condition in the past 12 months		2 **Patient with asthma** has demonstration of his/her condition reviewed in the last 12 months.	**B**
25 **Patient with asthma** has PEF or FEV_1 measurement at least once in the past 12 months.		3 **Patient with asthma** has this diagnosis confirmed by a reversibility test	-
26 **Patient with asthma and receiving inhaler** has a record of the demonstration of satisfactory technique in the past 12 months by a competent health care professional.		4 **Patient with asthma receiving inhaler** has demonstration of satisfactory technique in the past 12 months by a competent health care professional.	-
		5 **Patient with asthma and a record of last review by a physician** has a record of their status at that time regarding ☐ difficulty in sleeping, ☐ asthma symptoms usually experienced during the day (cough, wheeze, chest tightness, or	-

		breathlessness) ☐ interference with the usual activities (e.g., housework, work, school, etc.).	
INHALED STEROIDS USE			
27 **Patient with asthma and prescribed an inhaled steroid in the past 6 months** has a record of being initially started at the dose of 200-500mcg/day.*			
28 **Patient currently prescribed an inhaled steroid** is prescribed the steroid inhaler either once or twice daily.	**A**	6 **Patient with asthma and currently prescribed an inhaled steroid** is prescribed it no more frequently than twice daily.	**A**
29 **Patient with stable asthma and prescribed an inhaled steroid** has evidence documented of a step-down dose adjustment of 25-50%.	**B**	7 **Patient with asthma currently prescribed an inhaled steroid with a history of dose reduction (25-50%)** has a history of asthma control in the previous 12 months before dose reduction.	**-**
ADD-ON THERAPY USE			
30 **Patient with asthma and currently prescribed an inhaled steroid at a dose above 500mcg/day** has a documented trial of inhaled LABA	**A**	**8 Patient with asthma and on "add-on" therapy to ICS** has a documented trial of a LABA as first choice therapy.	**A**
31 Patient with asthma currently prescribed an inhaled steroid plus additional 'preventer' which is not a LABA has a record of a therapeutic trial	**A**	**9 Patient with asthma on ICS and documented unsuccessful trial of LABA** has a record of being stopped LABA, optimised the dose of ICS up to	**A**

	with a LABA.			800mcg/day* and, if necessary, added other add-on therapy.	
32	**Patient with uncontrolled asthma after addition of LABA therapy to ICS (<1000 mcg)** has had the following steps taken ❒ addition of sustained-release theophylline ❒ addition of leukotriene modifier ❒ addition of long acting anticholinergic ☐ increase of inhaled steroid up to 1000mcg/day	**B**	10	**Patient with record of uncontrolled asthma after addition of LABA therapy to ICS (<800mcg)** had the dose of inhaled steroids optimised up to 800mcg/day*.	**D**
33	**Patient with asthma and currently prescribed LABA** is also on an inhaled steroid.		11	**Patient with asthma and currently prescribed a LABA** is also on an inhaled corticosteroid.	**-**
34	**Patient prescribed higher doses of steroid (> 1000 ug/day of beclomethosone,** is prescribed an inhaled LABA.				
35	**Patient inadequately controlled* on higher doses (above 1000 ug/day)of steroid and inhaled LABA,** has the following steps taken:- ☐ addition of sustained-release theophylline ☐ addition of leukotriene modifier ☐ addition of oral steroid		12	**Patient with still uncontrolled asthma on 800mcg/day* despite concomitant LABA therapy** has been tried any of the following interventions: ☐ increasing inhaled steroid to 2000 mcg/day* ☐ leukotriene receptor antagonists ☐ theophyllines ☐ slow release β_2 agonist tablets	**D**

ORAL STEROID USE			
		13 **Patient on frequent oral steroid (>3 times per year)** has been considered for referral to a respiratory specialist.	-
		14 **Patient with asthma on continuous oral steroid (>3months)** is receiving it as result of a referral to a respiratory specialist.	-
36 **Patient with asthma on long term oral steroid (>3 months)** is prescribed once every day or alternate day.		15 **Patient with asthma on continuous oral steroid (>3months)** is prescribed as a single dose in the morning.	-
37 Patient on long-term oral steroid tablets (longer than 3 months) has had the dose reviewed at least twice in the past 12 months			
38 **Patient with asthma on long term oral steroid (>3 months)** is prescribed with preventive treatment for osteoporosis (calcium supplement, biphosphonates, HRT, vitamin D or related).		16 **Patient with asthma on continuous oral steroid (>3months)** has been offered therapy of oral biphosphonates/ calcium and vitamin D, or if not, patient has had a recent DXA scan which was proven to be normal.	-
		17 **Patient with asthma on continuous oral steroid (>3months)** has had blood pressure monitored within past 12 months	-
		18 **Patient with asthma on continuous**	-

		oral steroid (>3months) has been screened for diabetes within the past 12 months.	
		19 **Patient with asthma on continuous oral steroid (>3months)** is also prescribed inhaled steroids 2000mcg/day*, unless unable to use inhalers.	-
39 **Patient with exacerbation of asthma and prescribed with oral steroid** is prescribed with a dose of 30-40 mg prednisolone.			
40 Patient prescribed a short course of steroid is prescribed prednisolone for at least 5 days.			
PATIENT EDUCATIONAL NEEDS			
41 **Patient with asthma and receiving inhalers** demonstrates a satisfactory inhaler technique.		**20 Patient with stable asthma** who is receiving inhalers demonstrates a satisfactory inhaler technique.	**B**
42 **Patient with asthma and receiving inhalers** has had inhaler technique assessed at least once in the past 12-month period.		21 **Patient with stable asthma who is receiving inhalers** has had inhaler technique assessed at least once in the past 12-month period.	-
		22 **Patient with exercise–induced asthma** is advised to take inhaled SABA prior to exercise.	-

43 Patient with asthma **has received information on:** ☐ **triggers of asthma** ☐ **benefit /precautions of treatment** ☐ **importance of compliance** ☐ **regular monitoring** ☐ **smoking cessation**		**23** Patient on asthma treatment **has had their education needs met on** ☐ **triggers of asthma** ☐ **benefit /precautions of treatment** ☐ **importance of compliance** ☐ **regular monitoring** ☐ **smoking cessation**	-
44 Patient guided on self-management **has a written management plan.**		**24** Patient guided on self-management **has a written management plan.**	*A*
45 Patient with a written self-management plan **has had the following information written:-** ☐ **Signs and symptoms of attack** ☐ **Dose regimen** ☐ **Duration of medication** ☐ **When to seek medical advice** ☐ **Use of PEFR**			

14 common criteria in both tools

Appendix 2.4: Final MAT_{AST}

ASTHMA MEDICATION ASSESSMENT TOOL (MAT_{AST})

Patient Name Age Height Female /Male Chinese/Malay/Indian/Others Smoker/Non-smoker/ Ex-smoker	Current medication	Duration of asthma 1st onset of asthma **PEFR** PEFR(pred)

	Criteria	N/A	Yes	No	No, but J	ID (q)	ID (s)	Ref
	General Care							
	Patient with asthma							
1	has a PEF or FEV_1 documented in the past 12 months.	□	□	□	□	□	□	1,2
2	is prescribed inhaled short-acting β2 agonist.	□	□	□	□	□	□	1
3	has a record of a review of their clinical condition in the past 12 months	□	□	□	□	□	□	1,2
4	**Patient with asthma and receiving inhaler** has a record of the demonstration of satisfactory technique in the past 12 months by a competent health care professional.	□	□	□	□	□	□	1
	Inhaled steroids use							
5	**Patient with asthma and prescribed an inhaled steroid in the past 6 months** has a record of being initially started at the dose of 200-500mcg/day.*	□	□	□	□	□	□	1
6	**Patient with asthma and currently prescribed an inhaled steroid** is prescribed the steroid inhaler either once or twice daily.	□	□	□	□	□	□	1
7	**Patient with stable asthma for 3 months or more and prescribed an inhaled steroid** has evidence documented of a step down dose adjustment of 15-50%.	□	□	□	□	□	□	1

	Criteria	N/A	Yes	No	No, but J	ID (q)	ID (s)	Ref
	Add-on therapy use							
8	**Patient with asthma and currently prescribed long-acting inhaled β1-agonists** is also on an inhaled corticosteroid.	□	□	□	□	□	□	1
9	**Patient with asthma and currently prescribed an inhaled steroid at a dose above 500mcg/day** has a documented trial of inhaled LABA	□	□	□	□	□	□	1
10	**Patient with asthma currently prescribed an inhaled steroid plus additional 'preventer' which is not a long-acting β_1 agonist** has a record of a therapeutic trial with a long-acting β_1 agonist.	□	□	□	□	□	□	1,2
11	**Patient with uncontrolled asthma after addition of LABA therapy to ICS (<1000 mcg)** has had the following steps taken ❒ addition of sustained-release theophylline ❒ addition of leukotriene modifier ❒ addition of long acting anticholinergic ❒ increase of inhaled steroid up to 1000mcg/day	□	□	□	□	□	□	1
12	**Patient prescribed higher doses of steroid (> 1000 ug/day of beclomethosone,** is prescribed an inhaled LABA.	□	□	□	□	□	□	1
13	**Patient inadequately controlled* on higher doses (above 1000 ug/day)of steroid and inhaled LABA,** has the following steps taken:- ❒ addition of sustained-release theophylline ❒ addition of leukotriene modifier ❒ addition of oral steroid	□	□	□	□	□	□	1
	Oral steroid use							
14	**Patient with asthma on long term oral steroid (>3 months)** is prescribed preventive treatment for osteoporosis (calcium supplement, biphosphonates, HRT, vitamin D or related).	□	□	□	□	□	□	1
15	is prescribed once every day or alternate day	□	□	□	□	□	□	1
16	has had the dose reviewed at least twice in the past 12 months	□	□	□	□	□	□	1,2
17	**Patient with exacerbation of asthma and prescribed with oral steroid** is prescribed with a dose of 30-40 mg prednisolone	□	□	□	□	□	□	1
18	**Patient prescribed a short course of steroid** is prescribed prednisolone for at least 5 days.	□	□	□	□	□	□	1

	Criteria	N/A	Yes	No	No, but J	ID (q)	ID (s)	Ref
	Patient educational needs							
19	**Patient with asthma and receiving inhalers** has had inhaler technique checked once in the past one year.	□	□	□	□	□	□	1,2
20	demonstrates a satisfactory inhaler technique.	□	□	□	□	□	□	1
21	**Patient with asthma** has received information on: ❒ triggers of asthma ❒ benefit /precautions of treatment ❒ importance of compliance ❒ regular monitoring ❒ smoking cessation.	□	□	□	□	□	□	1,2
22	**Patient guided on self-management** has a written management plan.	□	□	□	□	□	□	1
23	**Patient with a written self-management plan** has had the following information written:- ❒ Signs and symptoms of attack ❒ Dose regimen ❒ Duration of medication ❒ When to seek medical advice ❒ Use of PEFR	□	□	□	□	□	□	1,2

***** BDP or equivalent

N/A – Not applicable; **No, but J** – No, but Justifiable; **ID(q)** – Insufficient data (Qualifier); **ID(s)** – Insufficient data (Standard); **LABA** – Long-acting β1 agonist, **SABA-** Short-acting β1 agonist

Key to guideline recommendation sources

1. GINA (Global Initiative for Asthma). Workshop Report. Global Strategy for Asthma Management and Prevention. 2005.
2. Local decision. Panel Review

Appendix 3.1: Interview Schedule (Draft 1)

Interview Schedule (Draft 1)

1. What type of medication was given by your doctor to you?
2. What is the purpose of the medication?
3. How long have you been using the medication?
4. Who educate you about your medication?
5. Did you experience any problem with the medication?
6. Did you try to change your medication without doctor's instructions?
7. Did you attempt to stop taking medication without doctor's instructions?
8. Why did you change your medication without doctor's instructions?
9. Why did you stop taking your medication without doctor's instructions?
10. What do you do if you forget to take your medication?
11. What do you do if you do not feel well?
12. What is your opinion in regard to your health and medication?
13. What are other elements that will affect your health?
14. What do you like to be changed in your care?
15. What is your opinion if you are ask to change the medicine dosage in written instructions?
16. What do you feel about taking medication according to written instructions?
17. How much are you worried about your health?
18. How much are you satisfied with your health care?
19. How confident are you that you can deal with matter pertaining to your medication according to written instructions?

Appendix 3.2: Interview Schedule (Final)

A Study of Patients' Views on
Clinical Management and Self-Management Concept
Interview Schedule

Knowledge Questions

What is asthma?

What are your medications for?

Who educated you about your medication?

Experience/Feelings/ Behaviour Questions

Have you ever forget to take your medicine?

What do you do when you don't fell well?

To what extent do you feel worry about your condition?

To what extent do you feel happy with the way you are managed?

What component of care that you are not satisfied with?

Opinions Questions

What do you think about your condition and medication? [Benefits, side effects, convenience]

What would like to see change in your management?

What do you think if you are asked to adjust your dose and take your medication when you are feeling unwell?

How do you feel about taking medication as according to a written plan?

To what extent do you feel confident that you will be able to manage your medication as according to a written instruction?

Appendix 3.3: Interview Schedule: Back Translation Outcomes

Interview Schedule: Back-translation Outcomes

Original Questions	Malay Translated Version	Back-translated version	Outcomes
1. What is asthma?	Apa itu asthma?	What is asthma?	Accepted
2. What are your medications for?	Apakah kegunaan ubat itu?	What is the purpose of the medication?	Accepted
3. Who educated you about your medication?	Siapa yang mendidik anda tentang ubat anda?	Who educate you about your medication?	Accepted
4. Have you ever forget to take your medicine?	Pernahkah anda terlupa mengambil ubat anda?	Have you ever forget to take your medication?	Accepted
5. What do you do when you don't fell well?	Apakah yang anda buat bila anda tidak rasa sihat?	What do you do if you do not feel well?	Accepted
6. To what extent, do you worried about your condition?	Setakat mana anda berasa bimbang tentang keadaan anda?	How much are you worried about your health?	Accepted
7. To what extent do you feel happy with the way you are managed?	Setakat mana anda berasa gembira dengan penjagaan keadaan anda?	How much are you satisfied with your health care?	Accepted. The choice of words in Malay version are close to original question.
8. What component of care that you are not satisfied with?	Apa jenis penjagaan yang anda tidak puas hati?	What parts of healthcare that you are not satisfied with?	Accepted.
9. What do you think about your condition and medication?	Apa pendapat anda tentang penyakit and ubat anda?	What is your opinion about your disease and medication?	Accepted.

10. What would like to see change in your management?	Apakah yang anda ingin lihat ditukar dalam penjagaan anda?	What do you like to be changed in your care?	Accepted.
11. What do you think if you are asked to adjust your dose when you are feeling unwell?	Apakah pendapat anda sekiranya anda disuruh untuk mengubah dos bila anda sakit?	What is your opinion if you are ask to change the medicine if you are sick?	Accepted.
12. How do you feel about taking medication as according to a written plan?	Apakah perasaan anda tentang pengambilan ubat mengikut arahan bertulis?	What do you feel about taking medication according to written instructions?	Accepted.
13. To what extent do you feel confident that you will be able to manage your medication as according to a written instruction?	Setakat mana anda berasa yakin yang anda akan boleh mengurus ubat anda mengikut arahan bertulis?	How confident are you that you can deal with matter pertaining to your medication according to written instructions?	Accepted.

Appendix 3.4: Transcripts of Patient Interviews

Patient IO1

Gender	:	Female
Ethnic	:	Indian
Age	:	40
Yrs of asthma	:	5
Severity of asthma	:	Mild Persistent Asthma
Current Treatment	:	Becotide (Beclomethasone) 200ug bd, Theophylline 125mg tds, Respolin (Salbutamol) 2puffs prn

I Kak, nama saya W. Saya farmasi. Saya sedang buat saya kajian ini tentang asthma. Kami nak tahu macam mana asthma telah mengganggu kehidupan kak. So, saya akan tanya banyak soalan tentang kehidupan.
P Ok.
I Dah berapa tahun ada asthma sekarang
P Saya dari kecil ada
I Sekarang berapa umur dah?
P 40
I Sejak dulu sudah ambil ubat ini ke?
P Dulu kecil, ambil ubat pil sahaja, taka ada pam
I Pam bila start punya?
P Dari umur 30 tahun lebih baru ambil
I 30-tahun lebih. So, dalam 5 tahun ini lah.
P Ya.
I Lepas guna ubat rasa macam mana? Dalam bulan ini, ada batuk lagi tak?
P Batuk pun kurang. Saya ini, bila pergi kerja, saya rasa tenaga saya okay. Bila tak pergi kerja, mesti ada apa apa sakit punya. Ini satu bulan cuti, sebab tulang belakang saya sakit. Saya ambil makan pil sudah okay. Doktor kata jangan ambil barang berat, kena ambil betul betul, jangan ambil silap sikit .
I Ambil barang berat ada sesak nafas tak?
P Ada.
I Bila? Ada batuk lagi tak?
P Tak ada. Batuk sikit saja. Bila ada hujan, [Trigger : Rain]mesti selsema punya, kalau malam
sudah ada. Malam saya semput banyak kuat. Siang, saya kurang, Malam misal lepas kerja, rasa penat, kena kemas rumah lagi, mesti saya datang balik.
I Kak kerja apa?
P Kerja dalam kedai
I Dalam satu bulan , ada masuk klinik ambil gas lagi tak?
P Ini bulan tak ada, tiga bulan lepas ada.
I Bulan ini tak ada. Kak, kegiatan macam akan menyebabkan asthma, batuk ataupun sesak nafas? Duduk baring?
P Duduk , baring boleh tapi saya punya bantal tak boleh macam orang biasa tidur. Tak boleh rendah macam orang biasa.
I Ada ganggu tidur tak?

P 3 bantal, baru boleh tidur. Saya tidur bawah, saya tahu saya punya nafas sudah sesak

4 sikit. Saya mesti mahu bantal tinggi.

I Senaman atau naik tingkat boleh tak?

P Satu tingkat boleh. 1-2 tingkat boleh. 3-4 tingkat itu kurang sikit.

I Kak tahu tak kenapa kak sesak nafas atau batuk masa asthma?

P Makan.. sejuk .batuk lah.

I Apa yang kak rasa berlaku dalam paru-paru masa asthma?

P Tak tahulah. Tak boleh nafas

I Ubat rasa macam mana?

P Saya kalau ada makan ubat, saya rasa okay. Tiga empat hari tak payah ambil ubat.[E1 Medication reduces medication. Sometimes can stop for a few days – Incompliance]

I Sekarang ada berapa jenis ubat?

P Dua pam.

I Say Becotide yang warna chocolate kan?

P Ya

I Saya Respolin yang warna biru and lagi satu ubat makan?

P Ya

I Macam mana cara makan biasa?

P Saya makan malam, kalau kuat baru saya makan satu biji. Sana tulis dua biji tak, dua biji tak boleh telan sekali sebab tangan goyang-goyang. [E1 Side effect of medication (tremor)]

I Yang Becotide yang chocolate macam mana pakai?

P Itu pagi satu pan, petang satu pam, malam satu pam.

I Siapa yang ajar cara guna pam?

P Saya duduk Johor dulu, doktor ajar punya. (E3 Doctor involvement in asthma education)

I Pernah tak doktor, ke siapa-siapa farmasi ke, nurse ke yang bincang dengan kak tentang apa kegunaan ubat ini? macam mana ubat ini tolong asthma?

P Tak ada. (E3 No pharmacist involvement in education of medication use)

I Pernah bincang tak apa-apa yang perlu dielakkan dalam asthma?

P Makan-makan kena saja sikit. Barang –barang sejuk semua tak bolh tapi saya banyak-banyak suka makan timun, tapi itu pun kena marah. Baranag sejuk tak boleh makan lah. Macam ais. Minum ais ke – tak boleh (E3 Education include triggers)

I Ka rasa? Pernah tak lupa ambil ubat?

P Ada , kadang-kadang terlupa.

I Macam mana buat, kalau lupa?

P Kadang-kadang pagi saya mahu pergi kerja, saya ambil dua biji taruk dalam satu plastic letak dalam purse, ubat sembut letak dalam poket. Kalau cepat, sampai kedai, terlupa. Panggil anak ambil datang. Pasal, rumah dan kedai dekat saja.

I Pernah tak ubah ubat , ke ubah cara makan sendiri?

P Tak ada, Ikut sahaja. Tak pernah ambil ubat lain. Kalau bila saya kuat sekali, tak sempat pergi hospital, anak bawa pergi klinik, ambil gas.

I Kak rasa kak punya keadaan sekarang macam mana?

P Hujan susah sikit.

I Kak rasa cara penjagaan kak macam mana – ubat yang dibagi, doktor yang menjaga

kak, klinik apointment memuaskan tak?

P Saya selalu datang 2 bulan sakli atau 3 bulan sekali, selalu tengok doktor. (E2 Follow appointment accordingly)
Saya makan ubat okay tak ada masalah, kalau terlupa makan saja, ada masalah sikit sajalah.

I Doktor macam mana?

P Doktor baik. Biasanya dia akan tengok cara guna ubat. (E2 Happy with doctor care. Doctor monitor use of medication.)Itu baik.
Dia bincang. (V2 Prefer doctor who discuss with them on medication use)

I Ada apa yang doktor, farmasi boleh buat untuk tolong kak tak?

P Rasa tak ada lah. Kalau tak payah tunggu itu baiklah. (V2 Prefer if care given quick assess to care)

I Kak rasa keadaan kak akan bertambah baik lagi tak?

P Belum tahu lagi. Pasal sebab ini sejak kecil lagi sudah ada. Dulu nenek dan mak saya pun kena. Tapi mak saya sudah meninggal sudah lalu, masa saya umur 2 tahun , dia lahir anak nombor tiga.

I Kalau kita beritahu kak yang kita bagi arahan bertulis untuk makan ubat, untuk tengok keadaan kak, tulis sendiri. Kak yakin tak kak boleh buat?
(Showing an example of written asthma self-management plan)

P Buat dekat rumah ya

I Ya. Kak. Kak boleh libat dalam penjagaan sendirilah.

P Boleh juga. Kala doktor ajar. (V4 Willing to try if doctor teach self-management.)

I Ada apa tak yang kak rasa kita perlu kita beritahu kak?

P Kalau tak pakai pam, terus makan ubat makan pun tak boleh ke. (V3 Wish to know the reason of taking inhaler; not using tablet only)

I Kak rasa makan ubat lagi baik ke?

P Ya. Sebab pakai pam pun, tarik nafas dan lepas nafas pun susah juga. Pasal dulu masa kecil saya makan pil saja, tak pakai pam. Tapi baik sikit. Pasal dulu pun, dokot bagi ubat batuk, asthma, bat selsema, kita boleh tahu kita baik atau tidak. Tapi sekarang guna pil tak tahu lah

I Kak rasa masalah kak dalam kawalan kak tak?

P Memang. Boleh kawal lagi.

I Ada apa yang kak bimbang ncang?

P Kalau saya tengok, badan saya makin lama makin naik,itu yang saya takut.(E1 Side effect –weight gain with medication causes concern)

I Rasa sebab ubat ke?

P Itu pun saya tak tahu. Sebab anak saya nombor 5, saya baru 65 kg, lepas ini saya tengok badan saya terus naik. Anak sebelum itu, badan tak ada naik. Last anak saja. Ubat masuk badan, pasal itu badan naik.

I Pernah bincang dengan doctor tentang berat badan?

P Dia cakap badan naik sebab anak, Dia cakap saya tak percaya lah.(E2 In confident with some of the information provided on medication side effects)

I Ok .Terima kasih kak.

Patient IO2

Gender	:	Female
Ethnic	:	Indian
Age	:	43
Yrs of asthma	:	8
Severity of asthma	:	Mild Persistent Asthma
Current Treatment	:	Budesonide MDI 2puffs bd, Theophylline SR 250mg on, Asthalin (Salbutamol) MDI 2 puffs prn

I How have you been for the past one-month?

P I have been taken a lot of leaves because there have been affected a lot. Can't even teach, suddenly '*wheeze*'. I can hear the wheeze. When I hear the wheezing, I know is bad. My asthma when there is no wheezing(K1), I am fine.

I These only happened for the past one-month. What about before that?

P When the bad one comes, then the wheezing I know is bad.

I This problem has been going on for the past one month. What about before that?

P I have problem with rains(K2 Trigger: Rain). When there is slight rain, light drip, I am '*wheeze sounds'*, starts. Quite bad for the past one-month due to the weather. I have problem.

I If there is no rain and the weather is okay, normally you are fine?

P Normally I am fine. Even if I don't pump a day. I'm okay

I How many medications are you on now?

P Becotide and Respolin .

I How do you take it?

P Morning and night. Actually earlier they make that you get asthma only you pumped, if not don't pump. And then suddenly a few years back, the doctor said you have to pump everyday. I also don't know don't know why like that. (E1)

I Have anyone explain to you why?

P They only thing they said is, `bila dapat (*when you get it)*' pump, `tak dapat'*(when you don't get it)* is okay. One is morning and night and then the Asthalin is given

I But they do tell, you need another inhaler which you use everyday?

P They said use Asthalin is when Becotide doesn't work, and then you pump Asthalin. If both don't work, go emergency. (E3) That's about it.

I Ever forget to take your medication?

P Have it take. If not the asthma will go really bad. I usually try to take it before I go to work.

I What types of activities nowadays affect breathing difficulty or cause breathing difficulty?

P Walk a lot or very fast. Walk slow. I can't walk much. Even when I try to exercise, it starts. Plan to a exercise machine, maybe a bit a bit then okay. Too fast cannot (R1: Limitation with asthma)

I You have to do everything slower compared to normal and you can do much exercise?

P I have to admit, no. I considered walking is an exercise

I Is it because you felt that exercise is not safe? Is that true?

P No. Sometimes, after pumping, I felt too tired. I felt I need to relax and sometimes, my fingers shiver when I pump much. Becotide and Asthalin, I shiver. Even nebuliser shivers a lot, when I use nebuliser

I You have home nebuliser?

P No No. I mean the one in emergency. Is like when I do that, 4 or 5 hours go back home sleep.

I What about your work? Does your asthma affect your work?

P I have to talk extremely slow. Even now, I am planning to change, instead of teaching go into administration line. (R1: Limitation with asthma) Teaching has been affected a lot especially this past one-month. And I don't want it to get worse. Sometimes, can't talk, you have that; and then you have to take 5 minutes break and 'puff-puff'. And then come back

I Are you worried about your condition?

P Yes .yes.

I What are you worried about?

P I always thought that when the years go by, it will get better. Now that I'm 34, I thought maybe with the growing it will get better, seems like is still there. And then other doctor once, not this doctor, said this is a sudden death situation. I am in shock when she told me that. She said you could suddenly die, in kecemasan (emergency). She said 'Do you know that asthma is a sudden death?' Then she tell me, I asked her why doctor? She said you can just suddenly die. (R1: Concerns with asthma disease)

I Certainly, if you don't take care of it. So, do you feel you are in control of the problem?

P Years go by and the new technology, IT and bla bla, you may get better. Even cancer, they are having new treatment but why asthma, we can't. Is like is still the same(E1: Limitation with asthma treatment)

I How long have you been on your medication, I mean the pumps?

P 11 years. Becotide same. Earlier was Respolin. Then two years back was Asthalin. They said they have changed.

I Do you think they helped?

P The Respolin, I prefer Respolin I don't know why. When I pumped I get better fast, Asthalin is a bit, I (E1 Experiences with medication) don't know how to explain it, but is like I have to do it twice, and then three times. And then Respolin was a bit lesser than this one, is like 100ug of salbutamol.

I It won't cause so much of side effects on you?

P I feel very me weak. very very very weak

I After taking that (Asthalin)?

P Yes. In those days Becotide and Respolin not weak, only nebuliser. Now, Asthalin and nebuliser very tired. Very very tired

I You don't think that the weakness is caused by your asthma problem, is caused by your medication?

P I think so. When I asked the pharmacist, can they get me the Respolin, they said no. They said Asthalin. I did explain to them but they said asthma must take it.

I What do you do when you have asthma attack?

P I take the Respolin . I take one or twice. (R2) I have to go emergency
I Have anyone educate you on your medication?
P No, when I was young, When I was on tablets, then jump to inhalers. You do it; if not you will die.I mean is like that. (E3)
I What about methods of using these inhalers? Who have taught you?
P First time 11 years old, they just taught us inhaler pump. (E3)
I Have anyone checked you inhaler technique for the past one or two years?
P No.No. Even the blowing (Peak flow) just now, the last time I think, maybe 4 years Ago
I Have anyone talked to you the function or benefits of the inhalers?
P No. Like just now I was asking the doctor, I didn't know. (E3)
I Anyone talk to you on how to avoid asthma?
P Never, if (E3) I do, I will love the person.
I How do your know about asthma?
P Stress. Because a lot of stress (K2). Like my dad past away last month.
I I am sorry to hear that.
P And he was like the idol. So, it affected me a lot, I was two weeks on leave and then the asthma started – going into kecemasan (*emergency)* and then coming back. So, that's why the doctor said stress, because when I'm happy and when I am not doing my work, it doesn't come, even two three days no pump, you won't get it. When the stress comes, you get it.
I What do you think about the current management- I am talking in terms as a whole – the medication you are given, the doctors who see you, and the clinic appointment that you get?
P I obviously think that asthma patient should be given first priority.(V2) There is once I came, the beginning of the year or something, the asthma was bad. I went here, I went there, and my sister followed me. I have to wait for a number. And then this doctor is on leave; I went to number 1 or 2. They told me; I should have gone to kecemasan (*emergency)*, Why did I come? I have to take 3 times of the nebulisers, and my body was like 'tired'. I think this is a serious mistake; they should take care of it immediately because we are so sick.(V2)
I What about the doctor and nurse?
P They are okay. Sometimes they really tell me a lot. Sometimes, they don't. (E2 Staisfactory) I hope the doctor tell me more about my condition, how to improve it. But they don't normally say much. Only said take medication. (V2)
I What other that you find?
P The toilet is quite dirty.
I So, you are quite happy with rest of thing?
P I think maybe they should have once a month a seminar for asthma patient, the proper exercise, the proper method (V3), how are you doing, what's happening. Blowing every month to do it. Is not a check-up, is like a seminar, or something at least we know where we stand. Now she told me is 180, I am not sure what is it, why is it low, what is these blowing all about? All these are something new. Even the method that you told me is something new. 11 years I have been doing it, now only I know. Even in emergency, I told am pumping like that, they said is correct.

I So, you felt that it would be better if we can strengthen a little bit on the education part? What you more alert of you problem?

P As I know most us, most patients I know, if working taking a day leaves for something for own good.

I What about follow-up every month? If follow-up you every month?

P No problem. No problem.

I You find it useful?

P Suddenly I learned new thing in just an hour. Pumping technique, the blowing (peak flow). (V3) Honestly, I never know what the blowing is for. I have never done it.
Even in emergency I never did it. I never blow it, they just give nebuliser, and they checked after half an hour, ok you can go.

I Do you feel that if you know more about your condition, you can help yourself more, you are more in control?

P Yes, I want to know more. I want to be better.

I What we have here is an idea in which we can have a few things for you – we can a management plan for you, a written one, in which you check yout lung performance everyday using the flow meter – on certain time of a day, and you chart down, and then if it drops certain level, you will increase your dose or you go emergency immediately. So, is constructed for you, and we will teach you how to do it and you have to follow accordingly? What do you think about plan like this? Will that help?

P I love planning. I love to plan everything in my life. (V2)I think this is good. Definitely

I Are you confidences that you can follow the written plan like this?

P Definitely, if is going to help me even 30% of not getting it, I see heaven. Sometimes, I just can't control it; I get so angry when I get it. Sometimes, I get so mad, I don't pump. Biar saja. I just get mad you know. Pumping you still get like that. Sometimes, I can't take the care, I can't drive. Get somebody and sometimes, I have to wait, imagine I have to wait for someone to be drive and then drive me.

I You feel like you are not in control and you are no clue at all how you have been doing?

P Just fed up. Sometimes why do I need to do this? Watch what happened to me. Sometimes, better if just drop dead. Because is so sickening. Pump in pump in. Lunchtime, I went into the toilet and pump; sometimes in the teaching it comes. Is fed up sometimes.

I Thank you for your time.

I How have you been for the past one-month?

P I have been taken a lot of leaves because there have been affected a lot. Can't even teach, suddenly '*wheeze*'. I can hear the wheeze. When I hear the wheezing, I know is bad. My asthma when there is no wheezing (K1), I am fine.

I These only happened for the past one-month. What about before that?

P When the bad one comes, then the wheezing I know is bad.

I This problem has been going on for the past one month. What about before that?

P I have problem with rains.(K2 Trigger: Rain) When there is slight rain, light drip, I am '*wheeze sounds'*, starts. Quite bad for the past one-month due to the weather.

I have problem.

I If there is no rain and the weather is okay, normally you are fine?

P Normally I am fine. Even if I don't pump a day. I'm okay

I How many medications are you on now?

P Becotide and Respolin .

I How do you take it?

P Morning and night. Actually earlier they make that you get asthma only you pumped, if not don't pump. And then suddenly a few years back, the doctor said you have to pump everyday. I also don't know don't know why like that. (E1)

I Have anyone explain to you why?

P They only thing they said is, `bila dapat (*when you get it)*' pump, `tak dapat'*(when you don't get it)* is okay. One is morning and night and then the Asthalin is given

I But they do tell, you need another inhaler which you use everyday?

P They said use Asthalin is when Becotide doesn't work, and then you pump Asthalin. If both don't work, go emergency. (E3) That's about it.

I Ever forget to take your medication?

P Have it take. If not the asthma will go really bad. I usually try to take it before I go to work.

I What types of activities nowadays affect breathing difficulty or cause breathing difficulty?

P Walk a lot or very fast. Walk slow. I can't walk much. Even when I try to exercise, it starts. Plan to a exercise machine, maybe a bit a bit then okay. Too fast cannot (R1: Limitation with asthma)

I You have to do everything slower compared to normal and you can do much exercise?

P I have to admit, no. I considered walking is an exercise

I Is it because you felt that exercise is not safe? Is that true?

P No. Sometimes, after pumping, I felt too tired. I felt I need to relax and sometimes, my fingers shiver when I pump much. Becotide and Asthalin, I shiver. Even nebuliser shivers a lot, when I use nebuliser

I You have home nebuliser?

P No No. I mean the one in emergency. Is like when I do that, 4 or 5 hours go back home sleep.

I What about your work? Does your asthma affect your work?

P I have to talk extremely slow. Even now, I am planning to change, instead of teaching go into administration line. (R1: Limitation with asthma)
Teaching has been affected a lot especially
this past one-month. And I don't want it to get worse. Sometimes, can't talk, you have that; and then you have to take 5 minutes break and 'puff-puff'. And then come back

I Are you worried about your condition?

P Yes .yes.

I What are you worried about?

P I always thought that when the years go by, it will get better. Now that I'm 34, I thought maybe with the growing it will get better, seems like is still there. And then other doctor once, not this doctor, said this is a sudden death situation. I am in shock when she told me that. She said you could suddenly die, in kecemasan

(emergency). She said 'Do you know that asthma is a sudden death?' Then she tell me, I asked her why doctor? She said you can just suddenly die. (R1: Concerns with asthma disease)

I Certainly, if you don't take care of it. So, do you feel you are in control of the problem?

P Years go by and the new technology, IT and bla bla, you may get better. Even cancer, they are having new treatment but why asthma, we can't. Is like is still the same(E1: Limitation with asthma treatment)

I How long have you been on your medication, I mean the pumps?

P 11 years. Becotide same. Earlier was Respolin. Then two years back was Asthalin. They said they have changed.

I Do you think they helped?

P The Respolin, I prefer Respolin I don't know why. When I pumped I get better fast, Asthalin is a bit, I (E1 Experiences with medication) don't know how to explain it, but is like I have to do
it twice, and then three times. And then Respolin was a bit lesser than this one, is like 100ug of salbutamol.

I It won't cause so much of side effects on you?

P I feel very me weak. very very very weak

I After taking that (Asthalin)?

P Yes. In those days Becotide and Respolin not weak, only nebuliser. Now, Asthalin and nebuliser very tired. Very very tired

I You don't think that the weakness is caused by your asthma problem, is caused by your medication?

P I think so. When I asked the pharmacist, can they get me the Respolin, they said no. They said Asthalin. I did explain to them but they said asthma must take it.

I What do you do when you have asthma attack?

P I take the Respolin . I take one or twice. (R2) I have to go emergency

I Have anyone educate you on your medication?

P No, when I was young, When I was on tablets, then jump to inhalers. You do it; if not you will die.I mean is like that. (E3)

I What about methods of using these inhalers? Who have taught you?

P First time 11 years old, they just taught us inhaler pump. (E3)

I Have anyone checked you inhaler technique for the past one or two years?

P No.No. Even the blowing (Peak flow) just now, the last time I think, maybe 4 years ago

I Have anyone talked to you the function or benefits of the inhalers?

P No. Like just now I was asking the doctor, I didn't know. (E3)

I Anyone talk to you on how to avoid asthma?

P Never, if (E3) I do, I will love the person.

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P Stress. Because a lot of stress.(K2) Like my dad past away last month.

I I am sorry to hear that.

P And he was like the idol. So, it affected me a lot, I was two weeks on leave and then the asthma started – going into kecemasan (*emergency)* and then coming back. So, that's why the doctor said stress, because when I'm happy and when I

am not doing my work, it doesn't come, even two three days no pump, you won't get it. When the stress comes, you get it.(A1)

I What do you think about the current management- I am talking in terms as a whole – the medication you are given, the doctors who see you, and the clinic appointment that you get?

P I obviously think that asthma patient should be given first priority(V2). There is once I came, the beginning of the year or something, the asthma was bad. I went here, I went there, and my sister followed me. I have to wait for a number. And then this doctor is on leave; I went to number 1 or 2. They told me; I should have gone to kecemasan (*emergency)*, Why did I come? I have to take 3 times of the nebulisers, and my body was like 'tired'. I think this is a serious mistake; they should take care of it immediately because we are so sick.(V2)

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P They are okay. Sometimes they really tell me a lot. Sometimes, they don't. (E2 Staisfactory)I hope the doctor tell me more about my condition, how to improve it. But they don't normally say much. Only said take medication. (V2)

I What other that you find?

P The toilet is quite dirty.

I So, you are quite happy with rest of thing?

P I think maybe they should have once a month a seminar for asthma patient, the proper exercise, the proper method(V3), how are you doing, what's happening. Blowing every month to do it. Is not a check-up, is like a seminar, or something at Least we know where we stand. Now she told me is 180, I am not sure what is it, why is it low, what is these blowing all about? All these are something new. Even the method that you told me is something new. 11 years I have been doing it, now only I know. Even in emergency, I told am pumping like that, they said is correct.

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I Thank you for your time.

Patient IO3

Gender	:	Female
Ethnic	:	Indian
Age	:	48
Yrs of asthma	:	5
Severity of asthma	:	Mild Persistent Asthma
Current Treatment	:	Qvar MDI 1 puff bd, Asthalin (Salbutamol) MDI 2 puffs prn

I How are you today?
P Better
I Can you tell me about your asthma? What causes it?
P Because I was having some sinus problem(K1) last time. So, I went to India to do my operation. I think is already few years now, 4-5 years, before that I was having some allergy problem to dust (K1) or something. So, I used to take some medicine, after that stop. So lately, I went India did my operation, I came back and it was okay for a few months. Then came back again. Then I do some housework and the dust, I start sneezing and or this, I feel very cold or something or when I feel gardening or something likes that, my body sejuk sejuk like that. So then it starts. Sometimes I take late bath night, early morning, I sneezing and sneezing none stop. So, I thought just normal this one so I didn't take any medicine. Because every time take lots of medicines also a problem. One day, I felt like I cannot breathe, something blocking my throat. I went to hospital there, emergency. They told I have asthmatic person, they send me to take nebuliser, I was there for 10-15 minutes. Then the doctor gave me some medicine(R3). Because it was Sunday, and then they asked me to come on Monday to take medicine. So, I continued till now. After that it was normal. Lately I was the phlegm, I was coughing and then my badan sejuk sejuk and or this, every morning very cold, with my body shivering like that. Everyday in my whole life I am taking hot bath, I never take air sejuk.(K1) Then I came to this hospital here to see doctor, she checked me few times, I can feel my heart got some noisy, something watery, something I can feel it. When drink water I feel like the water is not going down, is blocking there. So, I was telling my doctor, maybe something wrong with my lungs. The doctor checked me and said maybe is infection or something like that..
I And you said you are allergy to dust?
P Last time yes, to dust. When I do my operation in India they told me I got allergic to dust, pollen and green vegetables. (K1)
I The heaviness, when does it started?
P Just recently, about 3 months,.
I Do you smoke?
P No no.
I Tell me how asthma has affected you.
P I feel very lembik.(*Tired*). But, morning I have to wake up to do my housework, normal la. I have to do, if walk a lot also not cannot breath but, I feel like uneasy.

I How do you know you have an attack?

P Wheezing at night.(K2) If is like cold, rainy days, early morning I get more, I cannot sleep. I cannot breath. Smetimes cough a lot. Last time, I used to get pain here (chest), direct to the back, just one jarum (*needle)* like that. Not my whole chest.

I What do you then?

P Take the medicine. The doctor said has asthma take this (Salbutamol). Then go emergency.. (R1)

I How does it feel like? Crushing?

P Just like one pain, going behind, after few minutes, stop

I When you first detected the problem, you went to emergency unit were you admitted?

P Yes, I don't know what wrong wit me I just went there. I was not admitted. Because they said I looked very healthy. I even also I don't feel like I am sick.

I What kind of activities usually makes you breathless?

P I cannot, because when I do continuous work like walking there, doing there, like heavy work, continuously, I feel like uneasy, but still I do work. I don't stop like; I feel like tired I never sleep, I still do the work. Finish then only I will take rest

I What about when you sitting or lying?

P No problem at all. Nowadays I cannot walk very fast, I mean very long distance, last time I used to play badminton. Now about one year, I stopped(R1)

I Why do you stop playing badminton?

P I feel like uneasy. My chest is like heavy. But I not yet try. After the doctor told me that I am asthmatic, I am scared to go. Maybe one day I will try to do it, but not yet. I stopped for about 1 year now.

I So, no sport at all?

P Sometimes, I walk.

I How about like if you go shopping?

P No problem. Because I am having a restaurant also. So, I have to walk here and there to see my staff working.

I What type of restaurant is that?

P Restaurant for food. Just opposite the Bata shop

I Do you always feel tired?

P No no always. Sometimes only. I have to do my normal work. Washing, cleaning, sweeping.

I How about your sleep?

P Night I cannot sleep at all. Because I have to breathe through my mouth, not my nose. So long, for don't know how many months, getting to one year, I am breathing through my mouth not my nose. Like morning I can breath through my nose, but night I cannot, is blocked. Few days I was having cough also.

I Do you actually work in the restaurant?

P I used to help. Sometimes I have to work. But is normal

I After your problem started?

P I am getting it every time. Suddenly only. Like when I do overworked, I will get it.

I Have you ever panic when you have problem?

P No. I never. I am a strong lady. I never felt panic. I just want to be strong.

I Are you worried about your problem?

P No not really. Because I am going to be 52, so I am not.(R1)
I Do you think you are in control of your problem?
P If I cannot, I will come back to hospital to see the doctor. In the meantime, I take the medicine properly.. (E2)
I What do you think about your asthma? Do you think it will get better in future?
P Of course, yes. I feel better after taking medicine(E1). But. I have keep taking. I hope I don't have to take one day.
I So, nothing of your worries relating to your asthma?
P No no.
I Do you know what is the medication for?
P I don't know.
I You get inhalers right? Tell me how you used it.
P Yes. Two types. One is for asthmatic. She said if you feel like breathless, then you used the thing. The other one, morning two, night two. She gave me two types.
I You know the name?
P No. She asked me to finish the thing before coming.
I Did the doctor teach you how to use the inhaler?
P Yes(E3)
I How do you think about the management of your problem now –about the clinic, about the doctor? How do you feel? Is it okay? Not okay?
P I think is okay. (E2)
I What do you think of the management here?
P Okay
I How about the doctor, nurse, pharmacist here?
P Doctor is okay. She told me about my problem. (E3)
I Is there anything in the management that you would like to be changed?
P I don't think so. I think I wanted to tell, because I just want to tell management here, when you see some asthmatic person, really problematic, so you must give them the chance to see the doctor, no letting them sit there.(V2) You can't say, you don't know what is going to happen to them. Because they are just holding the numbers, so suddenly if somebody cannot breathe, and then they just collapse. Then very bad. Only the asthma, you have to handle faster. And some people with the heart problem also. Other than that, the normal person who comes to hospital to take medicine, I guess is okay. Must have two types of these - emergency, must send these people first.
I Let say if you are given a written instruction, of the kind of when you should take your medication, how many dose, let say if you have an asthma attack, what are the action you should do, whether you should see the doctor or you should take medication, do you think is good? A written form for you.
P Can, better. At least, people will know thing and other get also they will inform how to do, go and see the doctor. Sometimes, doctors they tell only to myself, and I keep to myself, if I got something written then, I can read and tell some like my friends, somebody got asthmatic, she also don't know, maybe I can advise them, because the doctor give me like this like this, you better go to hospital. (V4)
I But, different people will have different management given to them. What's given to you might be different to another person in terms of medication, dose. Let say is for

you?
P Better
I Does it give you more confident to have a written instruction?
P Yes.
I I think that's about it. Thank you

Patient I04

Gender	:	Female
Ethnic	:	Indian
Age	:	38
Yrs of asthma	:	26
everity of asthma	:	Persistent Severe Asthma
Current Treatment	:	Budesonide MDI 600ug bd, Formoterol 18ug bd, Theophylline Sr 250mcg on, Salbutamol 2 puffs prn

I Ada kerja?
P Tak
I Suami?
P Suami kerja sendiri
I Anak berapa orang?
P Tiga
I Tiga orang. Berapa besar ke kecil lain?
P Kecil tu sembilan tahun
I Yang lain dah besar?
P Besar 15 tahun.
I 15 tahun. PMR ke?
P Dia tak masuk ni. Dia masuk sekolah agama.
I Sekolah agama. Dulu kak ada asthma leboh kurang 12 tahun tu, kak ingat tak kenapa kena?
P Dia macam sebab penat tu dia kena.
I Sebelum itu, tak penat tu tak kena, sebelum 12 tahun tu?
P Kira tak pernah. Masa masa kecil kecil itu, tak adan Sebelum 12 tahun take penat sangat. Ikut mak saudara. Di rumah emak saudara tu, macam macam kerja buat. Rumah dia tu ada kucing banyak. Mungkin sebab bulu kucing itu(K2: Trigger: Cat). Kita ini ikut macam orang besar , kerja buat kerja ,kena mop semua tu. Sebab tu penat
I Kak sekarang kesihatan macam mana?
P Sekarang ini okay la. Makan pun jaga sebab kita puasa kan. Lepas itu pam pagi pagi, sebelum habis sahur tu nak pam dulu kan.
I Ada tak bila tenah macam bila sakit kan, masalah pernafasan tu, rasa macam mana ?
P Rasa macam tak boleh bernafas.(R2)
I Tak dapat nafas, ada batuk tak?
P Ada. Kalau kita tengah masak, macam goreng cili kan , batuk lah
I Batuk berkahak tak?
P Kalau nak datang asthma tu, batuk tak berkahak. Batuk saja(R2)
I Batuk kering
P Ya
I Selsema?
P Lama-lama sekali. Macam hari tu kena. Bulan lapan tu, teruk tu. Kena pergi ke kecemasan
I Masuk wad ke?

P Tak masuk wad, tapi dia macam tak baik. Tak baik sampai kak datang jumpa doktor ni, doktor ini bagi ubat prednisolone tu yang makan 10 hari, yang makan 6 biji 6 biji.. kecil-kecil tu. Dan antibiotik 10 hari, baru kurang. Sekarang ini dah okay. Tapi pam dengan makan ubat, kena makan juga.

I Bulan lapan tu, masa jerebu kan?

P Tengah tengah jerebu itu la kena (K2 Haze)

I Masa sesak nafas tu, ada bunyi tak?

P Ada bunyi

I Kuat tak? Siang banyak ke malam baru kena?

P Kuat la. Orang lain pun boleh dengar. Kalau kena, dia siang pun kena , malam pun kena. Bila kita semput, dia kena la.

I Yang teruk tu bila, siang ke malam?

P Malam la kuat. Kena air-cond lagi teruk.(K2 Air cond)

I Tak boleh sejuk la.

P Ya.

I Pernah masuk hospital sebab asthma?

P Ada. Tahun ini tak adalah. Ubat tu boleh kawal sikit.

I Ubat apa itu?

P Doktor yang bagi. Dua ini (Pulmicort® (Budesonide) and Oxis® (Formoterol)) pakai, untuk kawal. Ini doktor (Pulmicort®) suruh tiga kali, masa itu teruk tiga kali pakai - pagi, tengah hari and malam. Tapi sekarang kak pakai pagi dengan malam saja.(E2) Yang ini (Oxis®) samalah dua kali dua kali.

I Ubat ini untuk apa bila sakit ke?

P Ini macam mengawallah.

I Bila sakit ini ada ubat lain ke?

P Bila sesak nafas itu guna inila (Respolin® inhaler).

I Kak rasa ubat ini macam mana, ada membantu ke?

P Membantu jugak.(E1: Medicine relieve asthma)

I Macam mana tu?

P Dia macam tak kena asthma la.(E1 Medicine prevents asthma)

I Pernah tak ada kesan kesan buruk lain?

P Cuma kadang-kadang kalau ambil banyak, rasa pening la. Pening kepala, macam nak tidur.(E1 Medicine occasionally caused side effects)

I Terlebih tu macam mana?

P Misalnya, kalau kita nak ambil kan , kita ambil lagi. Kadan-kadang kena, kita ambil, tak hilang lagi, kita ambil lagi. Pening lah .

I Tidur macam mana?

I kalau tak ambil pam?

P Tidur kalau sejuk pun tak boleh. Tapi kena guna pam ini sebelum tidur.

P Kalau tak ambil, kadang-kadang tengah tidur, dia datang. Kena bangun (E1 Noted that asthma comes if not taking medicine)

I Bila ka batuk, ada rasa malu ke?

P Kadang-kadang malu juga. Kalau kena guna pam depan orang malu. Kena pergi tempat orang tak nampak kan.

I Ada tak rasa panik ke takut ke masa sesak nafas?

P Kadan-kadang kalau teruk . Teruk itu takut juga. Nak mati ke.(R1: If asthma is worst, will caus fearing.)

I Pernah tak sakit sampai tak sedar ke?

P Tak sedar tu tak pernah. Biasany macam tak boleh tarik nafas. Kadang-kadang pam pun dia tak baik. Berpeluh-peluh, tak daya

I Kak bimbang tak?

P Ada lah sikit. Kadang-kadang risau juga. Kenapa kita adakan (R1 : Concern. Wonder why I have asthma). Risau.

I Sekarang kak rasa sakit ini makin baik ke macam mana?

P Berbanding dulu, kira baik sikit. Dulu-dulu, kak sebelum pakai Pulmicort dengan Oxis ini, lagi teruk, satu bulan sekali mesti pergi kecemasan. E1 Medicine improves asthma control. Better asthma with current therapy) Sekarang, batuk dengan selsema saja pergi kecemasan. Tak hilang kan(E3: Persistent cough, has to go emergency)

I Ubat ini dah guna berapa lama?

P Setahun lebih ini. Mula-mula , pergi klinik kesihatan jumpa Sister X. Dia recommend jumpa doktor ini, datang lah. Hampir setahun lebih dah

I Sebelum jumpa, dia dah okay ke?

P Sebelum jumpa dia, pakai pam satu ini ja. Teruk juga. Kalau teruk sikit, terus pergi kecemasan. Dua bulan sekali, tiga bulan sekali pergi. Kalau malam ada, pagi-pagi pergi. Sekarang dah okay. Tak masuk wad, sejak pakai ini Oxis ini lah.

I Ada tak orang ajar macam mana pakai?

P Doktor ajar.(E3 Doctor involved in asthma education)

I Doktor ajar macam mana tu?

P Doktor ini ajar, ini lain sikit. Ini sedut, ini lain sikit. Ubat ini kita kena sedut.lain sikit dari doctor lain

I Selain doktor ada orang lain ajar?

P Tak ada.

I Pernah tak kak ubah ubat?

P Belum lagi. Hari itu, doktor ini ada bagi lain sikit, kalau teruk ini lah. Kak kata tak sesuai.Doktor kata pakai ini la.

I Pernah berhenti tak?

P Bila pernah lagi..terus saja.

I Dalam satu tahun,pernah terlupa tak?

P Tak ada. Memang ambil pagi dan malam.

I Bila susah atau sesak nafas, kak buat apa?

P Kalau batuk atau selsema teruk tu, pergi klinik tak ada temujanji sini. Kena pergi klinik luar la. Ambil antibiotik.

I Biasanya apa dia bagi di kllinik ?

P Biasanya, antibiotik la kalau selsema teruk . Selsema dan batuk, asthma bunyi macam kecemasan

I Kak rasa penjagaan kak sekarang macam mana?

P Baik sikit.

I Ubat tak ada masalah lah? Doktor macam mana?

P Baik doktor. (E2 Happy with doctor)
I Klinik macam mana?
P Baik
I Ada apa yang kak rasa kena tukar ini?
P Tak ada apa-apa.Puas hati(E2: Satisfied with asthma care. No changed needed.)
I Masa kak mula-mula ambil ubat ini, ada tak arahan bertulis diberi?
P Macam surat
I Macam arahan macam berapa banyak nak ambil, bila nak ambil
P Dia ajar macam ini sahaja la . Bercakap sahajalah(E2: Education or training given is done verbally.)
I Kak rasa tulis lagi bagus tak?
P Tak tahu, pada kak sekarang macam ini pun okay. Macam sekarang ambil dekat farmasi, dalam kotak pun ada tulis. Ingatkan kita. (V3 happy with curremt instructions givem on medication.)
I Kalau kita bagi arahan betulis macam tak ada sesak nafas, kak kena ubah ubat sendiri, atau kita bagi pil sikit. Atau kita bagi spare prednisolone. Kak tengoklah, kalau ada batuk dengan kahak kuning, kak ambil sendiri. Kak rasa baik tak macam itu?
P Baik juga. Tak lupa lah. Boleh ingat sikit.(V4 Willing to try. Maybe is easier to remember)
I Kalau kita suruh kak beli satu yang kak tiup tadi and tiup sendiri lepas itu chart tiap-tiap, tengok fungsi paru-paru. Ikut arahan dan ubah dos sendiri. Kak rasa kak boleh buat tak?
P Boleh juga. Sekarang pun baik. Tapi kalau hospital nak buat , pun okay, boleh juga. Tapi macam sekarang ada ubat juga, kalau pam tak kawal ambil ubat lain. Hanya hari itu teruk yang mereka panggil kak datang tiap-tiap 2 minggu, kalau tak datang 3 bulan sekali. Dia dah tulis la dekat farmasi tu, ambil setip bulan lah ubat.
I Kak dalam satu bulan ini ada ambil prednisolone lagi ke?
P Prednisolone tu tak boleh ambil selalu. Kalau kita pergi kecemasan, dia dah bagi gas itu sekali, dua kali, ambil tiga kali tak boleh , dia bagi lah prednisolone. Kuat ubat itu- steroid .Mengigil – Kalau makan 6 biji sekali(1 Side effects of prednisolone).
I Kak masih ada makan pil Neulin lagi tak?
P Ada.
I Tapi doktor tak bagi kan?
P Kak terlupa nak cakap. Kak ada makan lagi.
I Kak ada lagi tak ubat itu?
P Ada sikit la.Terlupa tadi nak cakap dengan doktor.
I Tak apa, boleh cakap dengan doktor nanti. Terima kasih kak.

Patient M01

Gender	:	Male
Ethnic	:	Malay
Age	:	33
Yrs of asthma	:	25
Severity of asthma	:	Mild Persistent Asthma
Current Treatment	:	Budesonide MDI 200ug bd,Salbutamol MDI 200ug prn

I Tak kerja hari ini?
P Ikut memang kerja. Saya kerja tiga shift.
I Kerja apa?
P JBA. Jabatan Bekalan Air Seremban
I Kerja dalam office ke?
P Saya memang dalam office. Bahagian DPL.
I Hari ini tak masuk kerja la?
P Saya MC
I Mula-mula bila kena tu, sebab apa tahu tak?
P Punca, punca tu. Saya aku ini memang salah saya. Mungkin dulu tak tahu fikir, sekarang saya ada fikir. Saya dulu orang susah, kecik mak bapak tak ada, saya bekerja. Bekerja luar kemampuan saya. Bermakna saya angkat pasir dalam air ke lori, ambil 5 ringgit. Sampai sekarang, saya fikir saya memancing, bermakna hari hari memancing, merembum, tak pakai 'cap', tak pakai apa-apa, itu lah punca. Yang boleh mendatangkan asthma. Saya fikirlah. Saya rasa(K1,K2)
I Sekarang ada memancing lagi?
P Sekarang tak ada dah lah. Stop.
I Abang merokok tak?
P Merokok
I Sekarang ada hisap lagi?
P Hisap memang saya ada lagi. Tapi saya memang kuranglah. Kalau dulu 20 batang, sekarang 12, 12 batang. Turun turun
I Sekarang 15 batang satu hari?
P Sekarang dalam sepuluh – dua belas batang dalam satu hari
I Rasa akan lama-lama nanti berhenti tak?
P Saya rasa kalau nak berhenti saya payah jugak lah. Dah lama.
I Sekarang batuk tak?
P Sekarang ini, tak banyak . Tahun 2000 dulu ambil gas, dan injection. Sekarang ini saya pergi hospital, dia tak nak bagi injection, dia bagi gas, ubah lah. kira okla.
I Apa yang biasanya berlaku bila abang ada asthma?
P Tak sedaplah. Batuk banyak. Batuk tak henti henti. Lepas tu, nafas pun susah sikit.
I Ada tak nafas berbunyi?
P Malam ada. Susah tidur kalau nafas susah.
I Abang tahu tak apa yang menyebabkan ini?
P Kalau sejuk ini, dia datang lah. Kalau makan tak betul, kadang-kadang datang juga. Tahun lepas ,hujung tahun , masuk kecemsan dua kali ambil gas.
I Sebab hujan and sejuk ke?

P Hujan banyak. Dapat selsema.. Semput pun datang.
I Abang rasa penyakit asthma ini macam mana? Bimbang atau takut tak?
P Takut ini tak lah. Ada ubat. Tapi kadang-kadang bimbang juga. Tak tahu dia akan sembuh ke tak? Susah nak keluar mana-mana. Bimbang semput, tak tahu macam mana. Kadang-kadang, tengah kerja, ada semput. Kena ambil ubatla. Makan pun kena jaga sikit.(E1, R1)
I Dah lama guna ubat asthma?
P Dulu kalau susah, doktor bagi ubat pil. Sekarang doktor bagi banyak ubat ini (salbutamol and budesonide inhaler). Dah lebih kurang 2 tahun. Dulu warna lain.
I Rasa ubat macam mana?
P Bolehlah.
I Lepas makan ubat, rasa seput kurang tak?
P Lebih kurang sama.(E1)
I Ada kesam sampingan tak?
P Tak ada
I Biasanya ambil macam mana?
P Yang ini (budesonide) pagi and malam. Yang ini (salbutamol) satu kali.
I Ada ambil tiap tiap hari ke?
P Ada.
I Yang ini (salbutamol),doktor suruh ambil tiap tiap ke?
P Doktor kata kalau asthma ambilla. Saya ambil sebelum pergi kerja.(E1)
I Doktor tahu tak?
P Tahu.
I Abang rasa macam mana penjagaan di ini? Doktor,klinik semua okay tak?
P Baik juga. Satu jumpa doctor ini lebih kurang tiap tiap tiga empat bulan. Kalau saya tak selesa, saya ambil MC datang sini. Doktor ni baik.(E2)
I Pernah tak ada siapa beritahu aoa yang berlaku dalam paru paru masa asthma?
P Nurse pernah cakap tentang ubat asthma dulu. Dia kata ubat asthma ini tolong buka paru paru masa asthma sebab paru paru sempit masa asthma. Nurse tu ada tunjuk gambar. Ubat boleh tolong mengurangkan redang datang paru-paru.(E3)
I Rasa apa yang masih lagi dibaiki dalam penjagaan?
P Tak ada juga. Semua baik.(E2)
I Apa yang abang rasa baik?
P Biasanya appointment lebih kurang 3-4 bulan. Itu baiklah. Doktor pun baik juga
I Apa pendapat abang kalau kita ajar pesakit asthma secara kumpulan? Macam satu class?
P Boleh jugak
I Abang rasa abang akan datang tak?
P Kalau hari minggu susah sedikit. Sekarang pun okay lah. Nurse dulu dah ajar.
I Apa yang abang buat bila asthma susah?
P Ambil ubat 2 ke 3 pam.. (R3)
I Bila abang pergi kecemasan biasanya?
P Kalau ubat tak berkesan, banyak batuk , susah , datang kecemasan terus.(R3)
I Pernah tak doctor ke siapa beritahu kesan yang memerlukan rawatan segera?
P Tak tak ada. Tapi tahulah. Kalau ambil pam ini tak lega. Saya datang klinik atau kecemasan.

I Abang pernah tak buat ini (peak flow meter)?
P Pernah. Di kecemasan, kadan kadang ada suruh buat. Entahlah untuk apa.(E2)
I Doktor pernah beritahu ini untuk apa tak?
P Rasa ini boleh tahu nafas baik ke tak. Tapi, doctor ada cakap banyak nombor . 400.. kadang kadang lebih . taoi tak tahu untuk apa
I Saya nak tunjuk ini. Ini adalah satu arahan bertulis yang kita boleh bagi abang. Arahan ini akan tulis namae ubat, bila ambil dan bila abang kena datang hospital. Dia akan suruh abang buat ini (peak flow) dan tengok apa maksut ini? Abang rasa macam mana.
P Baik juga.
I Abang rasa boleh ikut tak?
P Kalau ajar boleh cuba lah.(V4)
I Terima kasih ya.

Patient M02

Gender	:	Male
Ethnic	:	Malay
Age	:	53
Yrs of asthma	:	10
everity of asthma	:	Moderate Persistent Asthma
Current Treatment	:	Budesonide MDI 400ug bd, Salbutamol 2 puffs prn

I Apa yang menyebabkan asma?
P Saya penjaga unit bangunan, sebab saya kena gas-gas air-cond(K2 : Occupational cause : Chemiical Air cond). Bangunan-bangunan kerajaan, macam banguan baru buat, macam sekolah, saya kena check. Jadi air-cond centralised, gas tu bursed, gas sembuh muka saya. Dalam tiga bulan tu, tekak saya kering, tekak kering tiap tiap hari, kahak berkahak bekahak. Makin lama-makin teruk. Selepas itu, saya mula sesak nafas. Pergi check, doctor kata paru-paru berair, itulah yang punca sampai sekarang. Bukan keturunan, bukan apa(K1: Not inherited).
I Keluarga tak adalah?
P Tak ada.
I Ada merokok?
P Sudah berhenti,
I Bila berhenti tu?
P Berhenti ini sudah16 tahun la.
I Sejak kena asthma?
P Sebelum ada asthma dah berhenti.
I Sekarang bila sakit tu datang, macam mana tu?
P Kalau sakit tu, punca tu, saya ni allergy pada makanan, kalau saya makan contoh ketam, asalkan seafood, ayam berlebihan, saya akan dapat ni la. Resdung. Hari-hari hingus, hidung berair-airkan.(K2 Cause: food, seafood, too much chicken, allergy) Kalau dia tak berhenti, dia(asma) akan mula la.
I Bersin tak?
P Bersin
I Batuk?
P Kalau dah mula ni, sesak la. Batuk berkahak
I Kahak warna apa tu?
P Buih warna putih.
I Ada bunyi tak?
I Kadang-kadang tidur , bantal tinggi. Kalau tidak, satu saja susah.
I Malam saja? Siang macam mana?
P Kadang Biasanya kali saya punya peak flow drop sampai 300, saya lari dalam hospital.(R3 If peak flow drop to 300, have to admit into hospital)
I Pernah masuk hospital tak?
P Tahum 2004, teruk 6 kali masuk wad.
I Dalam masa berdekat ini?
P Masa jerebu. Teruk, kuat
I Masuk wad berapa lama tu?
P 7 hari

I Kalau sesat nafas, biasa kegiatan harian macam mana?
P Kalau sesak nafas, kegiatan harian tu terpatanla.,(R1:If encounter difficulty in breathing, daily activitiy have to be stopped.)
I Kalau macam naik tangga?
P Tak boleh. Letih.
I Rasa semput la?
P Ya, rasa macam berat.
I Kalau macam benda yang mudah macam mandi?
P Itu boleh
I Kalau macam berjalan-jalan?
P Jalan tu, kalau kena asthma tu, terbentau sikit la.
I Kalau berjalan tak boleh, berlari memang tak boleh la. Sekarang ini, kata masa tak teruk ini, kalau bersukan tu boleh tak?
P Kalau bersukan ini, boleh . Boleh jogging
I Sekarang ada jogging. Dalam seminggu ini. berapa kali ?
P Seminggu dua kali, hari sabtu petang. Kadang-kadang main golf.
I Kalau jogging,berapa lama?
P Biasanya satu jam.
I Dalam satu jam tu, ada sakit
P Oka memang tak ada masalah
I Sekarang kerja lagi?
P Ya. Masih kerja
I Masih sama?
P Sudah tukar. Sekarang kerja dengan JKR. Hampir 30 tahun.
I Kerja tak ada masalah?
P Tak ada masalah.
I Kalau sakit macam mana?
P Kalau masa sakit tu, kena duduk dalam bilik. Kadang-kadang sakit sampai tak boleh kerja, memang kena panggil ambulan datang.
I Macam mana tahu, keadaan serius
P Kalau ubat tak berkesan, itu serius lar. Kadand-kadang masa jelebu, batuk, ada kahak, susah nafas, itu asma serius (R3: during haze, difficulty in breathing, cough indictes bad asthma, if medication not working, indicares poor asthma)
I Apa perasaan abang kalau batuk depat orang lain?
P Kalau kena ludah kahak tu, kena fikir. Kena ada spare tisu.
I Bila sesak nafas, ada panik ke takut?
P Kalau saya ada asthma, saya memang takut.(R1 If I have asthma attack, I wil be worried.)
I Takut apa tu?
P Takut collapsed.
I Pernah collapse ke?
P Ada pernah. Rasa macam tak ada lagila. Dah habisla. Terus hilang nafas.
I Pernah blank?
P Ya. Pernah pitam,
I Apa family buat?
P Pergi klinik swasta, ambil satu nebuliser, injection pulmicort. Doktor, tepuk

belakang, tepuk semua semua, kahak keluar. nafas datang balik

I Abang bimbang tak masalah asthma?

P Rasa-rasa ke mana-mana keluar contoh nak keluar dari negeri ini, kena pastikan yang badan mesti sihat baru boleh keluar.(1 Impact: travel) Tak sihat tak boleh keluar.

I Boleh jadi apa-apa kalau keluar?

P Boleh keluar pergi. Ada sekali, saya keluar ke Kem Ketenteraan , Pada masa tu, saya kena. Kelam kabut itu, check klinik swasta. Ubat pump tak bolehkan.

I Sekarang macam mana asthma itu?

P Saya rasa bertambah baik. Jaga makan, tidur, tidur tak boleh macam tengok bola macam tidur pukul 4 pagi. Kalau tidur tak cukup, masalah juga.

I Tidue nak berapa jam tu?

P Kalau biasa macam pukul pukul 11 saya sudah tidur.

I Kalau kurang?

P Kalau kurang, badan tak cukup tidur,rasa macam tak selesa. Dada sakit. Pergi check jantung, tetapi tak ada masalah

I Rasa apa yang menyebabkan asthma ini?

P Makanan, minuman . Kalau minuman ais tak boleh lah. Rambutan saya tak boleh makan jugak.

I Ada apa lagi yang boleh menyebabkan asthma?

P Masa hujan. Jerebu tak lepas pun saya pergi ambil gas.

I Ubat. Ubat yang abang pakai sekarang in dah berapa lama?

P Sejak dengan Dr X sudah 4 tahun. Saya guna Oxis and Pulmicort

I Cara pakai tu macam mana?

P Pulmicort ini 2 pagi 2 malam. Kalau tak ada serangan. Biru tu dengan Oxis kalau sakit la.

I Yang biasa pakai tu, mengawal lah?

P Mengawal la.

I Rasa ubat it macam mana? Membantu ke?

P **Sejak saya pakai Oxis tu, baiklah (**Satisfy with Oxis. Medication.) Chocolate ini (Pulmicort) 2 pagi 2 malam. Yang ini (Oxis), kalau ada serangan la. Dr X. kata, kalau tak ada serangan, tak payah. Terus ambil Pulmicort ja. Ubat biji tak pakai.

I Ubat biji tak makan, hanya ini ja? Pernah tak ada masalah apa-apa dengan ubat?

P Ubat tak ada masalah.

I Memang tak ada masalah dalam 4 tahun ini la. Ada tak orag ajar macam mana cara makan ubat?

P **Ada**

I Ada tak dalam 4 tahun ini, abang ubah ambil ubat lain?

P Ada. Ubah masalah datang balik

I Ubah datang balik, ubah ubat apa ini?

P Ubah Pulmicort. Pulmicort jenis pakai spray kan, macam Respolin dia warna biru. Tiba-tiba datang balik. Itu yang saya teruk tu,(E1 : Change in inhaler caused asthma and lead to worsening of asthma.) masuk ambulance tu.

I Ubah bila tu?

P Ubah tu, sebab pharmacy kata kalau tak ada pakar sign, tak boleh ambil. Jadi saya terpaksa lah. Dia kata yang tu tak ada, ini saja. Terpaksala. Dia kata ini lebih kurang

sama , yang tu tepung, kalau tak ini, itu lah, masalah

I Sebab kenapa? Memang ubat habis ke?

P Kena pakar sign

I Pernah tak berhenti makan ubat?

P Berhenti tu tak pernah,. Kalau berhenti pun sebab habis.

I Pernah tak lupa?

P Tu tak, memang ikut jadual (E1: Compliance with medication. Always follow schedule)

I Ikut la, memang pagi and malam la? Puas hati tak dengan penjagaan abang?

P Kira puas hatila.

I Puas hati dengan doctor?

P **Puas hati dengan doctor, hospital la(E2 Satisfy with doctor)**

I Puas hati dengan ubat?

P Puas hati. Ubat ini mahal.

I Berapa ini?

P Kalau ini beli luar ini, 90 puluh lebih

I Satu tu lah ?

P Satu 90 puluh lebih.

I Kalau sini?

P Sini, kakitangan kerajaan, regulatory lah.

I Memang rasa gembira la?

P Memang gembira

I Rasa ini nak tukar apa-apa tak? Yang lebih baik ke?

P Kalau ada lebih baik, baik. Tapi ikut Doktor R la.Kalau saya pandai-pandai ni, doktor marah.(V2: Respect doctor decision if certain care is needed.)

I Puas hati la?Masa mula mula doktor ada bagi tak arahan bertulis?

P Tak ada

I Yang mana lebih senang, arahan bertulis atau arahan bercakap?

P Saya rasa arahan bertulis itu lebih baik. Kira beberapa percent kita, persekitaran, tempat kerja, jumlah jam kerja, berapa kali nak ambil, bila nak ambil(V4: Prefer written action plan.) Tapi Doktor akan ajar ke?

I Kalau itu buat. Kita akan ajar. Pernah buat peak flow sendiri?

P Ya

I Masih ada buat lagi tak sekarang?

P Bila datang balik la. Dulu dah okay semua .

I Doktor ada suruh buat dekat rumah dan chart sendiri tak?

P Dekat rumah, memang ada alat. Semua ada. Peak flow memang buat tiap tiap hari. Lepas Pulmicort, lepas 20 ke 15 minutes, saya ambil peak flow tiup. Kalau tengok dalam 500 ,okayla.(E4 Used to do everyday. 15-20 minutes after Pulmicort , wil do peak flow rate. If is 500 above, then is considered good.)

I Abang rasa cara ini baik tak?

P Baik. Tapi bagi saya semua sama.juga. Doktor sama juga, semua sama, doktor kata ini ubat-ubat.(V4 Self-management is good. But felt is all the same. Most doctor is the same.) Yang penting kalau masuk wad, kad merah itu yang penting. Doktor mesti tahu kad merah itu.(E2 Most important is “red card” when go into ward.)

I Abang rasa tak, sebab ada ukur peak flow sendiri and jaga sendiri, abang dapat kawal

masalah dengan lebih banyak?

P Ya, memang baik sikit, dapat kawal sikit. Sebab itu, ada kawan sama-sama ada asthma, tapi tak boleh nafas. Tapi saya boleh jogging.(E2 Happy with care. Better control than patient who has asthma. I can do jogging.) Baik doktor cakap, asthma ini hanya mencegah sahaja.

Patient M03

Gender : Female
Ethnic : Malay
Age : 62
everity of asthma : Moderate Persistent Asthma
Current Treatment : Budesonide MDI 400ug bd, Montelukat 1 tablet daily, Salbutamol 2 puffs prn

I What causes your asthma?
P Hereditary(K2)
I Can you tell me about your medication?
P I have tablet and pump together since 1970 up till now, none stop. Then, it stopped for few years. I was formerly a teacher; I can even play netball with my student. Tak ada ini. When I am 50, it get serious again.
I What about now?
P Now, very bad. Even I sweep the house also I have to sit and rest. Just now, I parked my car down there, I climb the stairs, I have to rest first.(R1) Takut attack. Like before, I came early morning, sudah ada 2 puffs.
I What about your daily activities? Like showering, sitting and lying?
P Hot shower. I have my own nebuliser, when it attacks me, like jerebu, I used nebuliser twice a day.
I What about in normal days?
P I have to take care of my food. That day, I went to Klang to break fast there, I eat grape, I get wheezing, no attack but wheezing. I know the symptoms already.
I What about other types activities like a more aggressive one?
P Jalan lama –lama I cannot, climbing the stairs, I cannot.(Walk for a long time, climb stairs caused asthma)
I Walk fast?
P I feel very tired.
I When you mentioned tired, do you get shortness of breath or cough?
P Shortness of breath. I don't get cough.
I In normal day, do you still get shortness of breath a lot?
P See the things I do. Depends on the food I take.
I How many times of nebuliser do you use a day?
P Depends on condition. I don't get it every day. Like the haze problem, after that don't I use anymore. I take the pump that Doctor X gives one, very good one, and dia bagi tablet. I don't know what tablet, I forget.
I Pulmicort and Singulair?
P Singulair, that one very good for cough(E1 : Singulair good for cough). Take, I don't cough. Take, cough ok. That one is call Singulair?
I Yes. How do you take it?
P At night. When I phlegm, I also take one tablet, yang mati kuman tu , apa?
I Do you take Neulin?
P No. I cannot take Neulin. No effect at all.
I So, you are on Singulair and another tablet and pumps? Any side effects?
P No no. Dulu, doktor bagi punya, ada, Neullin and something, ada palpitation. Nebuliser ada palpitation.

I Can't avoid. Is high dose isn't it? What about ever miss dose?
P No no. Because Singulair, before sleep at night. Because I take together with another tablet, for something else – high cholesterol.
I Have anyone teach you how to use your inhaler?
P This inhaler only 10-15 years only. Before that, tak ada. Pharmacy taught me.(E3)
I When they give, or at any time, anyone told you what is the functions of these pumps?
P Yes.
P I am a matron. I have been suffering for so long. Many activities I can't do.
I Are you worried about your condition?
P Life has to carry on. So, carry on. I control myself.(R1)
I Do you think you will get better in future?

P I don't think so. It will be just control at this level.(R1
) You know yourself where you are with these medications. I take the medication, it will well, if I don't take it, it will not get well.(E1) Precautions.
I Do you do exercise?
P I cannot. I get tired. I wanted to go jogging because high cholesterol, but I cannot. Doctor asked me to go jogging, I walked a while, I feel tired. Even in the house, I sweep the room, I feel tired. Cleaning the carpet, using vacuum leaner (K2) ,
also I cannot do. I feel very tired
I Will it disturb your sleep?
P Person said cold weather trigger asthma, myself no. Cold weather I feel better. For example, I went to Sydney, very cold. I bring my nebuliser and my tablets, I didn't have attack. I came back here , I told the doctor , I didn't get asthma there. But, the weather is cold, he said because the air there is better. I am breathing populated air. I hate to get the attack, I feel very weak after using nebuliser.I feel weak, I feel palpitation.
I How do you feel about the current care? Are you happy with it?
P Yes.(E2) But, must have feedback from me, so that he knows what's happening(V2).
I Do you mean you should feel that you should part of the care?
P Of course, all this while. If not, I don't know what happen to me. (V2)
I What do you think of the doctor,nurse and pharmacist?
P They are ok.(E2 Satisfaction) Pharmacy taught me the inhaler last time.
I Have you doctor recommend or given you any written plan? Like writen instruction?
P No no..
I What if the doctor suggests that you do a few things – you do your own peak flow twice a day, adjust your own dose, and doctor gave you some steroid, and you adjust you own dose?
P I have steroids pill all the time.
I Does doctor give that?
P No I bought from pharmacy. This one is only for precautions.
I When do you normally take it?
P If after nebuliser, after my pump, it won't go off, I will take this.(E4)
I Who actually teach you how to take it?
P One day I got attack, that time I don't have my nebuliser yet. So, my husband send

me to emergency, so 3 times using nebulisers, it won't go off. The doctor doesn't know what to do with me. He gave me 12 tablets sekali makan and then goes home take 8, then 6, then 4 declining. I see is better. The effect I don't know. But the asthma goes off. The lung won't get worse. So, I buy some prednisolone to keep(E4 Self- medication)

I Doctor knows?

P I tell doctor X. He knows. I took it after my nebuliser not working. So, long I never take. I know the side effects. There is another asthma tablet, after I take, I hayal you know. Not the one Doctor X gave, is another one.

I Are you happy with you current care?

P Ya. Yes.

I Anything be improved

P No la. To me just take care of yourself. Don't do anything that you cannot do.

I Since you are given steroid tablet already, will it be better if you are given a written instruction on how to use it?

P I don't need. I know how to take. I think this is difficult to follow. I know what to take and when to take. I can remember.(E4)

I OK thank you for your time.

I What causes your asthma?

P Hereditary (K2)

I Can you tell me about your medication?

P I have tablet and pump together since 1970 up till now, none stop. Then, it stopped for few years. I was formerly a teacher; I can even play netball with my student. Tak ada ini. When I am 50, it get serious again.

I What about now?

P Now, very bad. Even I sweep the house also I have to sit and rest. Just now, I parked my car down there, I climb the stairs, I have to rest first.(R1) Takut attack. Like before, I came early morning, sudah ada 2 puffs.

I What about your daily activities? Like showering, sitting and lying?

P Hot shower. I have my own nebuliser, when it attacks me, like jerebu, I used nebuliser twice a day.

I What about in normal days?

P I have to take care of my food. That day, I went to Klang to break fast there, I eat grape, I get wheezing, no attack but wheezing. I know the symptoms already.

I What about other types activities like a more aggressive one?

P Jalan lama –lama I cannot, climbing the stairs, I cannot.(Walk for a long time, climb stairs caused asthma)

I Walk fast?

P I feel very tired.

I When you mentioned tired, do you get shortness of breath or cough?

P Shortness of breath. I don't get cough.

I In normal day, do you still get shortness of breath a lot?

P See the things I do. Depends on the food I take.

I How many times of nebuliser do you use a day?

P Depends on condition. I don't get it every day. Like the haze problem, after that don't I use anymore. I take the pump that Doctor X gives one, very good one, and dia

bagi tablet. I don't know what tablet, I forget.

I Pulmicort and Singulair?

P Singulair, that one very good for cough(1 : Singulair good for cough). Take, I don't cough. Take, cough ok. That one is call Singulair?

I Yes. How do you take it?

P At night. When I phlegm, I also take one tablet, yang mati kuman tu , apa?

I Do you take Neulin?

P No. I cannot take Neulin. No effect at all.

I So, you are on Singulair and another tablet and pumps? Any side effects?

P No no. Dulu, doktor bagi punya, ada, Neullin and something, ada palpitation. Nebuliser ada palpitation.

I Can't avoid. Is high dose isn't it? What about ever miss dose?

P No no. Because Singulair, before sleep at night. Because I take together with another tablet, for something else – high cholesterol.

I Have anyone teach you how to use your inhaler?

P This inhaler only 10-15 years only. Before that, tak ada. Pharmacy taught me.(E3)

I When they give, or at any time, anyone told you what is the functions of these pumps?

P Yes.

P I am a matron. I have been suffering for so long. Many activities I can't do.

I Are you worried about your condition?

P Life has to carry on. So, carry on. I control myself.(R1)

I Do you think you will get better in future?

P I don't think so. It will be just control at this level.(R1) You know yourself where you are with these medications. I take the medication, it will well, if I don't take it, it will not get well. (E1)Precautions.

I Do you do exercise?

P I cannot. I get tired. I wanted to go jogging because high cholesterol, but I cannot. Doctor asked me to go jogging, I walked a while, I feel tired. Even in the house, I sweep the room, I feel tired. Cleaning the carpet, using vacuum leaner ,(K2) also I cannot do. I feel very tired

I Will it disturb your sleep?

P Person said cold weather trigger asthma, myself no. Cold weather I feel better. For example, I went to Sydney, very cold. I bring my nebuliser and my tablets, I didn't have attack. I came back here , I told the doctor , I didn't get asthma there. But, the weather is cold, he said because the air there is better. I am breathing populated air. I hate to get the attack, I feel very weak after using nebuliser.I feel weak, I feel palpitation.

I How do you feel about the current care? Are you happy with it?

P Yes. (E2)But, must have feedback from me, so that he knows what's happening(V2).

I Do you mean you should feel that you should part of the care?

P Of course, all this while. If not, I don't know what happen to me.(V2)

I What do you think of the doctor,nurse and pharmacist?

P They are ok.(E2 Satisfaction) Pharmacy taught me the inhaler last time.

I Have you doctor recommend or given you any written plan? Like writen instruction?

P No no..
I What if the doctor suggests that you do a few things – you do your own peak flow twice a day, adjust your own dose, and doctor gave you some steroid, and you adjust you own dose?
P I have steroids pill all the time.
I Does doctor give that?
P No I bought from pharmacy. This one is only for precautions.
I When do you normally take it?
P If after nebuliser, after my pump, it won't go off, I will take this.(E4)
I Who actually teach you how to take it?
P One day I got attack, that time I don't have my nebuliser yet. So, my husband send me to emergency, so 3 times using nebulisers, it won't go off. The doctor doesn't know what to do with me. He gave me 12 tablets sekali makan and then goes home take 8, then 6, then 4 declining. I see is better. The effect I don't know. But the asthma goes off. The lung won't get worse. So, I buy some prednisolone to keep(E4 Self- medication)
I Doctor knows?
P I tell doctor X. He knows. I took it after my nebuliser not working. So, long I never take. I know the side effects. There is another asthma tablet, after I take, I hayal you know. Not the one Doctor X gave, is another one.
I Are you happy with you current care?
P Ya. Yes.
I Anything be improved
P No la. To me just take care of yourself. Don't do anything that you cannot do.
I Since you are given steroid tablet already, will it be better if you are given a written instruction on how to use it?
P I don't need. I know how to take. I think this is difficult to follow. I know what to take and when to take. I can remember.(E4)
I OK thank you for your time.

Appendix 3.5: Patients' Responses and Description

Study of Patients' Views on Asthma Management & Self-Management Concept
Patients' Responses and Descriptions

Nature of asthma

Patients' description of the nature of asthma	**Patients' responses**
Asthma is a common disease.	*'A lot of people also have asthma.''(C02)*
The lung is narrowed when one has asthma.	*'Lung is narrowed during asthma' (M01)* *"Lung is tightening. Cannot breath in" (I06)*
Asthma is not contagious	*'My friends thought that asthma is contagious. I told them no''(M07)*
Asthma control depends on lifestyle	*'The condition depends on the things I do and the food I take.'(M03)*
Asthma management requires self-control.	"*People cannot take care of you. You have to take care of yourself"(C01)*

The signs sand symptoms of asthma exacerbation

Patients' description of the signs and symptoms of asthma exacerbation	**Patients' responses**
Wheezing, coughing, difficulty in breathing and increased phlegm production	*"When the bad one comes, then the wheezing, I know is bad."(IO2)* *"If I inhale, there will be sound."(M05)* *"Usually is like I can't breathe (during exacerbation)." (M04)* *"Cough and the breathing are difficult…Because there is phlegm stuck inside (in the lung)...When it comes, it comes suddenly."(C101)* *"Cough and is difficult to cough out phlegm" (M07)* *'Shortness of breath. I don't get cough.'(M03)*
Chest discomfort which is described as 'tight' and 'congestion'	*"If I have asthma attack, here (patient shows chest) will be tight." (M05)* *"Not so much of phlegm, but congestion at the chest."(I06)*

Causes and triggers of asthma

Patients' description of the causes and triggers of asthma	Patients' responses
Certain food include fruits and vegetables and drink	*'Cold drink. Cannot. Some fruits like papaya, banana cannot'(C03)* *"I cannot eat mutton. Especially Australian mutton"(I08)* *'Food and drink. If I take drink with ice, I will have asthma. I also can't take rambutan (a type of local fruit)'(M02)* *'I can't even take chinese cabbage. Is cooling'(C03)* *'Bitter gourd can cause asthma'(C02)* '*Food which cold. I like cucumber, but I got scolded. Ice drink also cannot' (I01)* *'I cannot take a lot of cold food, mango, ice drink'. (M2)*
Occupational causes e.g. exposure to certain substance during work or certain activities	*'I am poor when I was young. I worked outside of my limit. I carry sand in construction site. I fish without anything. This is the cause of my asthma.'(M01)* *'Is not inherited. Is probably from my work (She worked as cleaner).'(F2)*
Dust	*'Whenever I get to places with a lot of dust, I feel tightness(C04)* *"I was having some allergy problem to dust."(I03)*
Inherited	*"Is between my dads's, my dad's mum, my dad's dad? Unfortunately, I got it. My 5 brothers are fine."(I02)*
Haze and smoke	*"When it attacks me, such as when there is haze, I used nebuliser twice a day."(M03)* *'When there is haze, I have to go emergency'. (M02)* *'If I cook such as fried chili. I will start coughing' (M04)'*
Pet e.g. cat	*"I used to have a lot of cats at home. Maybe is because of the fur of the cats'(M04)*
Weather	*'If rains, I find it uncomfortable'(I01)*
Exercise and activities including household activities	*'If I parked down the hill and walked up the stairs, I find it difficult. I also cannot carry heavy thing.'(C04)*
Stress and anxiety	*"The doctor said is stress. When stress comes, you get it (asthma)."(I02)* *'Cannot get nervous, it (asthma) will come'(C03)*

Impact of asthma

Patients' description of the impact of asthma on their life	**Patients' responses**
The need to be very cautious with food and drink and has to stop taking favourite food or drink	*"If I eat the wrong food, it (asthma attack) will come." (C04)* *'A bit of alcohol also cannot'(C02)* *'I cannot take a lot of cold food, mango, ice drink'. (M07)*
Unable to do exercise and heavy work.	*"I wanted to go jogging because high cholesterol, but I cannot"(M03)* *"I have to walk slowly."(I03)* *'If I parked down the hill and walked up the stairs, I find it difficult. I also cannot carry heavy thing.'(C04)* *'Must walk slowly'(C01)* *'Just now, I parked my car and climb the stairs, I have to rest first. I am afraid of attack… I cannot walk for too long.'(M03)*
Unable to enjoy social activities e.g. traveling	*'If go traveling, I am worried. What if I have asthma attack in the bus?'(C01)* *'If I have to go overseas, I must have good body, if I am not feeling well, I cannot go.' (M02)* *'I cannot go wedding party because of the smoke, and so crowded'(M04)*
Unable to perform household activities e.g. gardening and cleaning houses	*"If I do some housework, I start to sneeze. I feel very cold. Even when I do gardening Then it (asthma) starts." (I03)* *"Even if I sweep the house, I have to sit and rest."(M03)*
Job has been affected	*"I have to stop teaching and take my pump (inhaler) and then I start teaching again. When it comes again, I have to take the pump again."(I02)* *'I stopped working. It (the chemical and smoke exposed during working) makes me sick.'(C01)*

Concerns about asthma

Patients' description their concerns about asthma	Patients' responses
Recognised that asthma attack can be severe and may lead to hospitalisation and death.	*"People died of asthma" (I07)* *"I hate to get the attack."(M03)* *"She said you could suddenly die, in emergency. I am in shock when she told me that." (I02)* *'There is once I felt bad (during asthma attack) and got fainted in hospital. There gave me injection and blood test. I got so worried that I will die early'(C02)* *'If I have asthma, I am scared…. I am afraid that I will collapse.' (M02)* *'Sometimes if is severe, I am scared. I thought I will die'.(M04)*
Failed to prevent asthma due to lack of awareness of the trigger of asthma.	*'The doctor never said is asthma. He gave me medicine, not the pump. The second time, the doctor said is asthma. I don't know what asthma is. He gave me pump. I continued to work. I worked as mechanic. One day, while work. I felt uneasy again.'(C01)*
Failed to recognise the necessity to seek medical care when experiencing a severe episode	*'I fainted (due to asthma attack). I never thought is so bad'(C01)* *'I don't know what asthma is. So, I was not scared until I was admitted into ward' (C01)*
Asthma is inherited to children.	*'I am concerned because my third son also has asthma'(M05)*

Sources of asthma information

Patients' description of the sources of asthma information	Patients' responses
Doctor	*"Yes, the doctor talked to me before"(I01)* *"Doctor taught me" (IO4)* *"Doktor said if asthma, took it" (MO1)*
Nurse	*"Nurse showed me some picture." (M01)*
Pharmacists	*"Pharmacist has talked me "(C02)* *"No" when asked about involvement of pharmacist and nurse in education (IO1)*
Newspaper and television	*"Utusan Malaysia (newspaper) has this. I read it 2 or times in newspaper about what is asthma and how medicine used in asthma"(M07)* *"Sometimes newspaper has article about asthma"(C04)* *"I watched it in television" (I06)*

Experiences with medication

Patients' description of their asthma medication	**Patients' responses**
Asthma medication comprised of reliever and preventer.	*'This (Pulmicort) is like controller. When asthma, use this (Respolin®)'(M04)* *'She gave me two types. She said if you feel like breathless, then you used this (MDI Salbutamol). The other one, morning two, night two (MDI Beclomethasone).' (I03)*
Asthma attack can be prevented by complying with medication.	*'If I take my medicine, I am okay. I will have problem (asthma) if I forget to take it'(I01)* *"I feel better after taking medicine. But. I have to keep taking it." (I03)* *"Helpful also…. You don't get asthma" (IO4)* *'If I take one in the morning and one at night, I will not have attack. But, if I forget to take the morning one, it(asthma attack) will come'(M05)*
Asthma medication reduced inflammation, cough, sneezing, emergency visit and improved breathing and sleep.	*"It relieves cough"(IO2)* *'I don't get asthma attack after taking medicine' (M04)* *'The medicine can reduce inflammation' (M01)* *"Inhaler helps coughing. Once sputum is cough out, I felt better."(C03)* *'Before I used Pulmicort and Oxis, is severe and I have to go accident and emergency once a month. Now I only go when cough and flu were bad'(M04)*
Able to enjoy food e.g. fruits after taking medication.	*'In the past, I can't take anything cold, mango cold drink. Now I can take everything' (M07)*
Able to resume some social activities and exercise after taking medication.	*'After taking this (Symbicort®), I can mixed with people and I an play badminton' (M05)* *'I can jog.' (M02)*
Information provided with asthma medication include how much to take and when to take.	*'I can remember how much and when to take, but not know why.' (C02)* *'They only said that when you have asthma, you take it.'(C03)* *'You go pharmacy. They tell you to take this morning and night. That's about it.'(M06)*
Asthma medication has caused side effects such as tiredness, tremors, mouth ulcer and dizziness. Side effects occurred when usage of patients' medication i.e. salbutamol is high and when using nebuliser.	"*Sometimes, after use, I felt too tired. My fingers shiver when I pump too much (MDI Salbutamol). When I use nebuliser, I shiver a lot." (I02)* *'Cannot take more than 8 times a day. If take more than 8 times, I will shiver'(M05)* *'Sometimes when I take (MDI Salbutamol), it does not so away, I keep taking. I will feel dizzy after that.'(M04).* *'Medicine enters the body, therefore weight increases.'(I01)* *'When I take too much, my hands shiver.' (M05)*

Patient experienced variation between different brands of inhaler containing the same medication.	*"I prefer Respolin® I don't know why. When I pumped I get better fast, Asthalin® is like I have to do it twice, and then three times." (I02)*
Metered dose inhaler is difficult to use due to the breathing coordination.	*'Breath in and out is quite difficult (with inhaler).'(I01)*
Turbohaler works better and faster. It is also easy to use and convenient as compared to tablet.	*""The pill does not work. Inhaler (Pulmicort®) is faster" (I03)* *'The action is fast. About 5 minutes. And is easy to use (Symbicort®).' (M07)* *'Is hard when you have asthma. Need to take water. This one(Symbicort®), you only need to inhale' (M05)* *'They changed the medication…. They said it is the same. That one is powder form (dry powder inhaler) and this is not (MDI). But I have problem after taking this (MDI).'(M02)*
Patients changed dose of medication due to side effects and when asthma is controlled.	*"Is written as 2 tablets. But I cannot swallow 2 tablets, if swallow 2 tablets at one, my hand will shack (tremor)" (IO1)* *"Doctor said use Pulmicort 3 times a day. That time was serious - used morning, noon and night. Now, I used morning and night only." (IO4)*

Views on asthma medication

Patients' description of the views of their asthma medication	**Patients' responses**
There is no advance in the treatment of asthma.	*"Years go by and the new technology, I think I may get better. Even cancer has, they are having new treatment but why asthma, we can't." (I02)*
Side effects were of less concerned because medication was effective and occurred when using high dose of medication.	*'Use first, the rest think about it later'(C02)* *'Is working. That's more important.'(C04)* *'Is 'normal' after taking so much of medication'(M02)*
Medication can be recommended and shared with family member when they have signs and symptoms, which are believed to be asthma.	*'Sometimes, he (patient's son) smokes and gets asthma. He asked for my inhaler. I gave him some Ventolin® tablet. He gets better then' (M05)* *'My son also has asthma. Sometimes I gave him my inhaler. He does not have any prevention.'(I08)*
Self-medicate with prednisolone.	*"The doctor doesn't know what to do with me. He gave me 12 tablets to take and then goes home take 8, then 6, then 4 declining. I see is better. The effect I don't know. But the asthma goes off. The lung won't get worse. So, I buy some prednisolone to keep" (MO3)*

Responses to Asthma Exacerbation

Patients' description of their responses to asthma exacerbation	Patients' responses
Used reliever e.g. β_2 agonist or Symbicort® during asthma exacerbation.	*"I just increased the inhaler (MDI Sabutamol) dose when I have asthma attack."(I02)* *'I used the white one (MDI Salbutamol) when I have attack.'(M01)* *'Just take Symbicort®.' (M06)* *'When my breathing is difficult. I just pump 1 or 2 (Symbicort®)'(C01)*
Used home nebuliser	*'When it attacks me, I used nebuliser twice a day" (M03) 'I have nebuliser. I used to use it. Never use for a few years.'(C02)*
Seek medical attention e.g. private clinic doctor or hospital clinic.	*"I just go and see doctor."(I07)* *"Take medication 2-3 puffs.. If medication not working, a lot of cough, serious , go to emergency" (M01)*

Signs of asthma worsening (signs requiring medical attention)

Patients' description of the signs of asthma worsening	Patients' responses
When cough and wheezing have worsen or severe.	*"More and more wheeze" (I07)* *'When the cough is bad, I go straight to emergency' (M01)*
When peak expiratory flow rate dropped.	*'If is 200 (peak flow rate), I go and see doctor.'(M07)*
When 2 to 10 times use of reliever failed to control the symptoms	*"6-7 times (use of Bricanyl®). I think the maximum is 10…. I waited in between."(I06)* *"I used about more than 10 times."(I08)* *About 2-3 times' (C02)* *'Pump Asthalin® (MDI Salbutamol). If is not working, I will go emergency' (I02)* *'When the white one (MDI Salbutamol) not working… I used maybe about 2-3 times.'(M01)* *'I take 2 to 3 times (Symbircort®). The doctors said don't wait till 10 times. If still uneasy.' (M07)*

Experiences with the Clinical Management

Patients' description with the experiences with current management by health professionals	**Patients' responses**
Patients were satisfied with quick access of healthcare services	*"Now the service is very good. They see the card – asthma. Go first"(C04)*
Patient were satisfied asthma management	*"Nothing. Satisfy" (IO4)* *"Nothing. Everything is good) (MO1)*
Patients were satisfied with doctor who discussed their condition.	*"Doctor x is good. She told me a lot"(I02)* *"Doctor is okay. She told me about my problem." (IO3)* *"They are okay. But he (the doctor) must take feedback from me, so that he knows what happened."(M03)*
Information given from healthcare provider especially doctor was brief in some occasions. Patient left with uncertainty and may ignore the severity of disease.	*"I asked the doctor what this is. He said Ventolin® 12.5mg. That's all" (M05)* *"I asked the nurse when she will give me the medication. She said the doctor never said"(C01)* *"She (nurse) said the asthma medicine opens the lung in asthma, because lung is narrowed when asthma. Nurse showed me some picture." (M01)* *"When I was on tablets, then go to inhalers. He (doctor) said you do it; if not you will die. just like that."(I02)* *"She (Doctor) said 'Do you know that asthma is a sudden death disease?' I asked her why doctor? She said you can just suddenly die."(IO2)* *"Occasionally, I was asked to do (peak flow). Not too sure for what"(M01)* *"He (doctor) scolded me. He said blow harder. But I have asthma. How to blow harder."(M05)* *"I asked what happened. He said the report said my liver is damaged. Then he walked away…I treated it as 'okay'" (C01)*
Patients felt that doctors who did not obtain much information from them are not as knowledgeable as specialist. *Specialist refers to a respiratory consultant or a medical officer who run an asthma clinic.	*"If they are not specialist. They asked what happened, and some routine questions. And they checked your record. And then they gave you the medication. The same medication as the last doctor gave."(C04)* *"I have so many attacks. Until I see her. She (the doctor) asked me whether I have the one taken in the morning and night (preventer) everyday .Then only she gave me the white one (Pulmicort®):" (C04)* *"Maybe because he is not specialist. Knowledge is not sufficient. He didn't ask much." (M07)*

	"The blowing (Peak flow) just now, the last time I think, maybe 4 years ago" (IO2)
Patient was not aware of the role of pharmacist in asthma management.	*'Pharmacy, I don't know what they can help.' (M05)*
Patients were not confident with health professional's advice or information.	*"The technique is wrong. I told them I pump this way, they said is correct." (I02)* *"Doctor said is because of my pregnancy (weight gain problem). I don't believe him/her" (I01)*
Inhaler technique was checked occasionally.	*"Dr X will ask me to show him how I normally use the inhaler."(IO1)* *"They checked it once in a while."(C02)* *"Sometimes the nurse will check (inhaler technique)."(M02)* *"Yes. They checked my technique sometimes."(I04)*
Medicine used (injection) and test done during admission caused fear.	*"Go to hospital, they take blood and give injection. The hand will get bruises… I don't like to be admitted." (C03)*

Views on Clinical Management

Patients' description of their views about current management	**Patients' responses**
Patient preferred doctor to decide their care, due to perception that doctor will be unhappy if patient decide himself.	*"If there is better one, that's good. I will just follow the doctor advice. If I try to be clever, the doctor may scold"(MO2)*
Patients did not expect changes in care as management remained similar to patient.	*"But to me is all the same. Doctor is the same, all same including medicine."*
Patients preferred to be seen by the same doctor at follow up.	*'Is better if is seen by the same doctor. They know me better'.(C02)* *'If I go to the Wednesday clinic, is faster. I usually see Dr X. She knows me well.'(C01)*
Patients preferred to self-manage because patients know better about themselves.	*"I think our administration is better than them. They don't know what our condition is, what we take, and how to adjust. We are better than doctor"(I06)* *(them refers to healthcare provider)*
Patients preferred doctor to find out more about patient's progress and give feedback about their condition.	*'They never asked whether you are worse or better.'(C01)* *'The specialist (doctor from asthma clinic) is very thorough. She asked a lot.'(C04)*
Patients preferred to keep their own medical record	*'Is easier if we keep the medical card. They don't have to search. Is too slow' (C04)* *'They loss my record twice. It will not happened now because I kept it'(C01)*
Patients preferred to have priority of service to be given to asthma patient.	*"If no need to wait, it will be great (when asked about what else can be offered to them)" (IO1)* *"Asthma patient should be given first priority… should take care of it (asthma) immediately because we are so sick" (IO2)*

Views on Asthma Education by Health Professionals

Patients' description about the views on asthma education	Patients' responses
Patients were reluctant to participate asthma education activities	*"Is difficult to give to everyone. Many patients.'(C01)* *'I don't think I can come. I have to take leave.'(M02)* *'A bit difficult to come. I cannot go for too long". (I01)*
Patients did not need asthma education because asthma is well controlled and was taught in the past.	*"I am controlled .I don't think I need it." (I08)* *'Now I am fine, Nurse has taught it in the past' (M01).*
Group discussion is beneficial because it allows sharing of information.	*'I think this (focus group) is good. We can know more about asthma and listen to the rest.'(C02)*
Asthma education should include information about exercise, inhaler technique, monitoring of own condition and updates about asthma disease and medication.	*"I think maybe they should have once a month a seminar for asthma patient, the proper exercise, and the proper method, how are we doing, what's happening." (I02)*

Views on Asthma Self-Management

(After description of an example of written asthma self-management plan)

Patients' description of their views on asthma self management	**Patients' responses**
Patient has experienced with self-management via verbal instruction,	*"Doctor just said if I have asthma, double the dose of Symbicort® twice daily"(I06)*
Patient has past experience with peak flow monitoring. Failure to continue the recording of peak flow due to lack of support from health professional	*'I do it (peak flow monitoring) once in a while.' (C02)* *'Given by nurse for the study (clinical trial). I do it in the past. But not now.'(C03)* *'I was admitted to hospital. I brought my diary but the doctor is not looking at it. So, I stop doing it.'(C01)*
Does not have knowledge about peak expiratory flow rate (PEFR).	*'The lowest peak flow is 50?'(C01)* *'I can only get 250. Is always this low.'"(C02)*
Prefer to see doctor when unwell	*'I think is better if doctor decide the treatment. If I need immediate treatment, the doctor can give me.' (I01)*
Would like doctor to decide if self-management is good for them.	*"If the doctor think is good for me, I will do it"(I03)* *'Now is good. But if doctor decide to do it, I will follow.'(M04)*
Peak flow monitoring enhanced patient's confidence of their condition.	*'I do it everyday. After 15 to 20 minutes of Pulmicort®, I will do peak flow. If is 500, I know I am okay' (M02)* *'If I can get 500 (PEFR) at home it means is good. I feel better and more in control compared to my friends' (C02)*
Reluctance and lack of confident in asthma self-management because of the complexity and poor reading ability.	*"I don't need. I know how to take it (medicine). I think this (self-management) is difficult to follow."(M03)* *'How long do we have to do this?'(M07)* *'I am not good in reading'(I01)*
Confident with self-management if training is provided	*"I think our administration is better than them. They don't know what our condition is, what we take, and how to adjust. We can be better than doctor"(I06)* *"If is (self-management) going to help me even 30% of not getting it (asthma attack), I see heaven." (IO2)* *'If you can tell me how to do it, I can do it' (M02)* *'Because we see doctor about every 4 months. We can do this before I see the doctor.' (M06)* '*People cannot take care of you. You have to take care of yourself'(C01)* *'If can understand more, I feel more in control.' (C02)*

Appendix 5.1: Protocol of Development and validation of a pharmaceutical care model for the management of asthma in outpatient setting.

(To be submitted in 25 copies for each project)

APPLICATION FORM FOR RESEARCH GRANT
INTERNATIONAL MEDICAL UNIVERSITY

I. Project Identification

A. Project Title (Please indicate the title of the project; the title should be short and concise)

Development and validation of a pharmaceutical care model for the management of asthma in outpatient setting.

B. Project Leader (Name& Department)

Name : **Wong Pei Se**

Title : **Lecturer**

Department/ Section : **School of Pharmacy and Health Sciences**

_____ _____

Date Signature

Protected Time Required: ~~Yes~~ / No
IMU-Research Lab Bench Space Required: ~~Yes~~ / No
(If 'Yes' please fill in the Appendix 2)

C. Key words (Please provide a maximum of 5 key words that describe the research of the project. The key words will be incorporated in a database on Malaysian research)

Asthma management, pharmacist contribution

II. Objectives of the Project and Hypothesis

A1. Specific objective of the project (Please describe the measurable objectives of the project and define the expected results. Use results-oriented wording with verbs such as "to define..." "To determine..." "To identify...")

The objectives of this study are

- To validate the pharmaceutical asthma care model using consensus method.
- To establish consensus on the pharmacists' contributions to asthma management

A2. Research hypothesis of project

B. Research background of the project (Please indicate if the project is new, modified or extended. Give a summary of your literature review to indicate the originality of the proposed research, and describe related research to assist in assessing the research rationale and the potential for success)

- Project status (please indicate) [√] New [ ] Modification to previous project [ ] Extension of existing project

- Literature review summary

Many guidelines have been developed over the years to improve asthma management and patient care. Besides recommendation of pharmacological and non-pharmacological methods, some guidelines also emphasise on the importance of structured care and multidisciplinary approach to a better delivery a patient care. [1] Multidisciplinary approaches involving health professionals such as doctors, nurses, pharmacists, physiptherapies, dieticians, and others have shown to improve patient care. In asthma management, some interventions involving pharmacists have shown to be effective in improving compliance, knowledge and clinical outcomes.[2-6] Despite the evidences; there is a general lack of involvement or underutilisation of pharmacists in the asthma care in Malaysia. In order to establish the contribution of pharmacists in the asthma management, a pharmaceutical care model for asthma management has been developed based on literature and previous work on asthma patients. The aim of this study is to validate the care model developed and to establish the contribution of pharmacists in this model using Delphi consensus method.

1 British Thoracic Society and Scottish Intercollegiate Guideline Network. British guideline on the management of asthma. November 2005 Update. [Accessed via www.brit-thoracic.org.uk]
2 Park JJ, Kelly P, Carter BL, Burgess PP. Comprehensive pharmaceutical care in the chain setting. Journal America Pharmaceutical Association. 1996; 36:443-451
3 Munroe WP, Kunz K, Dalmady-Israel C, Potter L, Schonfeld WH. Economic evaluation of pharmacist involvement in disease management in a community pharmacy setting. Clinical Therapeutics. 1997;19(1):113-123
4 Narhi U, Airaksinen M, Tanskanen P, Erlund H. Therapeutic outcomes monitoring by community pharmacists for improving clinical outcomes in asthma. Journal of Clinical Pharmacy and Therapeutics. 2000;25(3):177-183
5 Schulz M, Verheyen F, Muhlig S, Mullller J, Muhlbauer K,Knop-Scheickert E, et al. Journal of Clinical Pharmacology: a controlled intervention study. Journal of Clinical Pharmacology 2001;41:668-676
6 Weinberger M, Murray MD, Marrero DG, Brewer N, Lykens M, Harris LE, et al. Effectiveness of pharmacist care for patients with reactive airways disease - a controlled trial. Journal of American Medical Association 2002;288:1594-1602

C. Type of research (Please indicate the type of research, one only; see definition of terms in the Guidelines)

[ ] 1. Scientific research (fundamental research)

[ ] 2. Technology development (applied research)

[√] 3. Product/process development (design end engineering)

[ ] 4. Social/policy research

III. Benefits of the Project

A. Outputs expected from the project (Please refer to the list of outputs in the Guidelines and give further details)
Provide recommendation to the model of care for asthma management for use in outpatient setting. Provide recommendation to the pharmacists' contributions to asthma management

IV. Project Team

Name	Organisation/Dept/Section
Project Leader (Please provide name) **Wong Pei Se**	School of Pharmacy and Health Sciences, IMU
Researchers (Please provide names or numbers of researchers) **Professor Dr Richard Loh Li-Cher** **Professor Steve Hudson**	Penang Medical College, Penang University of Strathclyde, Glasgow
Support Staff (Please indicate how many)	
Contract Staff (Please indicate how many)	

V. Research Approach

A. Research methodology (Please describe the research methodology to be followed. Identify specialised equipment, facilities and infrastructure which are required for the project, and indicate which are new)

Subjects & Setting

A Delphi survey involving at least 20 medical practitioners and 20 pharmacists.

Inclusion criteria for Delphi panel (medical practitioners):

- Respiratory specialist or consultant
- Senior medical practitioners
- Clinical pharmacist

Exclusion criteria for Delphi panel

- Junior medical practitioners (less than 3 years of practice)

Methodology

1. A search was performed using MEDLINE and Embase databases from 1994 to 2006 to identify published papers related to development of asthma care model. Combined keywords used include "asthma and pharmacist interventions", "asthma and care model" and "asthma and pharmaceutical care model". The search identified 41 published papers, of which 11 were found to be useful. Based on the published work identified, international guidelines of long term management of asthma, and previous work on asthma audit, a draft pharmaceutical care model for asthma management was developed (Refer Appendix 1). Evidences of pharmacists' contribution in asthma management were also summarised.

2. Questionnaires (Appendix 2 for medical practitioner and Appendix 3 for pharmacist) were designed based on the processes involved in the pharmaceutical care model developed and patents' contribution in asthma management. The questionnaire consists of 6 components; participant's demographic data, statements related to assessment and documentation, management plan, delivery of management plan, review/monitoring and roles of pharmacist in asthma management. A 7 points Likert scale (1=strongly disagree, 7=strongly agree) will be used to obtain participant's agreement to individual statements.

3. Field-testing was carried using 5 pharmacists and medical practitioners. Questionnaire will be revised based on findings from field-testing.

4. Medical practitioners and pharmacists will be invited to participate in this study via email, telephone, post or fax. The nature of the survey will be informed. Emails will be sent to participants who agreed to participate in the survey. The final questionnaires will be hosted in an online survey system [www.monkeysurvey.com]. A deadline for completion of the survey will be provided.

5. Consensus in this study will be defined when 80% or more participants had scored 6 or 7. Baseline findings will be analysed using first round of Delphi process. Statements, which failed to reach consensus, may be revised and will be graded in next round. The process will be repeated for a maximum of three rounds.

Data analysis

Percentage of consensus reached by each statement will be presented. Findings will be used to revise the pharmaceutical care model for asthma management and devise a model for pharmacists' contribution in asthma management.

B. Project activities (Please list and describe the main project activities, including those associated with the transfer of the research results to customers/beneficiaries. The timing and duration of these activities are to be shown in the Gantt chart in Form VI)

1. Development & testing of online questionnaire
2. Recruitment & 1st round of Dephi process (questionnaire sending)
3. Data collection (completion of questionnaire)
4. 2nd round of Delphi process
5. 3rd round of Delphi process
6. Data analysis

C. Key milestones (Please list and describe the principal milestones of the project. The timing of milestones is to be shown in the Gantt chart on Form VI. A key milestone is reached when a significant phase in the project is concluded, e.g. completion of test, review, commissioning of equipment, etc)

- Development & testing of online questionnaire
- Recruitment & 1st round of Dephi process (questionnaire sending)
- 2nd round of Delphi process
- 3rd round of Delphi process
- Data analysis

D. Risks of the project (Please describe factors the that may cause delays in, or prevent implementation of, the project as proposed above; estimate the degree of risk)

Factors:

Respondent rate

(Respondent will be identified before circulation of emails. Reminder will be done be emails and/ or phone call if necessary to remind respondents to complete the questionnaire by deadline)

	Low	Medium	High
Technical risk:	√		
Timing risk:		√	
Budget risk:	√		

E. Duration **(State the planned starting date of the project and the elapsed time, in months, to complete this project; technology transfer activities should** be excluded from elapsed time)

Starting date:
January 2009

Duration/elapsed time:
12 months (end by Jan 2010)

	2009												2010												2010	
Research Activities	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**S1**	**S2**
Development & testing of online questionnaire																										
Recruitment & 1st round of Dephi process (questionnaire sending)																										
2nd round of Delphi process																										
3rd round of Delphi process																										
Data analysis																										
Technology Transfer Activities (if applicable)																										

VII. Project Costs

A. Staff costs (Please include the yearly staff costs of the project. Numbers in parentheses refer to expense codes)

Staff Category	Total RM	Year 1	Year 2	Year 3
• Salaried personnel (11000) • Temporary and contract personnel (J 400)				
Sub-total staff costs				

B. Direct project expenses (Please include the yearly direct expenses of the project. Numbers in parentheses refer to expense codes)

Expense Category	Total RM	Year 1 2009	Year 2 2010	Year 3 200_
• Travel and transportation (J 500) • Rentals (J 600) • Research materials and supplies (J 700) Photocopying + Miscellanous • Minor modifications and repairs (J 800) • Special services (J 900)		**RM250** 1 Meeting in GH Penang **RM150** (100 x 0.10/page + 50 for Miscellanous e.g. phone card) **RM1000** Subsription www.monkeysurvey.com (USD 250x 4)		
Sub-total direct		**RM1400**		

C. Total cost (Please add the sub-totals of A and B)

RM 1,400

Special Equipment and Accessories (Please describe and provide justification for major purchases)

1. Description: Subscription to www.monkeysurvey.com

2. Justification:
www.monkeysurvey,com is online survey database that allows easy and fast collection of data. It allows responds to be viewed on daily basis and reminder can be sent or done as required basis.

3. Estimated Cost: **USD 250 (RM1000)**

Special Equipment and Accessories (Please describe and provide justification for major purchases)

1. Description:

2. Justification:

3. Estimated Cost:

Guidelines:

Type of research

The definitions of the terms Scientific Research, Technology Development and Product/ Process Development are based on those of the OECD Frascati Manual.

1. ***Scientific research (fundamental research)*** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.

2. ***Technology development (applied research)*** is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.

3. ***Product/ process development (experimental development)*** is systematic work drawing on existing knowledge gained from research and practical experience that is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

4. Social/ policy research: Original investigation undertaken in order to acquire new knowledge in the area of social sciences and public policy.

Outputs Expected from the Project

Project outputs reflect the direct benefits of the project. These benefits vary amongst the different types of research.

1. For ***scientific research (fundamental research)*** projects please use the following list of outputs:
   - Algorithm
   - Structure
   - Data
   - Other (please specify)

2. For t***echnology development (applied research)*** projects please use the following list of outputs:
   - Method/ technique
   - Demonstrator/ prototype
   - Other (please specify)

3. For ***product/ process development (design and engineering)*** projects please use the following list of outputs:
   - New/ improved product/ device
   - New/ improved process
   - New/ improved software
   - New/ improved material
   - New/ improved service
   - Others (please specify)

4. For ***social research*** projects please use the following list of outputs
   - Measurement
   - Policy recommendation
   - Other (please specify)

5. For ***public policy research*** projects use the following list of outputs:
   - Technical policy advice
   - Contribution of a code of practice
   - Tools to help with enforcement
   - Contribution to standards definition
   - Other (Please specify)

**Guidelines for the applications of R&D Funding under IRPA RM7*

Appendix A

		Cost (RM)
	Staff Costs	
1. (11000)		
2. (J 400)		
	Travel and Transportation Claim	
1. (J 500)	Return trip from KL-Penang	**250**
2. (J 500)		
Description of Research Materials		
3. (J 700)		
4. (J 700)		
5. (J 700)		
6. (J 700)		
7. (J 700)		
8. (J 700)		
Minor Modifications and Repairs		
9. (J 800)		
10. (J 800)		
Special Services		
11. (J 900)	Subscription to www.monkeysurvey.com	**1000**
12. (J 900)		
Special Equipment and Accessories		
13. (J 1000)	Photocopying + Miscellaneous e.g. phone card	**150**
14. (J 1000)		
	TOTAL	**1,400**

Appendix 5.2: Evidences of Pharmacist's contribution in Asthma Management

Evidences of pharmacist's contribution in asthma management

Published work	Setting and sample	Description of pharmaceutical care service or intervention	Outcome
Munroe WP et al. (1997)[166]	Community pharmacy chain stores, USA Study includes asthma, hypertension, hypercholesterolemia, diabetes patients. 188 (42 asthmatics) intervention and 401 (117 asthmatics) control patients; 6 months follow up	**Disease Management in a Community Pharmacy Setting** ▪ Systematic assessment of patients' adherence to medication, non-drug therapies and drug therapy efficacy (subjective and objective measures e.g. peak flow rate in asthma) performed according to guidelines. ▪ Education on nature of condition, medication administration, role of medication, non-drug therapy, self-monitoring, and adverse effects, early intervention, and behavior modification. ▪ Collaborative approach between physician, pharmacist and patients via active patient participation and regular communication with physician by telephone or letter of any problem identified. ▪ Documentation of patient information and interventions.	Monthly prescription costs significantly higher among asthma intervention group (113.65±84.10 for intervention group versus 86.35±64.05 for control group, p=0.030). The total cost per member (including medical resources cost) were however lower in intervention groups (findings however is insignificant). There is no data of the total cost per member for asthma subgroup.

Published work	Setting and sample	Description of pharmaceutical care service or intervention	Outcome
Narhi U et al. (2000)[157]	Community pharmacies, Finland 21 patients, follow-ups at baseline, 4, 8, 12 and 24 months using a pre/post-test design.	**Therapeutic outcomes monitoring by community pharmacist** ▪ Education on asthma pathology, instructions on the use of a PEF meter (method of use), use of medications and inhaler devices and recognisation and management of asthma symptoms (according to a management plan). ▪ Nurse and physician consultation when necessary. ▪ Regular monitoring ▪ Documentation using a structured form.	Significant improvement in daytime wheeze ($p<0.001$), mucus excretion ($p<0.05$), and allergic symptoms ($p<0.05$) one year after the intervention. Insignificant reduction in number of patients (7 patients to 4 patients) having PEF values below 85% of the optimal at 12 month. The number increased from 4 to 7 at 24 months. 57% of the patients had changes in their daily asthma medication during the intervention. Changes include conversion of metered-dose inhaler to dry-powder device and addition of long-acting β_2 agonist.
Schulz M et al. (2001)[65]	Multicentre community pharmacies, 161 intervention and 81 control patients, 12-month follow up	**Pharmaceutical care services provided by trained pharmacists.** • Assessment to identify and address individual drug- and health-related problems. • Drug and health related problems identified were need for additional drug therapy, inappropriate dosage form, inappropriate dosage regimen, adverse drug reaction, drug interactions and incompliance. • Self-management training which include use of peak flow meter and an asthma diary recording. **[**Training of the intervention pharmacist comprised medical, pharmaceutical, and pharmacological knowledge (5 hours), communication skills (6 hours), and the use of the study protocol and documentation forms (2 hours).]	Pharmaceutical care led to significantly improved inhalation technique. Asthma-specific quality of life and the mental health summary score of the SF-36 improved significantly in the intervention group. At 12 months, the intervention group showed significant improvements with regard to evening peak flow, self-efficacy, and knowledge

Published work	Setting and sample	Description of pharmaceutical care service or intervention	Outcome
Weinberger M et al.(2002)[234]	Multicentre drugstores, Indianapolis 3 arms; 262 intervention, and 233 peak flow monitoring control and 165 usual care control patients; 12 months follow up Intervention group monitored by pharmacists trained using Pharmaceutical Care Program and received full pharmaceutical care services. Peak flow monitoring and usual control patients follow up partially trained. Peak flow meter control group received partial pharmaceutical service while usual care control patients did not received any pharmaceutical care services.	**Pharmaceutical Care Program** ▪ Access to patient specific data (background, peak flow rates, emergency department visit, hospital visits, medications) ▪ Tailored patient education materials ▪ Resource guide ▪ Pragmatic strategies to facilitate implementation of pharmaceutical care ▪ Pharmacist training program ▪ Provision of pharmaceutical care services e.g. provide a peak flow meter, instruction about its use, and monitoring of PEF.	Significant improvement in PEFR (p=0.02) in pharmaceutical care group as compared to usual care control group.(No data for asthma subgroup) No significant between over health related quality of life scores among asthma groups. Patient receiving pharmaceutical care were more satisfied with their pharmacist than the usual care a 6 months. .

Published work	Setting and sample	Description of pharmaceutical care service or intervention	Outcome
Saini B et al. (2004)[167]	Multicentre community pharmacies, Australia 52 intervention and 50 control patients; 3 follow up visits over 6 months.	**Community Pharmacy based asthma care model** ▪ Performing individualised needs analysis of the Australian six-step asthma management plan 1. Assessment of patient's severity 2. Achievement of best lung function 3. Maintenance of best lung function though avoidance of triggers 4. Maintenance of best lung function through optimal medications 5. Provision of written action plan, and 6. Education and regular review ▪ Addressing identified needs with intervention ▪ Documentation of interventions delivered and outcomes measured ▪ Collaborative setting goals with the patient for following visit ▪ Monitoring of patient at fixed interval ▪ Collaborative approach in management with other healthcare professionals. ▪ Provision of diary for PEF and medication use recording ▪ Assessment of inhaler technique at each visit.	Significant improvement in asthma severity ($p<0.001$), days affected by asthma and quality of life scores in intervention group. Peak flow indices increased from 82.7%±8.2% to 87.4%±8.9% ($p<0.001$). Medication changes were also noted. There was significant decrease ($p<0.015$) in mean daily dose of salbutamol and a significant increase in mean daily dose of Seretide® (contains salmeterol and fluticasone). Number of patients on an ideal profile of reliever, preventer and symptom controller medication increased from 7.7% to 28.8% ($p<0.001$). There were no significant changes in the number of patients on with asthma action plan, perceived control of asthma and knowledge.

Published work	Setting and sample	Description of pharmaceutical care service or intervention	Outcome
Tsai AC et al. (2005)[169]	Multicentre clinics, USA A non-disease specific review Retrospective clinic database review of 520 patients seen in year 2002.	**The Pharmacist Review to Increase Cost Effectiveness (PRICE) Clinic** ▪ Patient interview to collect patient data, current medication regimen, health insurance status, prescription drug benefit information, income, and local and/or mail-order pharmacy information. ▪ Evaluation of appropriateness of the medication regimen including screening for adverse drug reactions, drug interactions, and duplicate and/or omitted therapy. ▪ Review for cost-cutting interventions, such as maximizing use of generic drugs, tablet-splitting, therapeutic interchange, and use of mail-order pharmacies ▪ Implementation of new medication regimens after consulting and approval from patient's physician. ▪ Documentation in the patient's medical record and subsequently in a clinic database. ▪ Provision of written and verbal information regarding medication regimens to patient	1,297 interventions (mean of 2.5 interventions per patient) were identified. The most common drug classes involved in interventions were lipid-lowering drugs, angiotensin-converting enzyme inhibitors, and asthma and allergy drugs. An increase of generic drug use from 51% to 56%. "Out of pocket" (paid by patient) medication expenditures decreased by 68%. The most common interventions were pharmaceutical industry- sponsored patient assistance programs, generic substitution, and therapeutic interchange.
Mangiapane S. et al. (2005)[155]	Multicentre community pharmacies, Germany 183 intervention patients, follow-ups at baseline, 6, 12 months using a pre/post-test design. A subgroup of 55 for evaluation of economic outcomes.	**Community based pharmaceutical care** ▪ Education on the pathology of asthma, use of asthma medication, inhalation technique, and self management skills. ▪ Identification and addressing drug related problems	Significant improvement in asthma severity ($p<0.002$), dypsnea ($p<0.05$), PEFR (402.9 L/min baseline, 436.6 L/min at 6 months and 433.4 L/min at 12 months, $p<0.001$), asthma symptoms rated by patients and inhaler technique (both MDI and DPI). Improvement was also significant ($p<0.001$) in humanistic outcomes (self- efficacy, adherence and patient's knowledge).

Reviews		Description of review services/interventions	Outcomes
Roughead EE et al. (2005)[153]	Systematic review	**Systematic review of pharmaceutical care services** (*systematic review involving asthma, chronic obstructive airways disease, hypertension, diabetes management)* ▪ Intervention involving one to one consultation between patient and pharmacist focusing on managing health and drug related problems, development of care plan and follow up.	Improvement in Quality of Life scores (Juniper questionnaire and Nottingham Health Profile and living with asthma questionnaire) among intervention group in 2 out of 4 studies involving asthma patients. No significant effect on numbers of days absent form work or school was reported. Significant improvement in symptoms scores, shortness of breath, chest tightness, phlegm production, nocturnal wakening and nasal symptoms were reported in one study[235]. The paper also reported significant improvement in PEFR. Reduction in hospitalisation reported in 2 published papers[236, 237].

Appendix 5.3: Consensus on a Pharmaceutical Care Model for Management of Asthma Questionnaire

Consensus on a pharmaceutical care model for management of asthma: [Questionnaire for Medical Practitioner]

Demographic Data

Position in practice

□ Medical officer □ Registrar □ Consultant/Specialist

Number of years of qualification: _____years

Number of years of practice: _____years

Approximate number of asthma patients (in-patient and out-patient) seen in a week

□ 0-5 patients □ 5-15 patients □ 15-30 patients

□ >30 patients

Consensus on a pharmaceutical care model for management of asthma: Questionnaire for Medical Practitioner

	Strongly disagree						Strongly agree
	1	**2**	**3**	**4**	**5**	**6**	**7**
Assessment and documentation should be carried out for asthma patients on							
1. past medical history & past drug history	□	□	□	□	□	□	□
2. potential trigger factors	□	□	□	□	□	□	□
3. asthma severity based on PEF or FEV_1 and symptoms or asthma control test	□	□	□	□	□	□	□
4. predicted peak expiratory flow rate (PEFR) or FEV_1	□	□	□	□	□	□	□
5. patients' expectations of treatment	□	□	□	□	□	□	□
6. patient educational needs including self-manage ability	□	□	□	□	□	□	□
7. co morbidity: poor cognitive skills to use inhaler, fears with medication use, concerns about asthma morbidity	□	□	□	□	□	□	□
A patient management plan should include							
8. individualised treatment plan	□	□	□	□	□	□	□
9. individualised goal of therapy	□	□	□	□	□	□	□
10. patient education including asthma self-management plan	□	□	□	□	□	□	□
Asthma patients should be							
11. prescribed with a reliever e.g. short acting β_2 agonist and preventive medication as necessary	□	□	□	□	□	□	□
12. assessed on their inhaler technique if prescribed with inhaler & oral medication use e.g. dose and frequency	□	□	□	□	□	□	□
13. provided with an asthma action plan and suitable educational materials if necessary	□	□	□	□	□	□	□
Asthma patients should received education on							
14. asthma pathology and triggers	□	□	□	□	□	□	□
15. treatment goals	□	□	□	□	□	□	□
16. use of medication e.g. how and how much to take.	□	□	□	□	□	□	□
17. medication benefits and precautions	□	□	□	□	□	□	□
18. inhaler technique	□	□	□	□	□	□	□
19. signs of asthma exacerbation	□	□	□	□	□	□	□
20. self-management skills	□	□	□	□	□	□	□
21. Patients should be informed of their asthma status.	□	□	□	□	□	□	□

On follow up / review of asthma patients, assessment and documentation should be carried out on							
22. control of asthma e.g. daytime symptoms, limitations of activities, frequency of exacerbation, nocturnal symptoms & frequency of use of reliever in a week	□	□	□	□	□	□	□
23. peak expiratory flow rate (PEFR)	□	□	□	□	□	□	□
24. adherence to medication	□	□	□	□	□	□	□
25. the need to step up or step down of therapy	□	□	□	□	□	□	□
26. risk of side effects or complications e.g. osteoporosis	□	□	□	□	□	□	□
27. individualised goal of therapy e.g. best PEFR	□	□	□	□	□	□	□
28. inhaler technique	□	□	□	□	□	□	□
29. patient educational needs	□	□	□	□	□	□	□
30. compliance to self-management plan	□	□	□	□	□	□	□
The roles of pharmacist are to							
31. identify patients who needs support	□	□	□	□	□	□	□
32. monitor patients' adherence to medication	□	□	□	□	□	□	□
33. monitor patients' severity or drug efficacy using subjective and objective measures e.g. peak flow rate.	□	□	□	□	□	□	□
34. assess use of non-drug therapy.	□	□	□	□	□	□	□
35. assess patients' inhaler technique	□	□	□	□	□	□	□
36. screen for drug therapy problems e.g. adverse effects, drug interactions, duplication therapy	□	□	□	□	□	□	□
37. identify cost-saving interventions e.g using generic	□	□	□	□	□	□	□
38. communicate with doctor if problem is identified	□	□	□	□	□	□	□
39. recommend changes in type of inhaler	□	□	□	□	□	□	□
40. recommend removal or addition of medication	□	□	□	□	□	□	□
41. recommend changes in dosage regimen	□	□	□	□	□	□	□
42. recommend cost-saving interventions e.g. change therapy to generic	□	□	□	□	□	□	□
43. document outcomes of patients' assessment in medical record	□	□	□	□	□	□	□
44. document problems identified in medical record	□	□	□	□	□	□	□
45. document actions taken to solve the patients' problems in medical record	□	□	□	□	□	□	□
46. reinforce patient counseling	□	□	□	□	□	□	□
47. educate patient on self-management skills using asthma action plan	□	□	□	□	□	□	□
48. provide educational materials if necessary	□	□	□	□	□	□	□

Consensus on a pharmaceutical care model for management of asthma: [Questionnaire for Pharmacists]

Demographic Data

Number of years of qualification: _____years

Number of years of practice: _____years

Approximate number of asthma patients (in-patient and out-patient) seen in a week

□ 0-5 patients □ 5-15 patients □ 15-30 patients □ >30 patients

Consensus on a pharmaceutical care model for management of asthma: Questionnaire for Pharmacists

	Strongly disagree 1	2	3	4	5	6	Strongly agree 7
Assessment and documentation should be carried out for asthma patients on							
49. past medical history & past drug history	□	□	□	□	□	□	□
50. potential trigger factors	□	□	□	□	□	□	□
51. asthma severity based on PEF or FEV_1 and symptoms or asthma control test	□	□	□	□	□	□	□
52. predicted peak expiratory flow rate (PEFR) or FEV_1	□	□	□	□	□	□	□
53. patients' expectations of treatment	□	□	□	□	□	□	□
54. patient educational needs including self-manage ability	□	□	□	□	□	□	□
55. co morbidity: poor cognitive skills to use inhaler, fears with medication use, concerns about asthma morbidity	□	□	□	□	□	□	□
A patient management plan should include							
56. individualised treatment plan	□	□	□	□	□	□	□
57. individualised goal of therapy	□	□	□	□	□	□	□
58. patient education including asthma self-management plan	□	□	□	□	□	□	□
Asthma patients should be							
59. prescribed with a reliever e.g. short acting β_2 agonist and preventive medication as necessary	□	□	□	□	□	□	□
60. assessed on their inhaler technique if prescribed with inhaler & oral medication use e.g. dose and frequency	□	□	□	□	□	□	□
61. provided with an asthma action plan and suitable educational materials if necessary	□	□	□	□	□	□	□
Asthma patients should received education on							
62. asthma pathology and triggers	□	□	□	□	□	□	□
63. treatment goals	□	□	□	□	□	□	□
64. use of medication e.g. how and how much to take.	□	□	□	□	□	□	□
65. medication benefits and precautions	□	□	□	□	□	□	□
66. inhaler technique	□	□	□	□	□	□	□
67. signs of asthma exacerbation	□	□	□	□	□	□	□
68. self-management skills	□	□	□	□	□	□	□
69. Patients should be informed of their asthma status.	□	□	□	□	□	□	□

On follow up / review of asthma patients, assessment and documentation should be carried out on							
70. control of asthma e.g. daytime symptoms, limitations of activities, frequency of exacerbation, nocturnal symptoms & frequency of use of reliever in a week	□	□	□	□	□	□	□
71. peak expiratory flow rate (PEFR)	□	□	□	□	□	□	□
72. adherence to medication	□	□	□	□	□	□	□
73. the need to step up or step down of therapy	□	□	□	□	□	□	□
74. risk of side effects or complications e.g. osteoporosis	□	□	□	□	□	□	□
75. individualised goal of therapy e.g. best PEFR	□	□	□	□	□	□	□
76. inhaler technique	□	□	□	□	□	□	□
77. patient educational needs	□	□	□	□	□	□	□
78. compliance to self-management plan	□	□	□	□	□	□	□
I am comfortable to							
79. identify patients who needs support	□	□	□	□	□	□	□
80. monitor patients' adherence to medication	□	□	□	□	□	□	□
81. monitor patients' severity or drug efficacy (subjective and objective measures e.g. peak flow rate)	□	□	□	□	□	□	□
82. assess use of non-drug therapy.	□	□	□	□	□	□	□
83. assess patients' inhaler technique	□	□	□	□	□	□	□
84. screen for drug therapy problems e.g. adverse effects, drug interactions, duplication therapy	□	□	□	□	□	□	□
85. identify cost-saving interventions e.g using generic	□	□	□	□	□	□	□
86. communicate with doctor if problem is identified	□	□	□	□	□	□	□
87. recommend changes in type of inhaler	□	□	□	□	□	□	□
88. recommend removal or addition of medication	□	□	□	□	□	□	□
89. recommend changes in dosage regimen	□	□	□	□	□	□	□
90. recommend cost-saving interventions e.g. change therapy to generic	□	□	□	□	□	□	□
91. document outcomes of patients' assessment in medical record	□	□	□	□	□	□	□
92. document problems identified in medical record	□	□	□	□	□	□	□
93. document actions taken to solve the patients' problems in medical record	□	□	□	□	□	□	□
94. reinforce patient counseling	□	□	□	□	□	□	□
95. educate patient on self-management skills using asthma action plan	□	□	□	□	□	□	□
96. provide educational materials if necessary	□	□	□	□	□	□	□

Appendix 6.1: Protocol for Development and evaluation of asthma self-management intervention for use in Malaysia

(To be submitted in 25 copies for each project)

APPLICATION FORM FOR RESEARCH GRANT
INTERNATIONAL MEDICAL UNIVERSITY

I. Project Identification

A. Project Title (Please indicate the title of the project; the title should be short and concise)

Development and evaluation of asthma self-management intervention for use in Malaysia

B. Project Leader (Name& Department)

Name : **Wong Pei Se**

Title : **Lecturer**

Department/ Section : **School of Pharmacy and Health Sciences**

Date _____ Signature _____

Protected Time Required: ~~Yes~~ / No
IMU-Research Lab Bench Space Required: ~~Yes~~ / No
(If 'Yes' please fill in the Appendix 2)

C. Key words (Please provide a maximum of 5 key words that describe the research of the project. The key words will be incorporated in a database on Malaysian research)

Asthma education, self-management

II. Objectives of the Project and Hypothesis

A1. Specific objective of the project (Please describe the measurable objectives of the project and define the expected results. Use results-oriented wording with verbs such as "to define..." "To determine..." "To identify...")

1. To evaluate the level of success of implementation of clinician's action points for patient self-management and patient's self-management level.
2. To evaluate the effect of self-management on clinical outcomes: - asthma control test score, number of hospital admission and unscheduled doctor visit due to asthma attack.
3. To make recommendations for the delivery of patient educational programme include self-management training in Malaysia.

A2. Research hypothesis of project

Self-management intervention by pharmacist will improve patients' self-management level.

B. Research background of the project (Please indicate if the project is new, modified or extended. Give a summary of your literature review to indicate the originality of the proposed research, and describe related research to assist in assessing the research rationale and the potential for success)

- Project status (please indicate) [√] New [ ] Modification to previous project [ ] Extension of existing project

- Literature review summary

Self-management education has been shown to reduce hospital admission, emergency room visit, and unscheduled visit to doctor.[1] There is however evidences of under use of self-management as part of asthma care in many countries include Malaysia.[2] Some of the possible reasons leading to under use of self-management are lack of awareness of self-management, perceived lack of time and lack of confidence among practitioners and patients. Nevertheless, self-management is an important component of asthma care to equip patients with the ability to monitor their asthma control and adjust medication according to the severity of condition which in turn brings a sense of partnership in managing of their condition. **The aim of this study is to develop and inform ways of extending patient self-management through educational intervention.**

1. Self-management education and regular practitioner review for adults with asthma. Cochrane Database of Systematic Reviews 2002, Issue 1. Art. No.: CD001117. DOI: 10.1002/14651858.CD001117
2. Canonica GW, Baena-Cagnani CE, Blaiss MS, Dahl R, Kaliner MA, Valovirta E. Unmet needs in asthma: Global Asthma Physician and Patient (GAPP) Survey: global adult findings. Allergy 2007; 62(6) :668-674

- Related research

- Van der Palen J, Klein JJ, Rovers MM. Compliance with inhaled medication and self-treatment guidelines following a self-management programme in adult asthmatics. European Respiratory Journal 1997; 10: 652–657
- Klein JJ, Van der Palen J, Uil SM, Zielhuis GA, Seydel ER, Van Herwaarden CLA. Benefit from the inclusion of self-treatment guidelines to a self-management programme for adults with asthma. European Respiratory Journal 2001; 17: 386–394

C. Type of research (Please indicate the type of research, one only; see definition of terms in the Guidelines)

[ ] 1. Scientific research (fundamental research)

[ ] 2. Technology development (applied research)

[√] 3. Product/process development (design end engineering)

[ ] 4. Social/policy research

III. Benefits of the Project

A. Outputs expected from the project (Please refer to the list of outputs in the Guidelines and give further details)
Development of self-management training for use in Malaysia.

IV. Project Team

Name	Organisation/Dept/Section
Project Leader (Please provide name) Wong Pei Se	School of Pharmacy and Health Sciences , IMU
Researchers (Please provide names or numbers of researchers) Professor Dr Richard Loh Li-Cher Professor Steve Hudson Professor Dr Martyn Partridge Dato' Dr Abdul Razak B. Muttalif.	Penang Medical College, Penang University of Strathclyde, Glasgow Charing Cross Hospital, London, UK Penang General Hospital, Penang
Support Staff (Please indicate how many)	
Contract Staff (Please indicate how many)	

VI. Research Approach

A. Research methodology (Please describe the research methodology to be followed. Identify specialised equipment, facilities and infrastructure which are required for the project, and indicate which are new)

Subjects & Setting

Adult patients currently treated for asthma from medical outpatient clinic (chest clinic) in General Hospital Penang will be invited to participate in the study. The target sample size aimed is 80 patients.

The inclusion criteria are:

- Patients with confirmed diagnosis of asthma.
- Patients with stable/controlled asthma (without medication changes) for at least 3 months.
- Patients aged between 18 to 65 years old.
- Patients currently on regular preventive asthma medication e.g. inhaled corticosteroids, inhaled long acting beta-blocker or theophylline.

The exclusion criteria are:

- Asthma patients only receiving reliever and not preventive medication
- Patients with such visual or auditory impairment that normally counselling procedures would not be possible
- Patients unable to communicate in English, Malay or Chinese
- Patients with any type of mental health condition
- Patients diagnosed concomitant respiratory diseases such as chronic obstructive airway disease.
- Patients with in a severe condition in whom their doctor prefers that they not be inconvenienced e.g. cancer patients.
- Patients not agreeing to participate

Methodology

1. Based on literature review and previous work on self-management from different hospitals and organisations, two template asthma action plans (written and pictogram) were designed. The written asthma action plans were designed in two languages; English and Malay. The pictograms action plans were developed based previous work by Charing Cross Hospital, London. The action plans were reviewed by a panel, which consists of 3 respiratory consultants and 3 medical officers involved in the asthma management. Field-testing for pictorial action plan was carried out using guessability and trasnluency tests. Protocol for specific action points were discussed and agreed among the panel.

2. Eligible patients will be identified and invited to participate in the training.
3. Data collection

- Demographic data, patient's asthma status (measured PEFR, asthma control using Asthma Control Test®, number of hospitalization in the past 1 month/3 months, unscheduled visit to doctor, days off from work in the past 1 month/3 months, [using patient counseling procedure/checklist, and self-management skills will be assessed.
- At the end of interview, education and training on self-management will be provided. Written or pictorial action plan will be provided. [Patients will be asked of their preferences for the action plan].

4. Follow up assessments will be conducted at 4-month and 8 month. At each follow-up, patients will be asked assessed on success of implementation of clinician's action points for patient self-management and patient's self-management level. Evaluation of patient's asthma status will also be evaluated.

Data analysis

Percentages of patients who have managed/failed to implement the action points will be calculated. Correct responses by patients will be quantified. Incorrect responses by patients will be analysed into categories to identify any consistent misinterpretations. Number of hospital admission, unscheduled visit to doctor & day off from work prevented will also quantified..

B. Project activities (Please list and describe the main project activities, including those associated with the transfer of the research results to customers/beneficiaries. The timing and duration of these activities are to be shown in the Gantt chart in Form VI)

Recruitment of participants

1st follow up/visit

2nd follow up/visit

Data entry and analysis

Presentation/Publication

C. Key milestones (Please list and describe the principal milestones of the project. The timing of milestones is to be shown in the Gantt chart on Form VI. A key milestone is reached when a significant phase in the project is concluded, e.g. completion of test, review, commissioning of equipment, etc)

Recruitment of participants

1st follow up/visit

2nd follow up/visit

3rd follow up/visit

Data entry and analysis

D. Risks of the project (Please describe factors the that may cause delays in, or prevent implementation of, the project as proposed above; estimate the degree of risk)

Factors:

Patient willingness to participate in the study (will be reduce by detailed explanation of the nature of study and aim of study)

	Low	Medium	High
Technical risk:	√		
Timing risk:		√	
Budget risk:	√		

E. Duration **(State the planned starting date of the project and the elapsed time, in months, to complete this project; technology transfer activities should** be excluded from elapsed time)

Starting date:
February 2009

Duration/elapsed time:
12 months (Estimated to end data collection by November 2009; complete project by January 2010)

FORM VI

	2009												2010												2010	
Research Activities	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**S1**	**S2**
Recruitment of participants		—	—																							
1st follow up/visit				—	—	—	—																			
2nd follow up/visit								—	—	—	—															
Data Entry & Analysis								—	—	—	—	—	—													
Technology Transfer Activities (if applicable)																										

VII. Project Costs

A. Staff costs (Please include the yearly staff costs of the project. Numbers in parentheses refer to expense codes)

Staff Category	Total RM	Year 1	Year 2	Year 3
• Salaried personnel (11000) • Temporary and contract personnel (J 400)				
Sub-total staff costs				

B. Direct project expenses (Please include the yearly direct expenses of the project. Numbers in parentheses refer to expense codes)

Expense Category	Total RM	Year 1 2009	Year 2 2010	Year 3 200_
• Travel and transportation (J 500) • Rentals (J 600) • Research materials and supplies (J 700) Photocopying • Minor modifications and repairs (J 800) • Special services (J 900)		**6000** Return trip RM250 x 24 visits (8 visits every 3 months) **100** (200 x 0.05)	**1200** Return trip RM300 x 4 visits (4 visits for final assessments)	
Sub-total direct	**7300**	**6100**	**1200**	

C. Total cost (Please add the sub-totals of A and B)

RM 7,300

Special Equipment and Accessories (Please describe and provide justification for major purchases)

1. Description:

2. Justification:

3. Estimated Cost:

Special Equipment and Accessories (Please describe and provide justification for major purchases)

1. Description:

2. Justification:

3. Estimated Cost:

Guidelines:

Type of research

The definitions of the terms Scientific Research, Technology Development and Product/ Process Development are based on those of the OECD Frascati Manual.

5. ***Scientific research (fundamental research)*** is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.

6. ***Technology development (applied research)*** is also original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific practical aim or objective.

7. ***Product/ process development (experimental development)*** is systematic work drawing on existing knowledge gained from research and practical experience that is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed.

8. Social/ policy research: Original investigation undertaken in order to acquire new knowledge in the area of social sciences and public policy.

Outputs Expected from the Project

Project outputs reflect the direct benefits of the project. These benefits vary amongst the different types of research.

6. For ***scientific research (fundamental research)*** projects please use the following list of outputs:
   - Algorithm
   - Structure
   - Data
   - Other (please specify)

7. For t***echnology development (applied research)*** projects please use the following list of outputs:
   - Method/ technique
   - Demonstrator/ prototype
   - Other (please specify)

8. For ***product/ process development (design and engineering)*** projects please use the following list of outputs:
   - New/ improved product/ device
   - New/ improved process
   - New/ improved software
   - New/ improved material
   - New/ improved service
   - Others (please specify)

9. For ***social research*** projects please use the following list of outputs
   - Measurement
   - Policy recommendation
   - Other (please specify)

10. For ***public policy research*** projects use the following list of outputs:
   - Technical policy advice
   - Contribution of a code of practice
   - Tools to help with enforcement
   - Contribution to standards definition
   - Other (Please specify

**Guidelines for the applications of R&D Funding under IRPA RM7*

Appendix A

		Cost (RM)
	Staff Costs	
1. (11000)		
2. (J 400)		
	Travel and Transportation Claim	
1. (J 500)	Return trip from KL-Penang	**7200**
2. (J 500)		
Description of Research Materials		
3. (J 700)		
4. (J 700)		
5. (J 700)		
6. (J 700)		
7. (J 700)		
8. (J 700)		
Minor Modifications and Repairs		
9. (J 800)		
10. (J 800)		
Special Services		
11. (J 900)		
12. (J 900)		
Special Equipment and Accessories		
13. (J 1000)	Photocopying	**100**
14. (J 1000)		
	TOTAL	**7300**

INTERNATIONAL MEDICAL UNIVERSITY
MALAYSIA

STUDY INFORMATION SHEET

PROJECT TITLE:	**Development and evaluation of asthma self-management intervention for use in Malaysia**

What is the purpose of this research?

The purpose of this research is to evaluate the effectiveness of an asthma education programme which include asthma self management.

Why you are invited to this research?

You are invited because you have asthma.

What is involved in this research?

The research involves interview which takes about 20 minutes at 3 occasions (3 follow up visit). The research also involves a counseling session about your asthma, signs of asthma attack and treatment.

Is there any danger?

The research is not harmful.

How does this research help me?

The research may help you in managing your asthma and asthma attack better.

More information required?

Please contact Wong Pei Se at 012-3343502 if further information is required.

INTERNATIONAL MEDICAL UNIVERSITY
MALAYSIA

MAKLUMAT MENGENAI PENYELIDIKAN
(STUDY INFORMATION SHEET)

TAJUK PENYELIDIKAN: PERKEMBANGAN DAN PENILAIAN CARA PENGAWALAN ASMA SENDIRI UNTUK KEGUNAAN IN MALAYSIA.
(RESEARCH TITLE) **(Development and evaluation of self-managemeNT INTERVENTION for use in Malaysia)**

Apakah tujuan penyelidikan ini?

Tujuan penyelidikan ini adalah untuk menyiasat kesan satu program yang melibatkan kauseling tentang asma, tanda-tanda serangan asma and ubat.

Mengapa anda dijemput menyertai penyelidikan ini?

Anda dijemput kerana anda ada asma.

Apakah yang dilibatkan dalam penyelidikan ini?

Penyelidikan ini melibatkan soal selidik yang mengambil masa selama 20 minutes. Penyelidikan ini juga akan melibatkan kauseling tentang asma, ubat dan apa yang anda perlu buat apabila asma tidak terkawal.

Adakah penyelidikan ini bahaya?

Penyelidikan ini tidak berbahaya.

Bagaimana penyelidikan ini dapat membantu anda?

Penyelidikan ini mungkin dapat meningkatkan pengetahuan anda tentang asma anda dan juga membantu anda mengawal asma anda lebih baik.

Jika keterangan/maklumat lengkap diperlukan? Sila hubungi

Sila hubungi Wong Pei Se di 012-3343502.

INTERNATIONAL MEDICAL UNIVERSITY
MALAYSIA

WRITTEN CONSENT FORM

PROJECT TITLE: **Development and evaluation of asthma self-management intervention for use in Malaysia**

I _____ (NRIC No. _____)
(Name of Volunteer in block letters)

have read or have been verbally informed and understood all information given to me about **my** participation this study. I have been given the opportunity to discuss it and ask questions. All my questions have been answered to my satisfaction and I voluntarily **agree** to take part in this study. I understand that I will receive a copy of this signed Written Informed Consent Form.

_____ _____
Signature of Volunteer Date

I have explained the nature and purpose of the study to the Volunteer named above.

_____ _____ _____
*Signature of Principal Investigator/ Co-Investigator NRIC No Date

*Name of Principal Investigator/: _____
Co-Investigator

_____ _____ _____
Signature of Witness NRIC No Date

Name of Witness: _____

*Delete where necessary

INTERNATIONAL MEDICAL UNIVERSITY
MALAYSIA

Surat Perakuan
(Written Consent Form)

Tajuk Penyelidikan: Perkembangan dan penilaian cara pengawalan asma sendiri untuk kegunaan in Malaysia.
(Research Title) **(DEVELOPMENT AND EVALUATION OF SELF-MANAGEMENT INTERVENTION FOR USE IN MALAYSIA)**

Saya _____ (No. Kad Pengenalan _____)
(Nama Peserta, sila gunakan huruf besar)

telah membaca atau diberitahu dan memahami kesemua maklumat yang diberi berkenaan penyelidikan ini. Saya telah diberi peluang untuk membincangkan mengenai penyelidikan ini serta mengemukakan soalan. Kesemua soalan saya telah dijawab dengan memuaskan dan saya bersetuju secara sukarela menyertai projek penyelidikan ini. Saya telah difahamkan yang saya akan menerima satu salinan Surat Perakuan ini.

_____ _____
Tandatangan Peserta Tarikh

Saya telah menjelaskan keadaan dan tujuan projek penyelidikan ini kepada peserta yang bernama di atas.

_____ _____ _____
*Tandatangan Penyelidik Utama/ Penolong Penyelidik No. Kad Pengenalan Tarikh

*Nama Penyelidik Utama/: Penolong Penyelidik _____

_____ _____ _____
Tandatangan Saksi No. Kad Pengenalan Tarikh

Nama Saksi: _____

*potong yang mana tidak berkenaan

DATA COLLECTION FORM

Patient Name		
RN Number		
Contact Number		
Age	**Gender** Male / Female	**Race** Malay / Indian / Chinese / Others
Spoken Language		
Current asthma medication		**Remarks (Other medication/condition)**
History of training on asthma & medication **Training provided by**		Yes / No **Doctor/Pharmacist/Nurse/ Others_____**
Previous training on self-management **If yes, form of self-management training** **Availability of Peak Flow at home**		Yes / No Verbal / Written / Pictorial Yes / No

Details of 1st meeting	
Counseling provided	
Self-management training provided	
Action plan provided	
Type of action plan provided	Written (English) / Written (BM) / Pictorial
NOTE	

Predicted PEFR	**Predicted FEV_1**		**Predicted**	
DATE	1st assessment	2nd assessment	3rd assessment	4th assessment
Measured FEV_1				
Measured FVC				
Measured PEFR				
In the past 1 month **No of hospital admission** No of unscheduled GP visit No of days off work				
In the past 3 months **No of hospital admission** No of unscheduled GP visit No of days off work				
ACT score (max 25)				

		2nd assessment	3rd assessment	4th assessment
Have you implemented any of action according to action plan?				
Action Points				
Symptoms based Night time symptoms +/- Breathlessness	Use extra doses of reliever			
	Increase ICS dose			
	Increase ICS dose or taken prednisolone tablet + if symptoms persistent/ worsening e.g. breathless at rest or with daily activities, seek medical attention			
	Use of reliever has increased (more than 8 or less than every 4 hours), seek medical attention			
	Resume normal regimen if symptoms recovered			
PEFR based Night time symptoms +/- Breathlessness	Use extra doses of reliever			
	Measure PEFR to ensure >80%			
	Measure PEFR and if within 65-80% then Increase ICS dose or taken prednisolone tablet as appropriate			
	Increase use of reliever + measure PEFR and if 40-65%, seek medical help			
	Resume normal regimen if symptoms recovered			
Self-Management Skills Assessment				
Part 1 You woke this morning feeling perfectly well and spent the day doing your usual activities. At 7 o'clock in the evening you sit down to relax and you notice you are feeling a little wheezy and breathless. What would you do?	Take PEFR Reading (2)			
	Take extra reliever (2)			
	Repeat measure of PEFR/ check response (1)			
	Take increased dose of ICS or prednislone tablet(1)			
Part 2 Over the next half-hour the wheezing and breathlessness get worse and you find it a little difficult to walk to the kitchen for a drink. What would you do?	Take PEFR Reading (2)			
	Action Plan Take increased dose of ICS or prednislone tablet OR see doctor immediately (6)			
	Take extra beta agonist (2)			

Appendix 6.2: Pictogram Assessment Questionnaire: Guessability

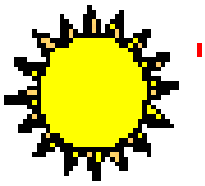
Pictogram assessment questionnaire 1 (Guessability)

Test Instructions

Please write one or two words on the line below each symbol that you feel best describes the meaning of each symbol.

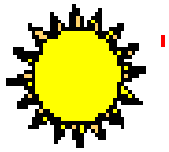
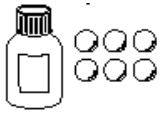
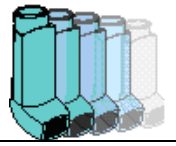
For example:

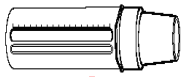
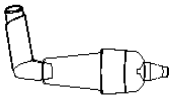
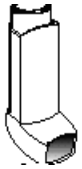
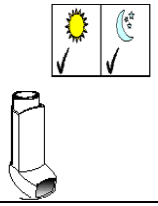
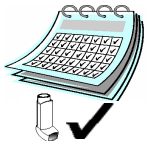
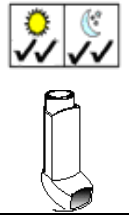
If you think this symbol represents daytime, write the word 'daytime' on the dotted line, as below:



Daytime

Do the same for all the symbols on the following pages. Try not to leave any blanks, always have a go at guessing the meaning. Do not refer back to earlier symbols once you have completed a page. At the end, please fill in the demographic detail questions. Thank you

	 999 AMBULANCE			
				
				

Demographic details

Gender:

Date:

Education level:

Realm test: (to be added in)

Current inhalers

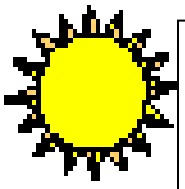
Peak flow meter used?

Appendix 6.3: Pictogram Assessment Questionnaire: Translucency

Test Instructions

You will see a series of symbols and their corresponding word meanings. Please rate how closely the symbol and its word meaning is related. A rating of 1 indicates there is no relationship between the symbol and its meaning. A rating of 7 indicates a very strong relationship. The numbers 2-6 indicate some degree of relationship between 'none' and 'very strong'. There is no correct or incorrect response.

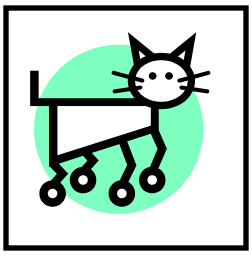
For example:



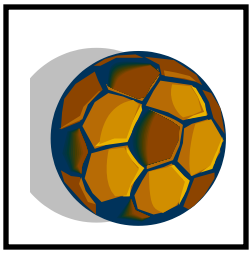
	No relationship						very strong relationship
daytime	**1**	**2**	**3**	**4**	**5**	**6**	**7**

Do the same for all the symbols on the following pages. Try not to leave any blanks, always have a go at rating your choice. Do not refer back to earlier symbols once you have completed a page. At the end, please fill in the demographic detail questions.

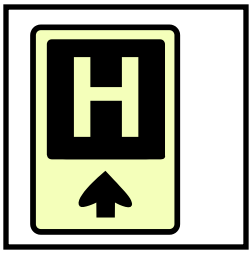
There are 6 practice symbols on the following page. Please ask any questions at this stage if you are unsure what to do. Thank you



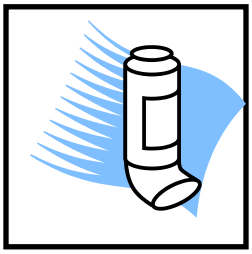
	No relationship					very strong relationship	
Cat	1	2	3	4	5	6	7



	No relationship					very strong relationship	
Football	1	2	3	4	5	6	7



	No relationship					very strong relationship	
Hospital	1	2	3	4	5	6	7

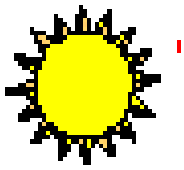


	No relationship					very strong relationship	
Inhaler	1	2	3	4	5	6	7

1

	No relationship					very strong relationship	
Nighttime	1	2	3	4	5	6	7

2



	No relationship					very strong relationship	
Day time	1	2	3	4	5	6	7

3

	No relationship					very strong relationship	
Caution	1	2	3	4	5	6	7

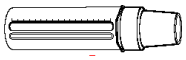
4

	No relationship					very strong relationship	
Sleeping	1	2	3	4	5	6	7

5

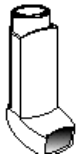
	No relationship					very strong relationship	
“Fit and well”	1	2	3	4	5	6	7

6



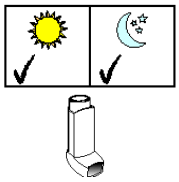
	No relationship					very strong relationship	
Peak flow meter	1	2	3	4	5	6	7

7



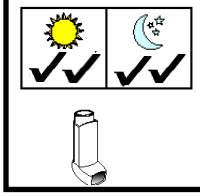
	No relationship					very strong relationship	
Inhaler	1	2	3	4	5	6	7

8



	No relationship					very strong relationship	
Take one dose of medication daytime and nighttime	1	2	3	4	5	6	7

9



	No relationship					very strong relationship	
Take two doses of medication daytime and nighttime	1	2	3	4	5	6	7

10

	No relationship					very strong relationship	
Walking	1	2	3	4	5	6	7

11

	No relationship					very strong relationship	
Breathless at night	1	2	3	4	5	6	7

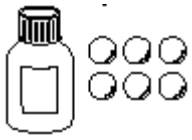
12

	No relationship					very strong relationship	
Using extra doses of your blue reliever	1	2	3	4	5	6	7

13

	No relationship					very strong relationship	
Breathless	1	2	3	4	5	6	7

14



	No relationship					very strong relationship	
Tablets	1	2	3	4	5	6	7

15

	No relationship					very strong relationship	
Telephone	1	2	3	4	5	6	7

16

	No relationship					very strong relationship	
Very breathless	1	2	3	4	5	6	7

17

	No relationship					very strong relationship	
Doctor & nurse	1	2	3	4	5	6	7

18

	No relationship					very strong relationship	
Fit and well	1	2	3	4	5	6	7

19

	No relationship					very strong relationship	
Very breathless	1	2	3	4	5	6	7

20

	No relationship					very strong relationship	
Turbohaler	1	2	3	4	5	6	7

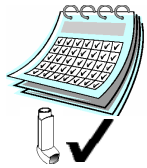
21

	No relationship					very strong relationship	
Accuhaler	1	2	3	4	5	6	7

22

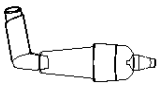
	No relationship					very strong relationship	
Everyday	1	2	3	4	5	6	7

23



	No relationship					very strong relationship	
Take inhaler everyday	1	2	3	4	5	6	7

24



	No relationship					very strong relationship	
Spacer	1	2	3	4	5	6	7

25

	No relationship					very strong relationship	
Well	1	2	3	4	5	6	7

26

	No relationship					very strong relationship	
Doctor	1	2	3	4	5	6	7

27

	No relationship					very strong relationship	
Ambulance	1	2	3	4	5	6	7

Appendix 6.4: Summary of Self-Management Steps based on Literature Search

		Self-Management Step 1	**Self-Management Step 2**	**Self-Management Step 3**
Asthma UK	*Signs and symptoms*	• no or minimal symptoms during the day or night • able to do all of your normal activities without asthma symptoms • peak flow reading at > 85% of best	• Use of reliever inhaler more than once a day • had difficulty sleeping because of your asthma • peak flow reading has fallen to (between 70% and 85%)	• take your reliever inhaler every four hours or more often • have symptoms all the time • peak flow reading is between and (50% and 75%
	Action to be taken	• Regular use of preventer & reliever if presented with asthma symptoms	• Increase of specific preventer for a period of time & continue reliever	• Take prednisolone & inform doctor
Asthma & Respiratory Foundation of New Zealand	*Signs and symptoms*	1. no asthma symptoms at most days (wheeze, tight chest, breathlessness, or a cough) 2. does not wake at night with asthma symptoms 3. able to continue with all your usual activities 4. use a reliever < 3 times per week	5. wake at night with asthma symptoms; or very breathless or wheezy; or 6. difficult to perform exercise or daily activities 7. use more reliever than usual or reliever lasts a much shorter time 8. drop of peak flow	9. have severe breathlessness; or 10. finding it hard to speak; or 11. feel faint or are frightened; or 12. reliever is not working 13. drop of peak flow

	Action to be taken	14. Regular use of preventer & reliever if presented with asthma symptoms	• Continue regular medicine • Take your reliever as required (up to a maximum of 12 puffs in 24 hours) • Initiate prednisolone if prescribed	• dial ambulance • sit upright and relax your shoulders • take 6 puffs of your emergency reliever every 6 minutes until your symptoms are relieved or the ambulance arrives • use a spacer with your metered dose inhaler if available
Asthma Society of Canada	*Signs and symptoms*	• no symptoms: • no cough, wheeze, chest tightness or shortness of breath • no coughing or wheezing when exercise or sleep • do all my usual activities • do not need to take days off work	• cough, wheeze, have chest tightness or shortness of breath during the day, when I exercise, or sleep • getting cold or the flu • use my reliever inhaler > 3 times a week for my asthma symptom	• had symptoms of Yellow Zone for 24 hours • asthma symptoms getting worse • reliever does not seem to be helping • can not do any type of activity • having trouble walking or talking • feel faint or dizzy • have blue lips or fingernails • frightened • attack came on suddenly
	Action to be taken	• Regular use of preventer & reliever if presented with asthma symptoms	• Increase regular medicine • Take your reliever as required (up to a maximum of 12 puffs in 24 hours)	• dial ambulance

		Self-Management Step 1	Self-Management Step 2	Self-Management Step 3	Self-Management Step 4
National Asthma Council Australia	*Signs and symptoms*	• no regular wheeze, or cough or chest tightness at night time, on waking or during the day • able to take part in normal physical activity without wheeze, cough or chest tightness • need reliever medication < 3 times a week (except if it is used before exercise) • drop of peak flow	• at the first sign of a cold • waking from sleep due to coughing, wheezing or chest tightness • use reliever puffer > 3 times a week (not including before exercise) 15. drop of peak flow	16. need reliever puffer every 3 hours or more often 17. increasing wheezing, coughing, chest tightness 18. difficulty with normal activity 19. waking each night and most mornings with wheezing, coughing or chest tightness 20. feel that asthma is out of control 21. drop of peak flow	22. extreme difficulty breathing 23. little or no improvement from reliever 24. lips turn blue Also for below: • symptoms getting worse quickly • severe shortness of breath or difficulty in speaking • feel frightened or panicked • low peak flow
	Action to be taken	25. Regular use of preventer & reliever	• Increase of usual treatment	• Start oral prednisolone	• Call ambulance

Appendix 6.5: Examples of Asthma Action Plan

Asthma and Respiratory Foundation of New Zealand Asthma Action Plan[238]

USING A SPACER

If you use a Metered Dose Inhaler (MDI), a spacer will help get the correct dose of medication into your lungs. Ask your doctor about a spacer. If you don't already have one, you need one. Spacers increase your medication's effectiveness by up to 50%.

1 Shake the inhaler well (holding it upright).
2 Fit the inhaler into the opening at the end of the spacer.
3 Seal lips firmly around the mouthpiece.
- press the inhaler once only.

4 Take 1–6 slow breaths in and out through your mouth. Do not remove the spacer from your mouth between breaths.
- remove the spacer from your mouth.

5 Repeat steps 1–4 for further doses.

Washing your spacer

Wash your spacer once a week with warm water and dishwashing liquid. **DO NOT RINSE. DRIP DRY** to ensure that your medicine gets into your lungs and doesn't stick to the sides of the spacer.

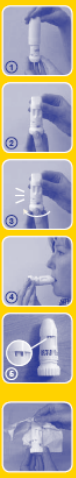
CLEANING YOUR MDI

All MDIs (Metered Dose Inhalers) need to be washed weekly. Here is how to wash and dry an MDI.

1 Remove the plastic mouthpiece cap.
2 Remove the metal canister (don't put it in water).
3 Rinse the mouthpiece and cap under warm water for at least 30 seconds.
4 Shake off any excess water and dry the mouthpiece and cap thoroughly.
5 Put the metal canister back in, and replace cap.

Check the manufacturers' instructions for any special instructions for your type of inhaler.

USING YOUR TURBUHALER



1 Unscrew and remove the protective cover.
2 Hold the Turbuhaler upright.
3 Twist the coloured grip as far as it will go in one direction and then back again until you hear a click.
- Your Turbuhaler is now loaded with a dose of medication. Breathe out gently.

4 Place the mouthpiece between your lips.
- Suck in deeply and forcefully through the Turbuhaler. You may not taste or feel the medication.
- Remove the inhaler from your mouth and breathe out. Do not breathe back into the mouthpiece as you will make it damp inside.
- If more than one dose is required, repeat the steps above.
- When you are finished, place the cover back on the inhaler and twist shut.

5 Your Turbuhaler has a dose indicator window just below the mouthpiece. When you see red in the window it is time to get a new Turbuhaler.

Caring for your Turbuhaler:

- Do not wash your Turbuhaler as it will not work properly if it gets wet.
- Wipe the mouthpiece with a dry tissue or cloth.

te hā

PHARMAC
Pharmaceutical Management Agency
supported by PHARMAC

Asthma
The Asthma and Respiratory Foundation of New Zealand (Inc.)
Te Taumatua Huanga, Mate Ha o Aotearoa

ASTHMA
Self Management Plan

This Asthma Self Management Plan belongs to:

See your doctor for an influenza vaccination every March

te hā

PHARMAC
Pharmaceutical Management Agency
supported by PHARMAC

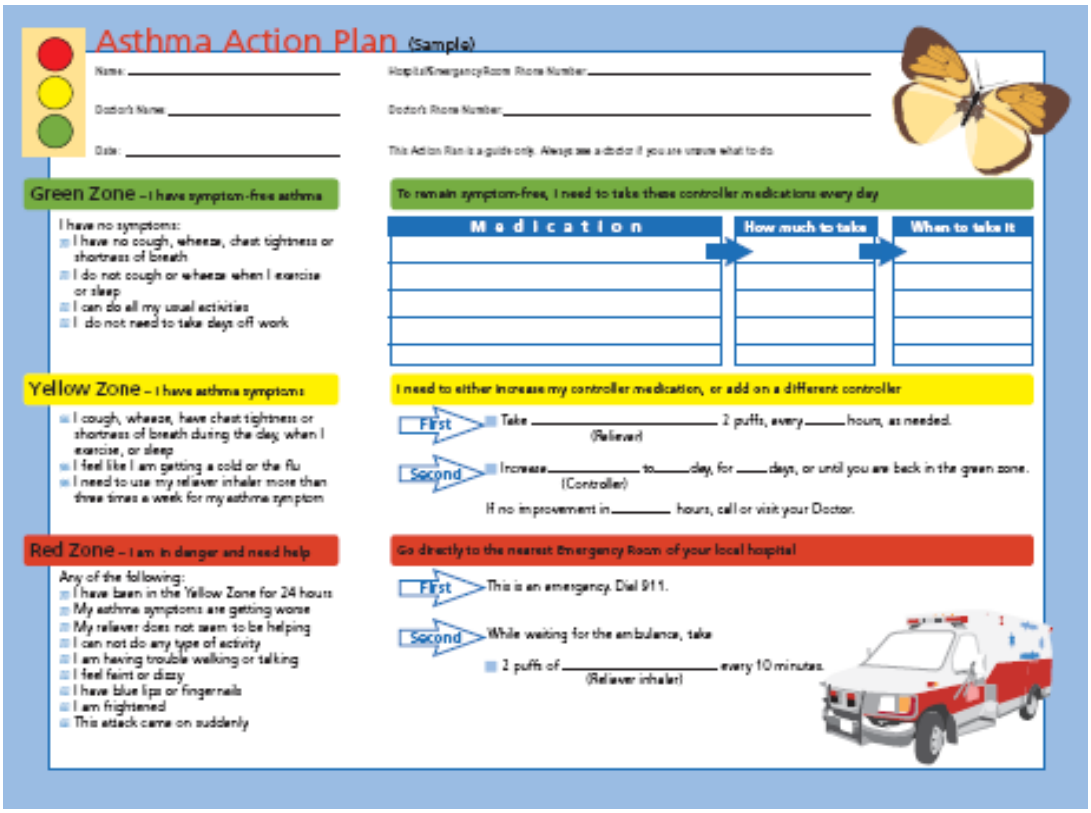
Asthma
The Asthma and Respiratory Foundation of New Zealand (Inc.)
Te Taumatua Huanga, Mate Ha o Aotearoa

www.asthmafoundation.org.nz

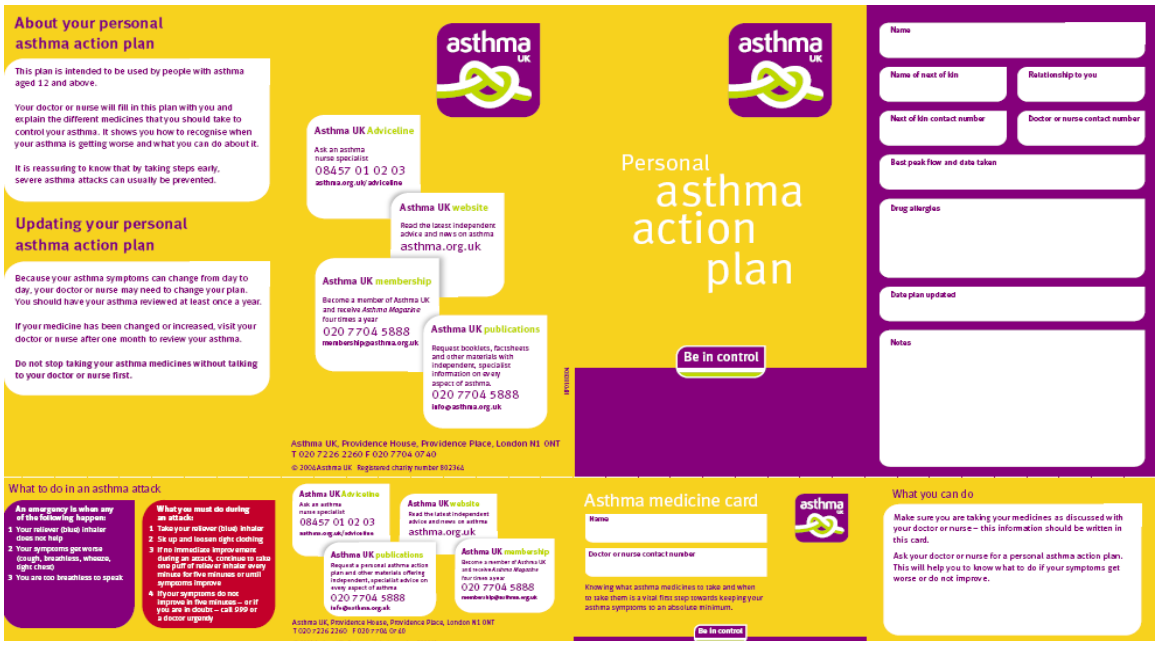
Your Asthma Self Management Plan

	ASTHMA SYMPTOMS	YOUR MEDICATION IS CRUCIAL	
FEELING GREAT	**Your asthma is under control when** • you don't have asthma symptoms most days (wheeze, tight chest, breathlessness, or a cough) • you don't wake at night with asthma symptoms • you can continue with all your usual activities • you use a reliever less than 3 times per week *your peak flow reading is above*	*Preventer* — puffs — morning and night every day *Symptom controller* — puffs — morning and night every day *Reliever* — puffs — as needed *Exercise management* — puffs — 6–10 minutes before exercise *Emergency reliever*	**MEDICATION ALERT** • if you regularly need to take more than 6 puffs of reliever every day, see your doctor as there is a risk of harmful side effects • if you regularly take more than 3 doses of reliever a week you should be taking regular preventer medication
GETTING WORSE	**Caution – your asthma is getting worse when** • you are waking at night with asthma symptoms; or • you are very breathless or wheezy; or • exercise or daily activities are becoming difficult because of asthma symptoms; or • you are using more reliever than usual; or • your reliever lasts a much shorter time *your peak flow reading is below*	**Let's keep calm, but get prepared...** • continue with your regular medication • take your reliever as required *(up to a maximum of 12 puffs in 24 hours)* • If you been prescribed prednisone begin as follows: *prednisone* — mg — for — days *and then*	**MEDICATION ALERT** • if you are not improving within 1 hour of taking your reliever or your symptoms worsen, move to the emergency zone • if you need to take more than 12 puffs of reliever in 24 hours, see your doctor today; or • if you have no prednisone see your doctor or pharmacist* today • if you are no better after 1–2 days of commencing prednisone, see your doctor • if you require 2 or more courses of prednisone see your doctor
EMERGENCY	**EMERGENCY** • you have severe breathlessness; or • you are finding it hard to speak; or • you feel faint or are frightened; or • your reliever is not working *your peak flow reading is below*	• dial 111 for an ambulance and explain you are having severe asthma • sit upright and relax your shoulders • take 6 puffs of your emergency reliever every 6 minutes until your symptoms are relieved or the ambulance arrives • use a spacer with your metered dose inhaler if available **Remember: 1 puff at a time into your spacer and 6 slow breaths in and out**	*Best peak flow:* ..... *Plan prepared by:* ..... *Date prepared:* ..... *Review date:* ..... *GP:* ..... *Doctor's signature:* .....

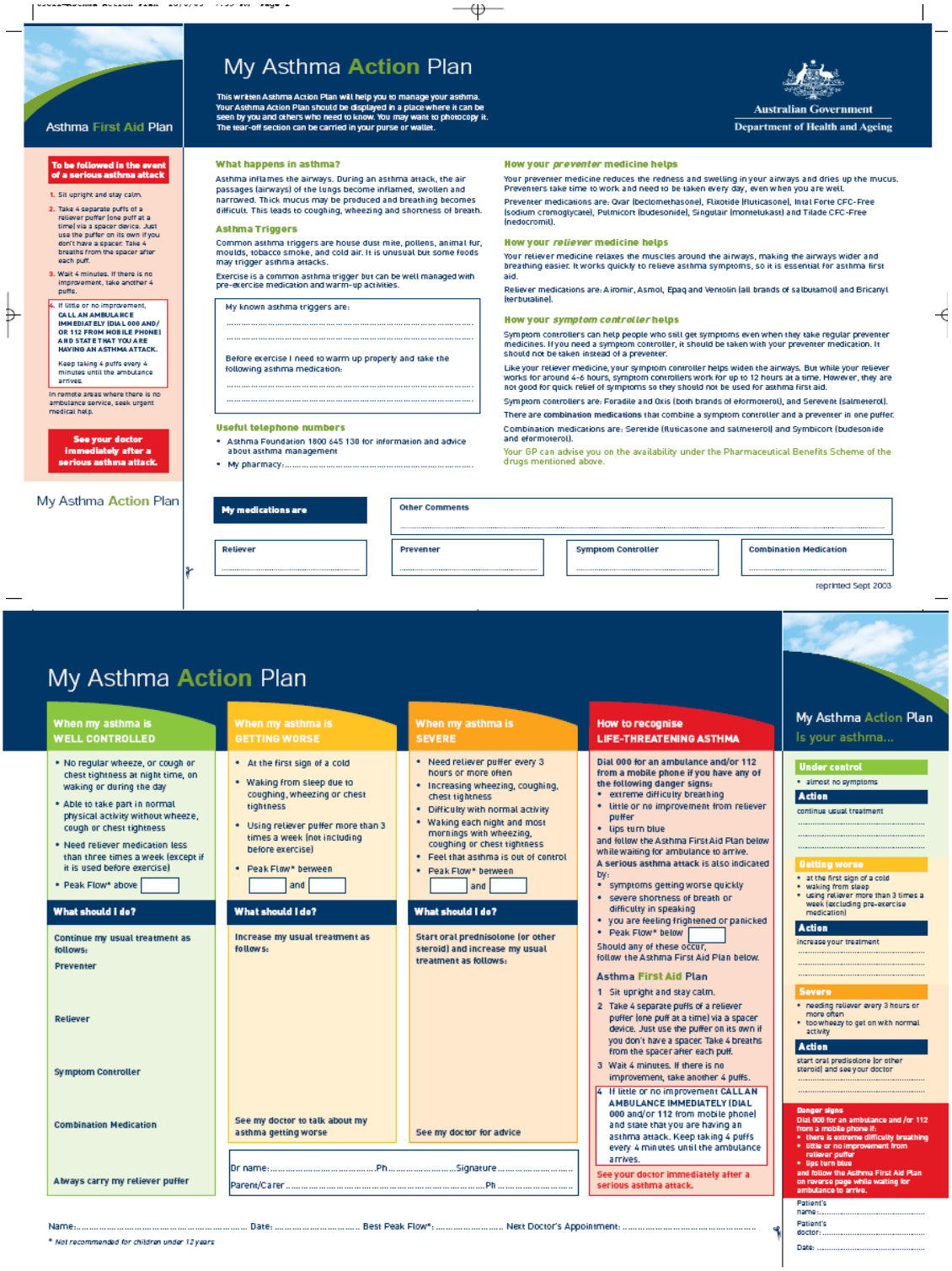
Asthma Society of Canada Asthma Action Plan[239]



Asthma UK Asthma Action Plan[240]



National Asthma Council Australia Asthma Action Plan[241]



Asthma First Aid Plan

To be followed in the event of a serious asthma attack

1. Sit upright and stay calm.
2. Take 4 separate puffs of a reliever puffer (one puff at a time) via a spacer device. Just use the puffer on its own if you don't have a spacer. Take 4 breaths from the spacer after each puff.
3. Wait 4 minutes. If there is no improvement, take another 4 puffs.
4. If little or no improvement, **CALL AN AMBULANCE IMMEDIATELY (DIAL 000 AND/OR 112 FROM MOBILE PHONE) AND STATE THAT YOU ARE HAVING AN ASTHMA ATTACK.**

   Keep taking 4 puffs every 4 minutes until the ambulance arrives.

In remote areas where there is no ambulance service, seek urgent medical help.

See your doctor immediately after a serious asthma attack.

My Asthma Action Plan

My Asthma Action Plan

This written Asthma Action Plan will help you to manage your asthma. Your Asthma Action Plan should be displayed in a place where it can be seen by you and others who need to know. You may want to photocopy it. The tear-off section can be carried in your purse or wallet.

Australian Government
Department of Health and Ageing

What happens in asthma?

Asthma inflames the airways. During an asthma attack, the air passages (airways) of the lungs become inflamed, swollen and narrowed. Thick mucus may be produced and breathing becomes difficult. This leads to coughing, wheezing and shortness of breath.

Asthma Triggers

Common asthma triggers are house dust mite, pollens, animal fur, moulds, tobacco smoke, and cold air. It is unusual but some foods may trigger asthma attacks.

Exercise is a common asthma trigger but can be well managed with pre-exercise medication and warm-up activities.

My known asthma triggers are:

.....

.....

Before exercise I need to warm up properly and take the following asthma medication:

.....

.....

Useful telephone numbers

- Asthma Foundation 1800 645 130 for information and advice about asthma management
- My pharmacy:.....

How your *preventer* medicine helps

Your preventer medicine reduces the redness and swelling in your airways and dries up the mucus. Preventers take time to work and need to be taken every day, even when you are well.

Preventer medications are: Qvar (beclomethasone), Flixotide (fluticasone), Inial Forte CFC-Free (sodium cromoglycate), Pulmicort (budesonide), Singulair (montelukast) and Tilade CFC-Free (nedocromil).

How your *reliever* medicine helps

Your reliever medicine relaxes the muscles around the airways, making the airways wider and breathing easier. It works quickly to relieve asthma symptoms, so it is essential for asthma first aid.

Reliever medications are: Airomir, Asmol, Epaq and Ventolin (all brands of salbutamol) and Bricanyl (terbutaline).

How your *symptom controller* helps

Symptom controllers can help people who still get symptoms even when they take regular preventer medicines. If you need a symptom controller, it should be taken with your preventer medication. It should not be taken instead of a preventer.

Like your reliever medicine, your symptom controller helps widen the airways. But while your reliever works for around 4-6 hours, symptom controllers work for up to 12 hours at a time. However, they are not good for quick relief of symptoms so they should not be used for asthma first aid.

Symptom controllers are: Foradile and Oxis (both brands of eformoterol), and Serevent (salmeterol).

There are **combination medications** that combine a symptom controller and a preventer in one puffer.

Combination medications are: Seretide (fluticasone and salmeterol) and Symbicort (budesonide and eformoterol).

Your GP can advise you on the availability under the Pharmaceutical Benefits Scheme of the drugs mentioned above.

My medications are

Other Comments .....

Reliever	Preventer	Symptom Controller	Combination Medication
.....	.....	.....	.....

reprinted Sept 2003

My Asthma Action Plan

When my asthma is WELL CONTROLLED	When my asthma is GETTING WORSE	When my asthma is SEVERE	How to recognise LIFE-THREATENING ASTHMA
• No regular wheeze, or cough or chest tightness at night time, on waking or during the day • Able to take part in normal physical activity without wheeze, cough or chest tightness • Need reliever medication less than three times a week (except if it is used before exercise) • Peak Flow* above [ ]	• At the first sign of a cold • Waking from sleep due to coughing, wheezing or chest tightness • Using reliever puffer more than 3 times a week (not including before exercise) • Peak Flow* between [ ] and [ ]	• Need reliever puffer every 3 hours or more often • Increasing wheezing, coughing, chest tightness • Difficulty with normal activity • Waking each night and most mornings with wheezing, coughing or chest tightness • Feel that asthma is out of control • Peak Flow* between [ ] and [ ]	Dial 000 for an ambulance and/or 112 from a mobile phone if you have any of the following danger signs: • extreme difficulty breathing • little or no improvement from reliever puffer • lips turn blue and follow the Asthma First Aid Plan below while waiting for ambulance to arrive. A serious asthma attack is also indicated by: • symptoms getting worse quickly • severe shortness of breath or difficulty in speaking • you are feeling frightened or panicked • Peak Flow* below [ ] Should any of these occur, follow the Asthma First Aid Plan below.
What should I do?	**What should I do?**	**What should I do?**	
Continue my usual treatment as follows: Preventer Reliever Symptom Controller Combination Medication Always carry my reliever puffer	Increase my usual treatment as follows: See my doctor to talk about my asthma getting worse	Start oral prednisolone (or other steroid) and increase my usual treatment as follows: See my doctor for advice	**Asthma First Aid Plan** 1 Sit upright and stay calm. 2 Take 4 separate puffs of a reliever puffer (one puff at a time) via a spacer device. Just use the puffer on its own if you don't have a spacer. Take 4 breaths from the spacer after each puff. 3 Wait 4 minutes. If there is no improvement, take another 4 puffs. 4 If little or no improvement **CALL AN AMBULANCE IMMEDIATELY (DIAL 000 and/or 112** from mobile phone) and state that you are having an asthma attack. Keep taking 4 puffs every 4 minutes until the ambulance arrives. **See your doctor immediately after a serious asthma attack.**

Dr name:.....Ph.....Signature.....

Parent/Carer.....Ph.....

Name:..... Date:..... Best Peak Flow*:..... Next Doctor's Appointment:.....

* Not recommended for children under 12 years

My Asthma Action Plan
Is your asthma...

Under control
- almost no symptoms

Action
continue usual treatment

Getting worse
- at the first sign of a cold
- waking from sleep
- using reliever more than 3 times a week (excluding pre-exercise medication)

Action
increase your treatment

Severe
- needing reliever every 3 hours or more often
- too wheezy to get on with normal activity

Action
start oral prednisolone (or other steroid) and see your doctor

Danger signs
Dial 000 for an ambulance and /or 112 from a mobile phone if:
- there is extreme difficulty breathing
- little or no improvement from reliever puffer
- lips turn blue

and follow the Asthma First Aid Plan on reverse page while waiting for ambulance to arrive.

Patient's name:.....

Patient's doctor:.....

Date:.....

Appendix 6.6: Draft 1 Asthma Self-Management Schedule (Asthma Action Plan Step-Up Plan and Peak Flow Guide for Penang General Hospital, Malaysia)

Zone	Patients' status	Action	Comment
Zone 1 (Stable Asthma)	▪ >80% best or predicted ▪ no asthma symptoms at most days (wheeze, tight chest, breathlessness, or a cough) ▪ does not wake at night with asthma symptoms ▪ able to continue with all usual activities	1. Regular use of preventer/ controller 2. Use reliever when necessary	[1] Most patients do not own a peak flow meter. Symptoms monitoring should be emphasised first.
Zone 2 (Progressive Asthma Attack)	▪ 60-80% best or predicted ▪ use more reliever than usual ▪ wake at night with asthma symptoms ▪ increasing asthma symptoms at most days	1. Take oral prednisolone or take Symbicort® when necessary (SMART approach) 2. Continue regular medication 3. Self-monitor of progress after 24 hours.	[1] Increase of ICS can be attempted for patients with low dose ICS. [2]Re-sequencing of patients' status to be consistent with Zone 1. [3] Peak flow to be arranged after symptoms based.
Zone 3 (Life-threatening Asthma Attack)	▪ <60% best or predicted ▪ persistent or worsening of asthma symptoms ▪ extreme difficulty in breathing & speaking ▪ little or no relief with use of reliever	1. Continue taking reliever as when required 2. Seek medical attention immediately [seek doctor immediately or call ambulance]	[1] Peak flow to be arranged after symptoms based. [2] Include attend emergency. [3] also include patient who used more than 8 doses of reliever a day. Include maximum dose of Symbicort a day in SMART action plan.

Appendix 6.7: Revised Self-management Schedule & Action Point for Zone 2 of Self-Management Plan

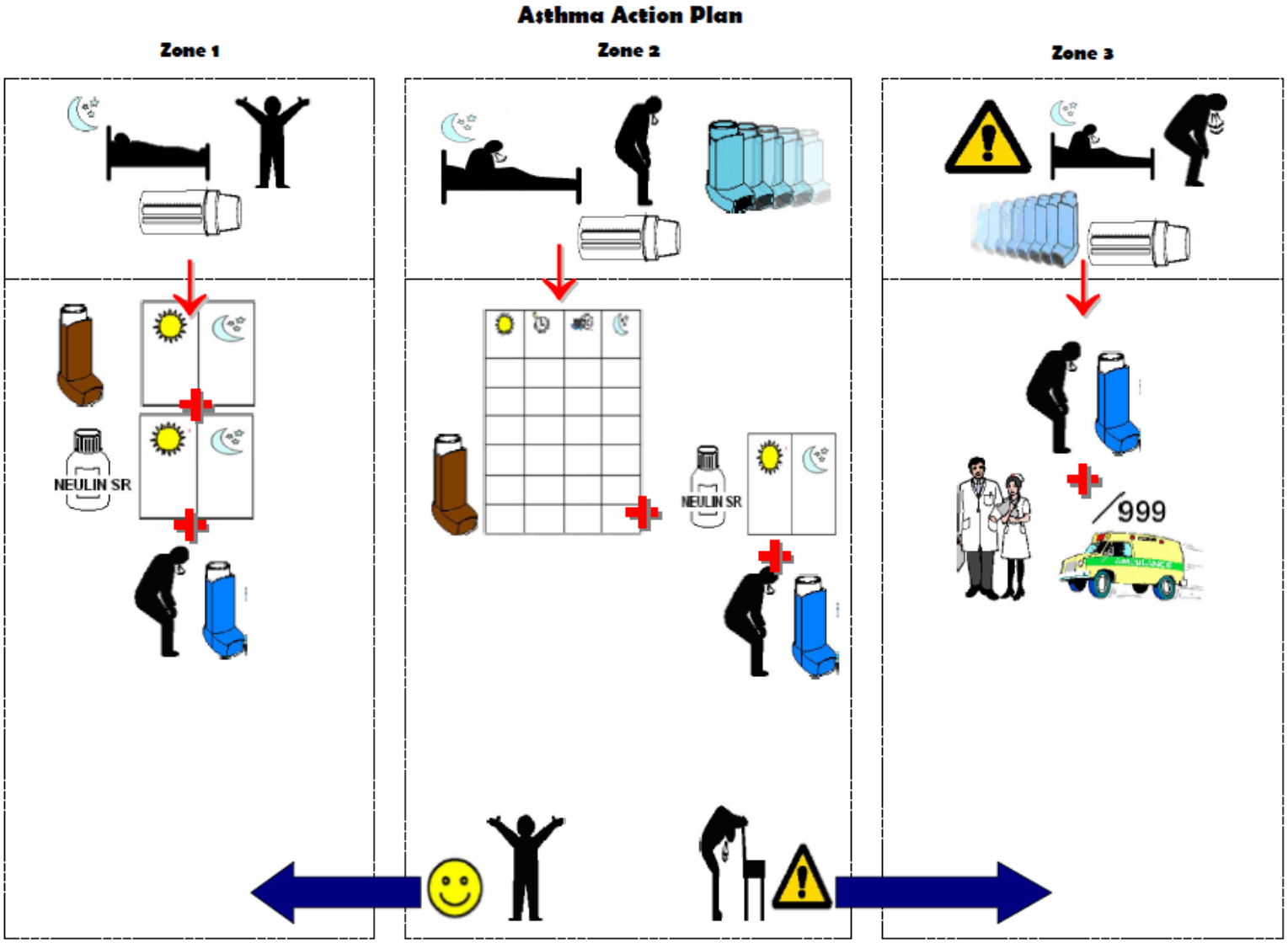
Asthma Self-Management Developed for study at Penang General Hospital, Malaysia

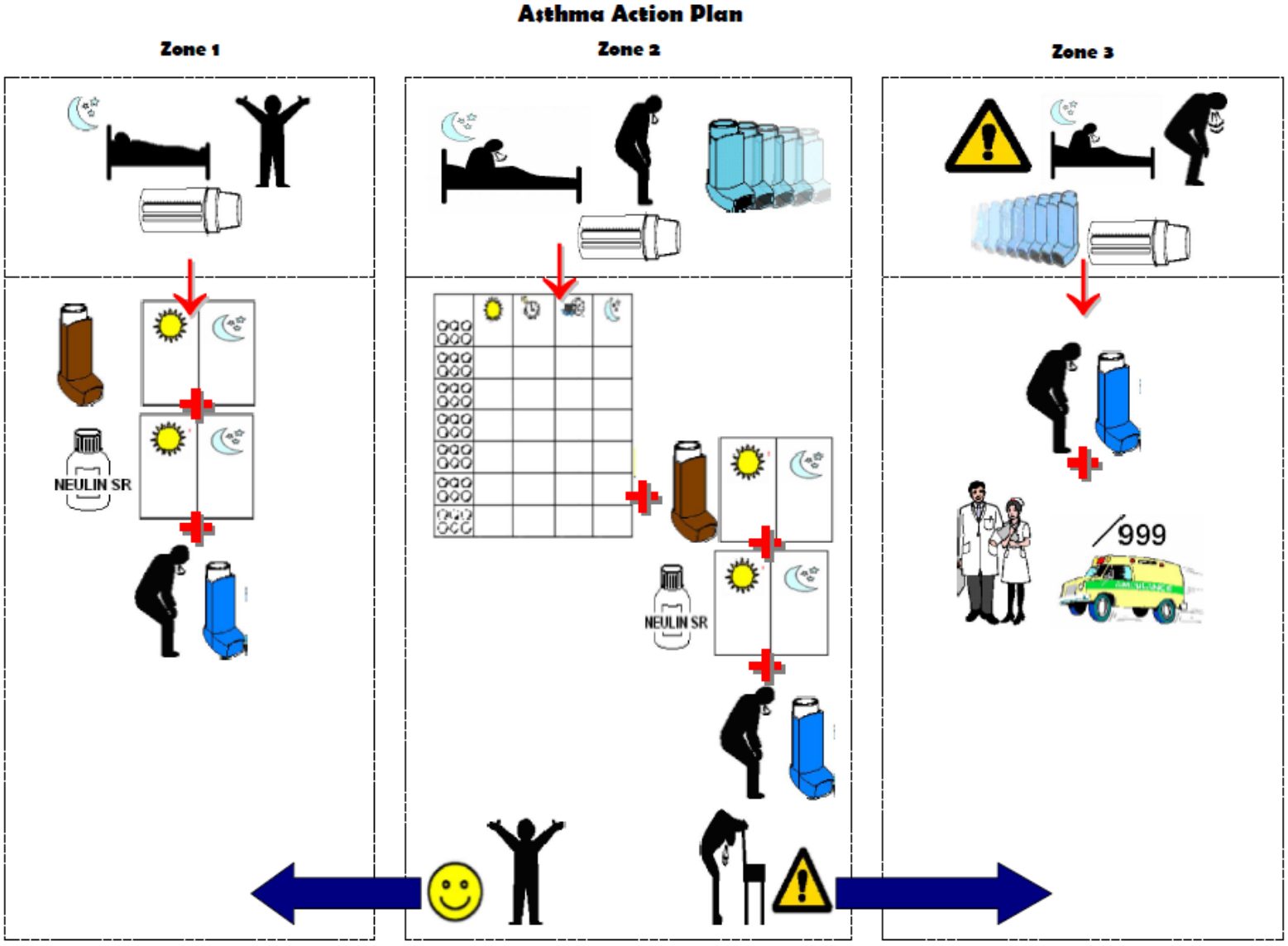
Zone	Patients' status	Action
Zone 1 (Stable Asthma)	▪ no asthma symptoms at most days (wheeze, tight chest, breathlessness, or a cough) ▪ does not wake at night with asthma symptoms ▪ able to continue with all usual activities ▪ >80% best or predicted	1. Regular use of preventer/ controller 2. Use reliever when necessary
Zone 2 (Progressive Asthma Attack)	▪ increasing asthma symptoms at most days ▪ wake at night with asthma symptoms ▪ use more reliever than usual ▪ 60-80% best or predicted	1. Increase to quadraple dose of ICS, oral prednisolone or take Symbicort® when necessary (SMART approach) 2. Continue regular medication 3. Self-monitor of progress after 24 hours.
Zone 3 (Life-threatening Asthma Attack)	▪ persistent or worsening of asthma symptoms ▪ extreme difficulty in breathing & speaking ▪ little or no relief with use of reliever ▪ use of reliever >8 doses/day ▪ <60% best or predicted	1. Continue taking reliever as when required 2. Seek medical attention immediately [seek doctor immediately or call ambulance]

Protocol for Action Point for Zone 2

	Regular ICS Daily Dose (mcg/day)	**Action Point for Zone 2 (Progressive Asthma Attack) (mcg/day)**
Beclomethasone MDI **available in 100ug/inhalation*	200	800 mcg /daily (200mcg qid) x 1/52
	400	1,600 mcg/ daily (400 mcg qid) x 1/52
	> 400	Oral Prednisolone 30mg od x 1/52
Qvar® MDI **available in 100ug/inhalation*	100	400 mcg /daily (100mcg qid) x 1/52
	200	800 mcg /daily (200mcg qid) x 1/52
	400	Oral Prednisolone 30mg od x 1/52
Budesonide **Pulmicort turbohaler available in 200ug/ inhalation, Inflammide MDI available in 100ug/inhalation*	200	800 mcg /daily (200mcg qid) x 1/52
	400	1,600 mcg/ daily (400 mcg qid) x 1/52
	>400	Oral Prednisolone 30mg od x 1/52
Symbicort Turbohaler **Available in 160mcg budesonide & 4.5 mcg formoterol/inhalation*	320 mcg/daily (1 inhalation bd)	Use as prn (max 12 doses/day – extra of 10 doses)
	640 mcg/daily (2 inhalations bd)	Use as prn (max 12 doses/day – extra of 8 doses)
Seretide Accuhaler **Available in 125mcg fluticasone & 25mcg salmeterol /inhalation*	250 mcg /daily (1 inhalation bd)	Oral Prednisolone 30mg od x 1/52
	500 mcg /daily (2 inhalations bd)	Oral Prednisolone 30mg od x 1/52

Appendix 6.8: Pictorial Action Plan for use in Asthma Self-Management Training in Malaysia


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
NEULIN SR
999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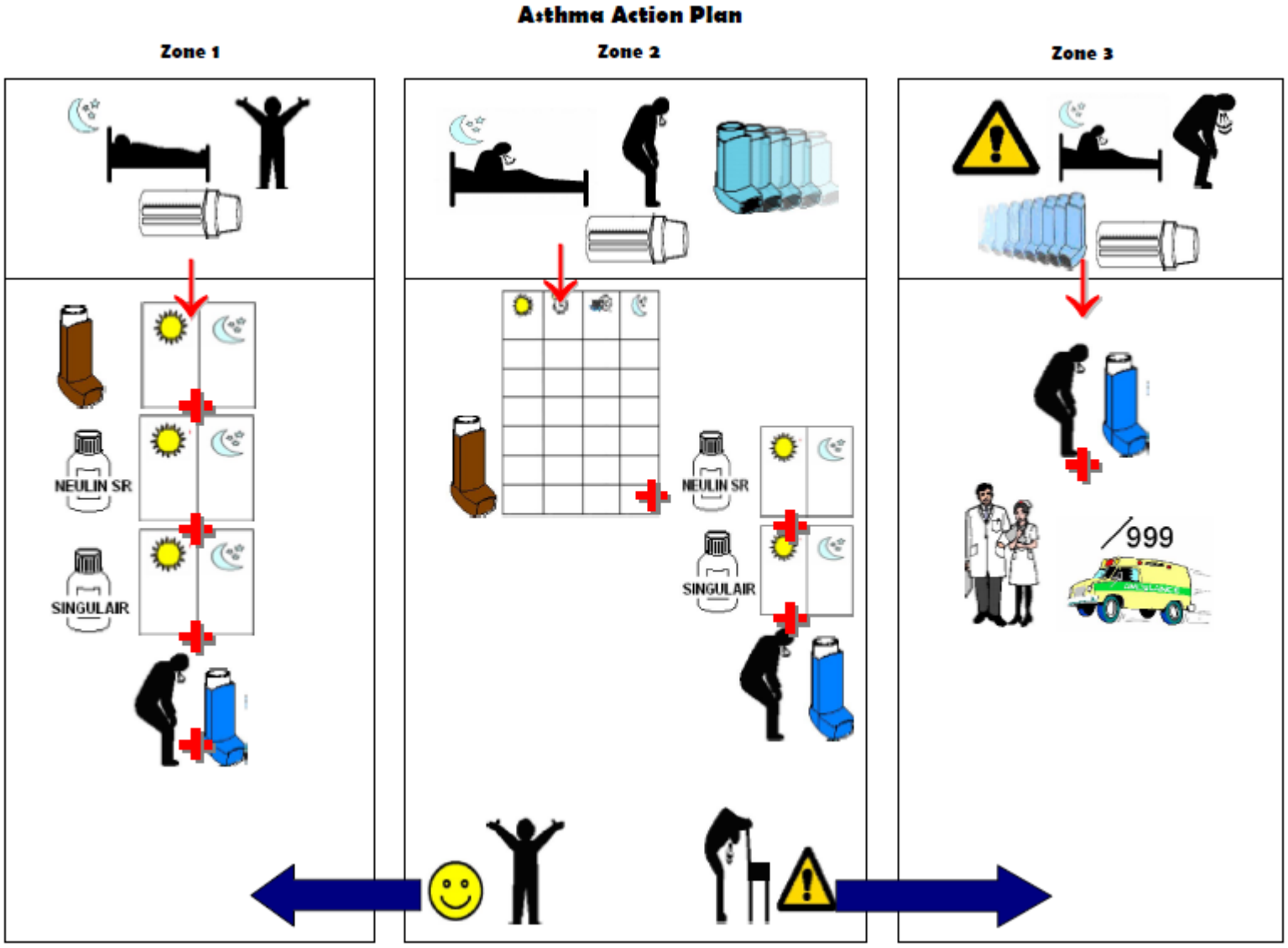
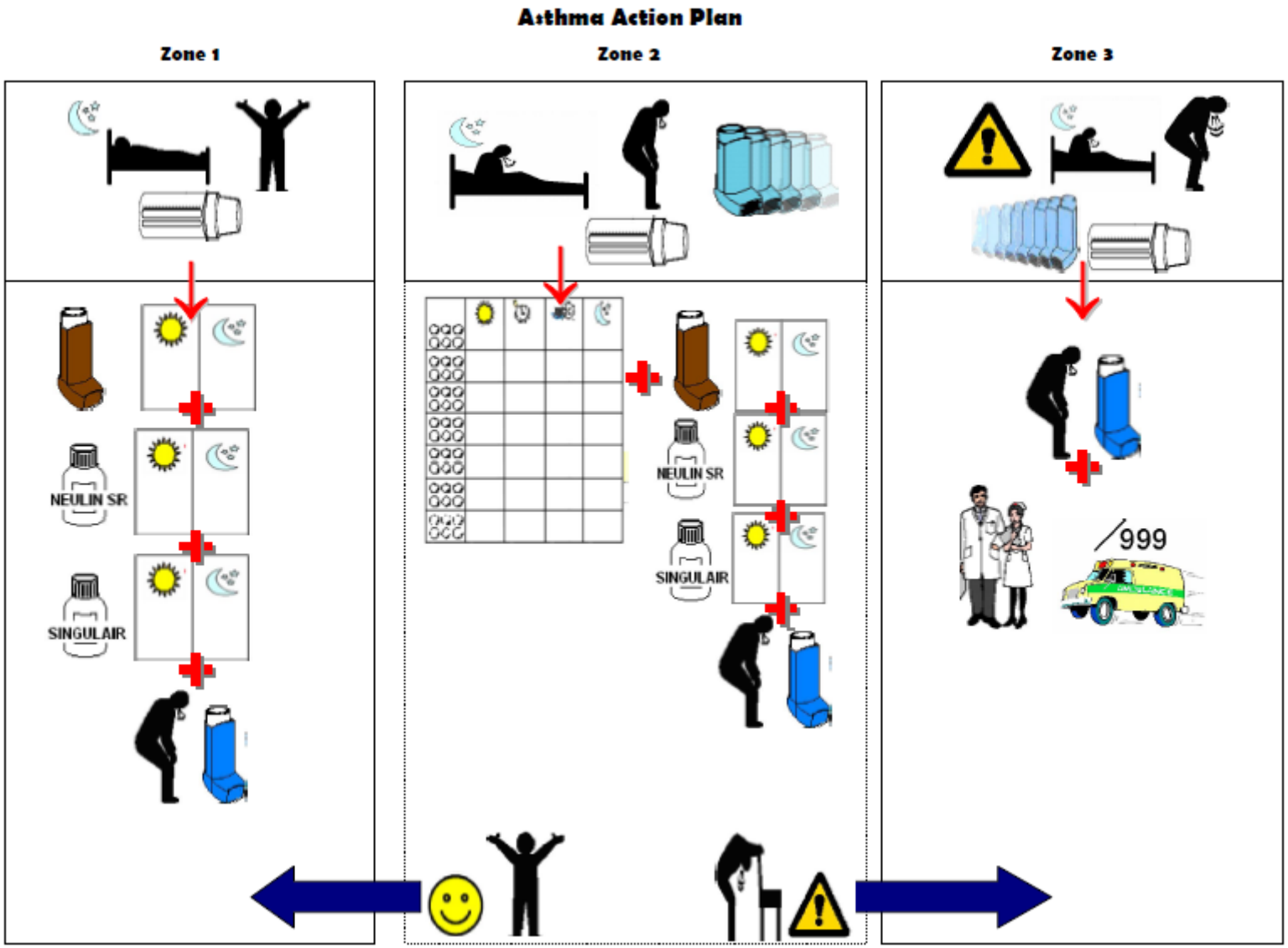
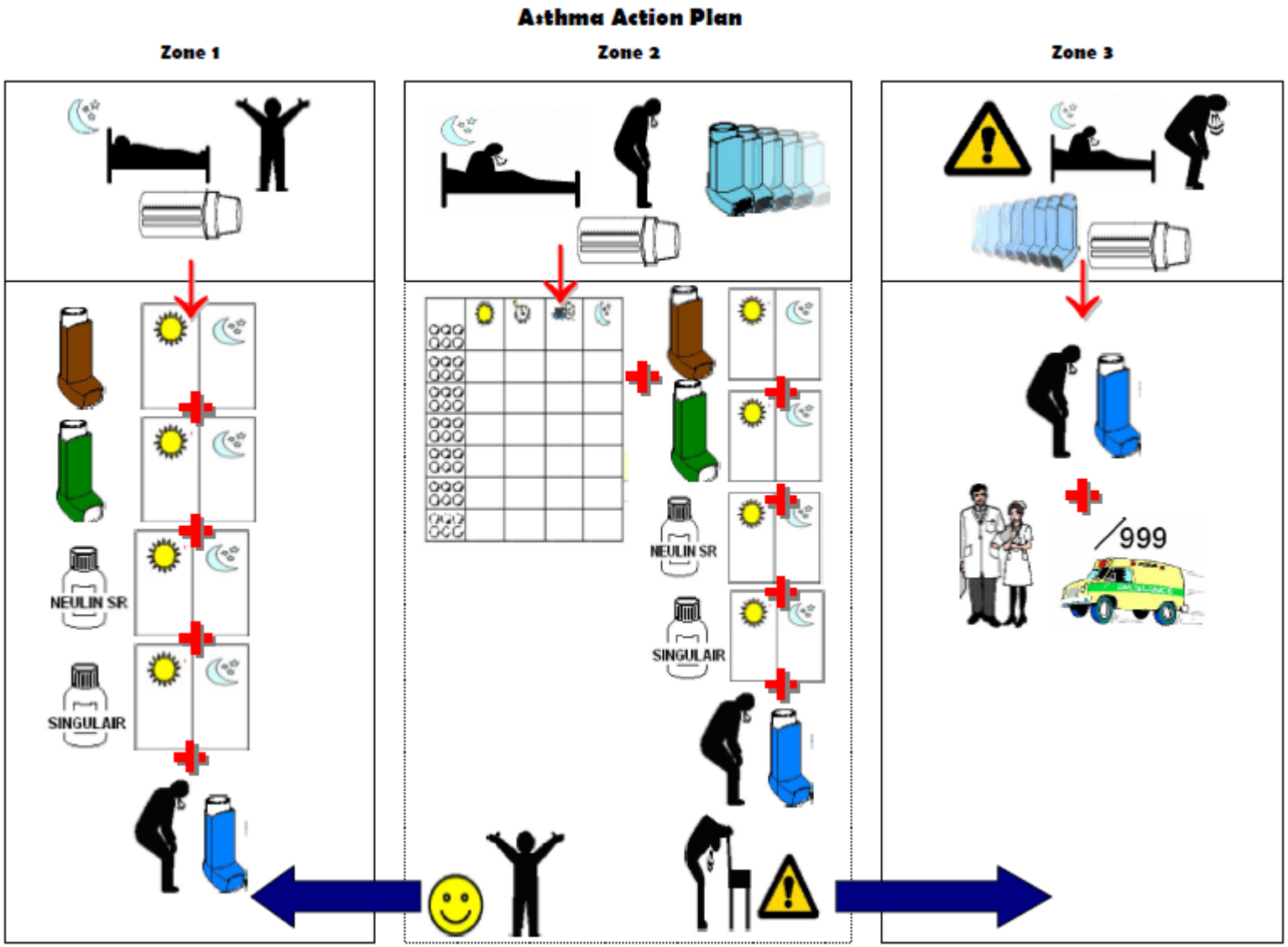
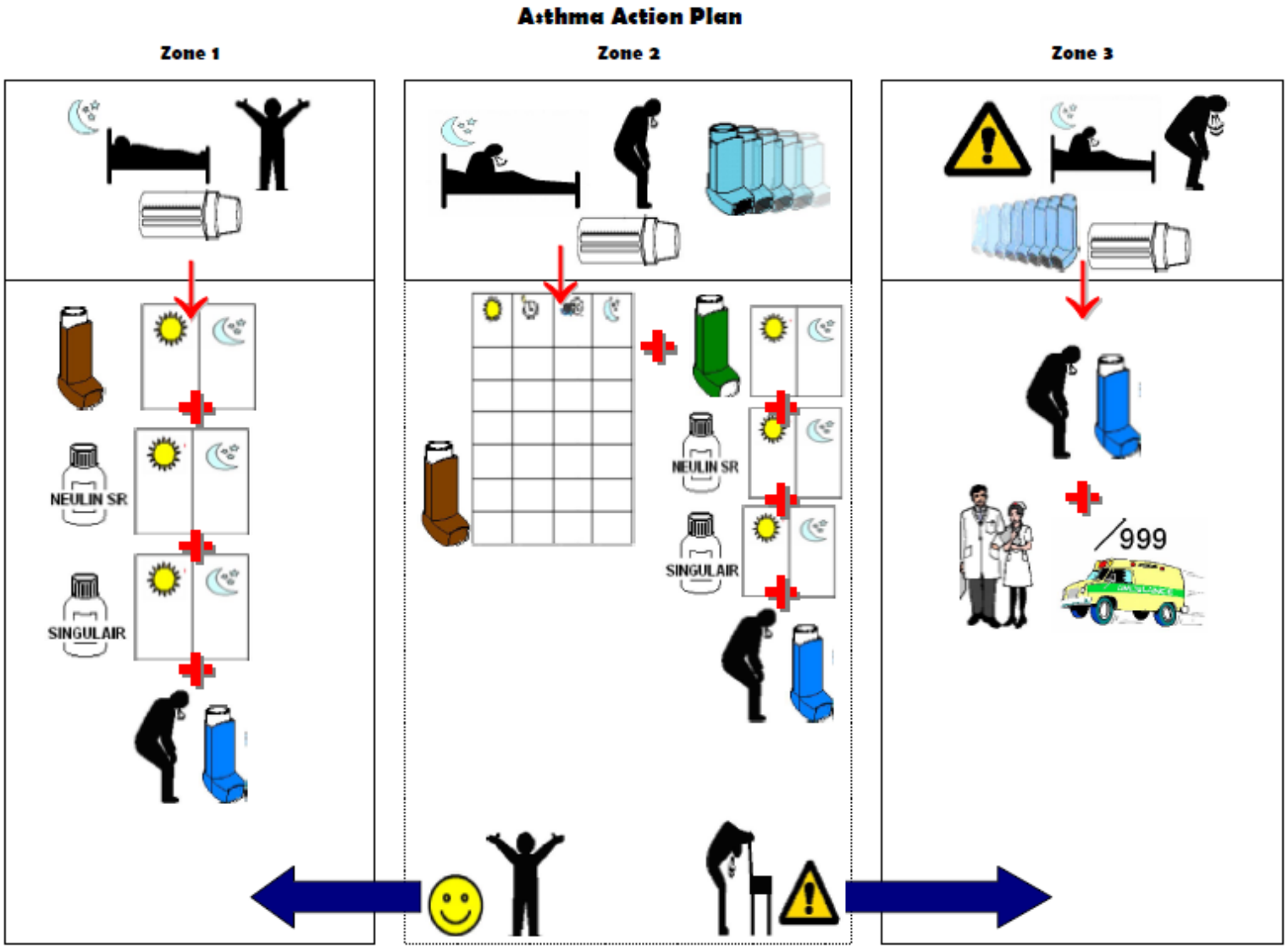
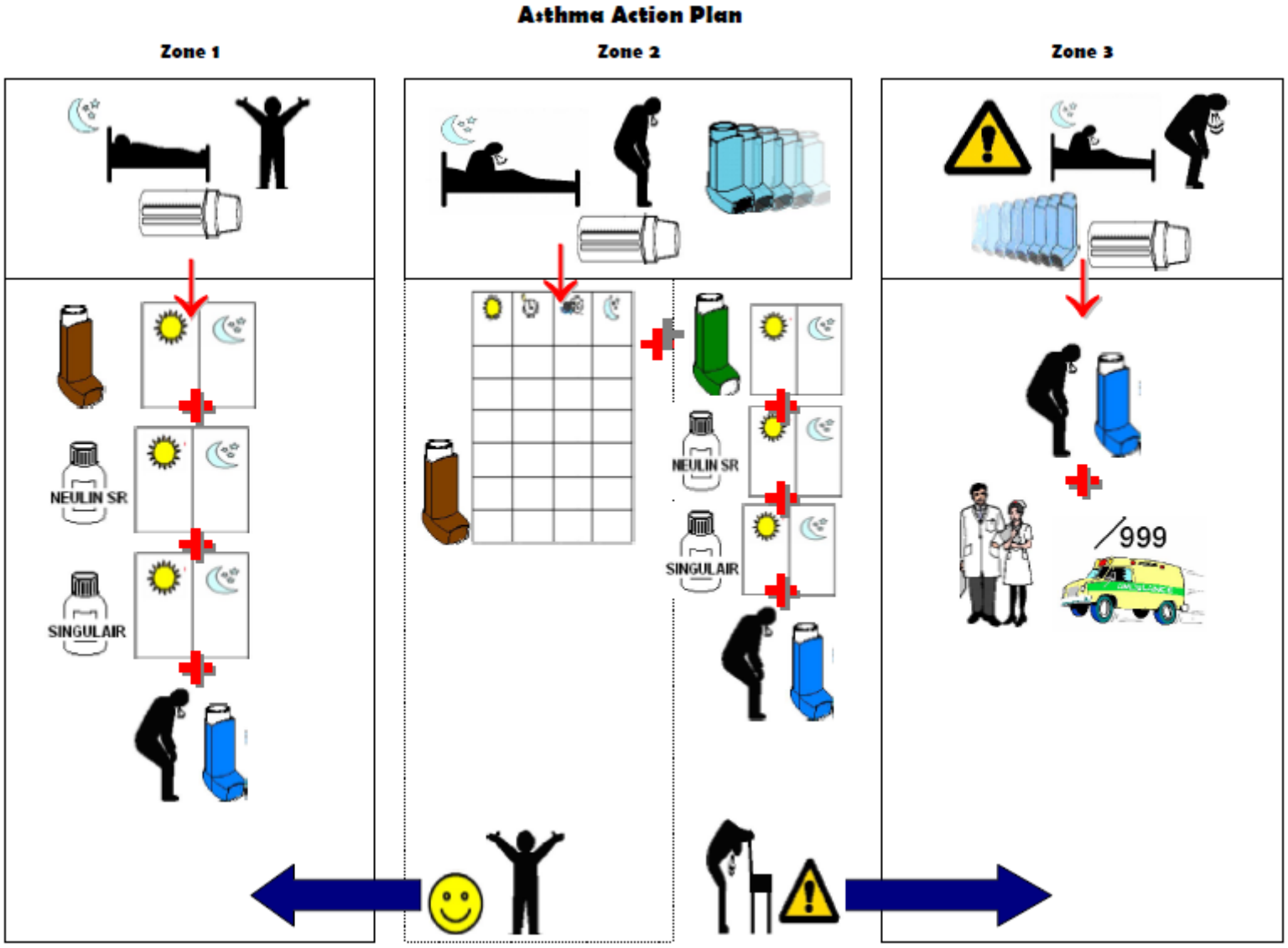
Zone 1
Zone 2
Zone 3
NEULIN SR
NEULIN SR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999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Zone 2
Zone 3
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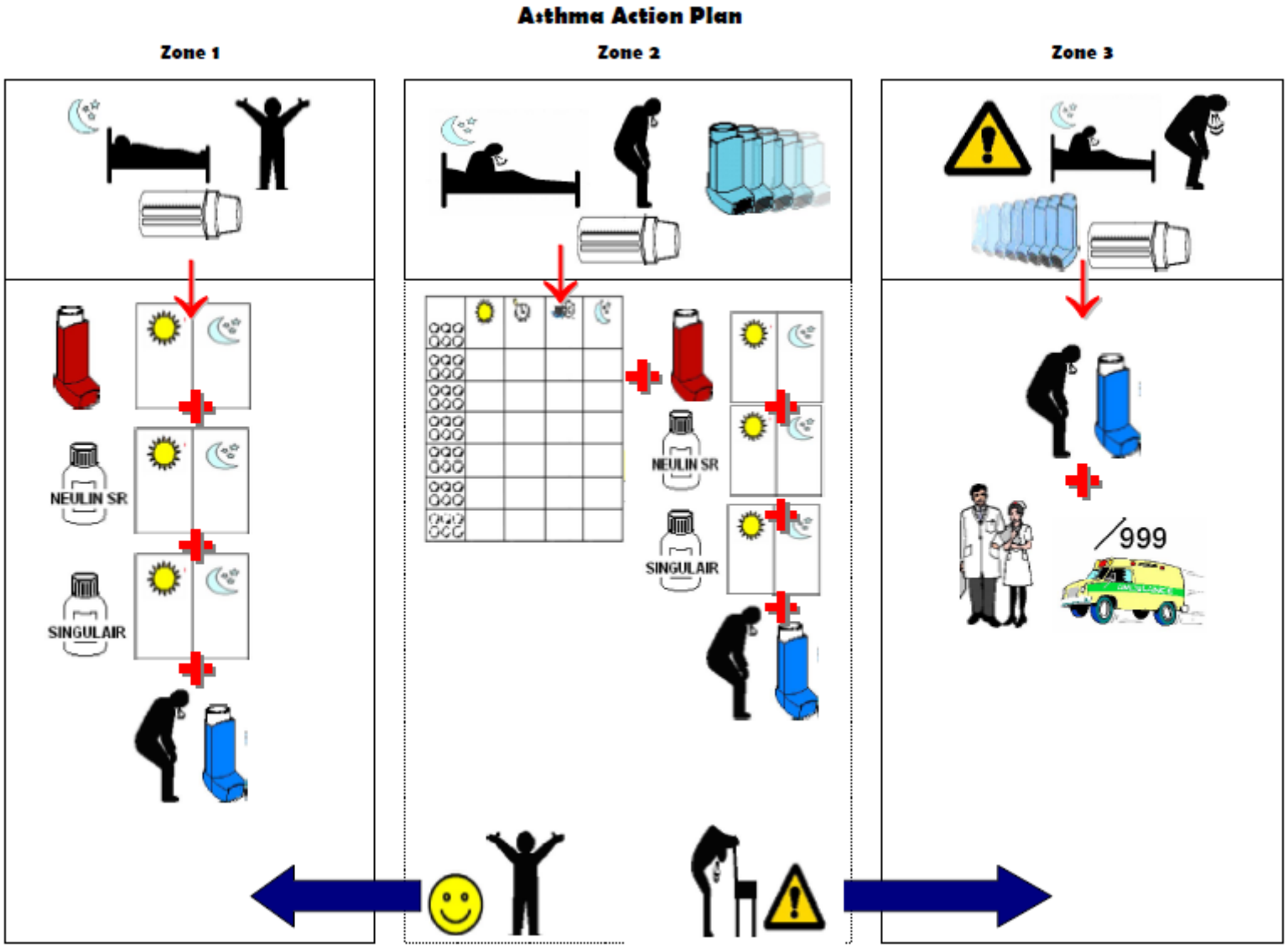
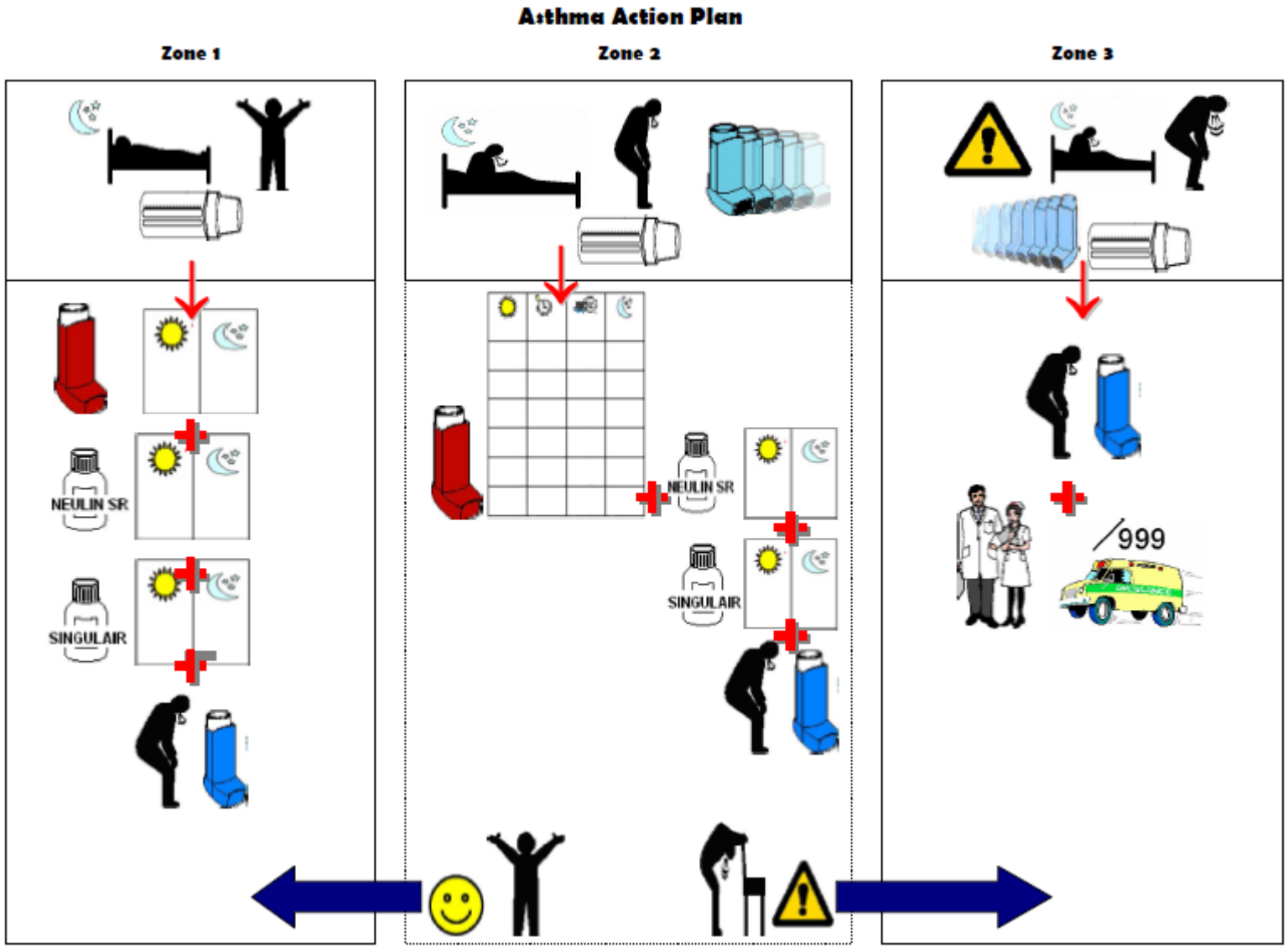
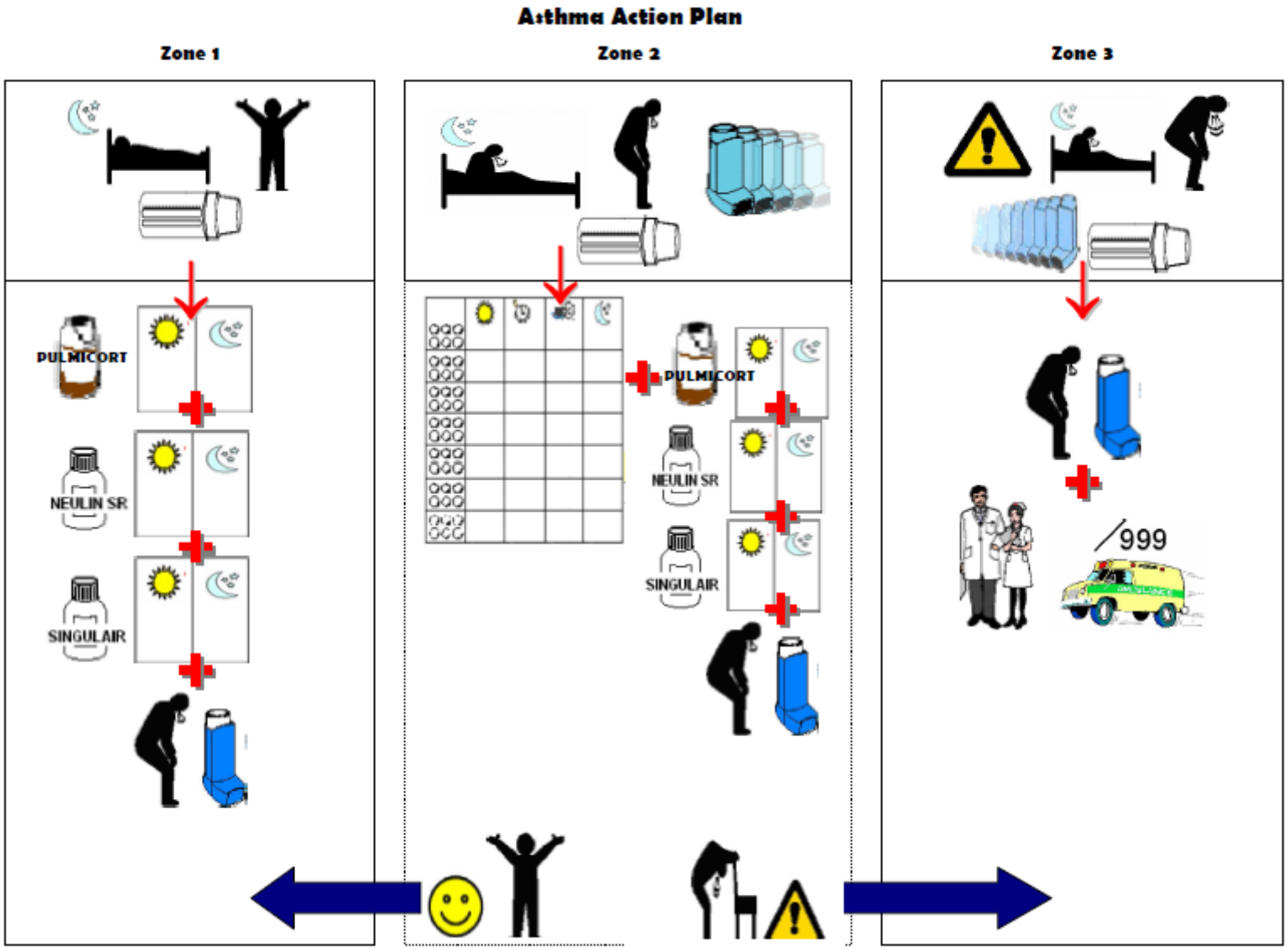
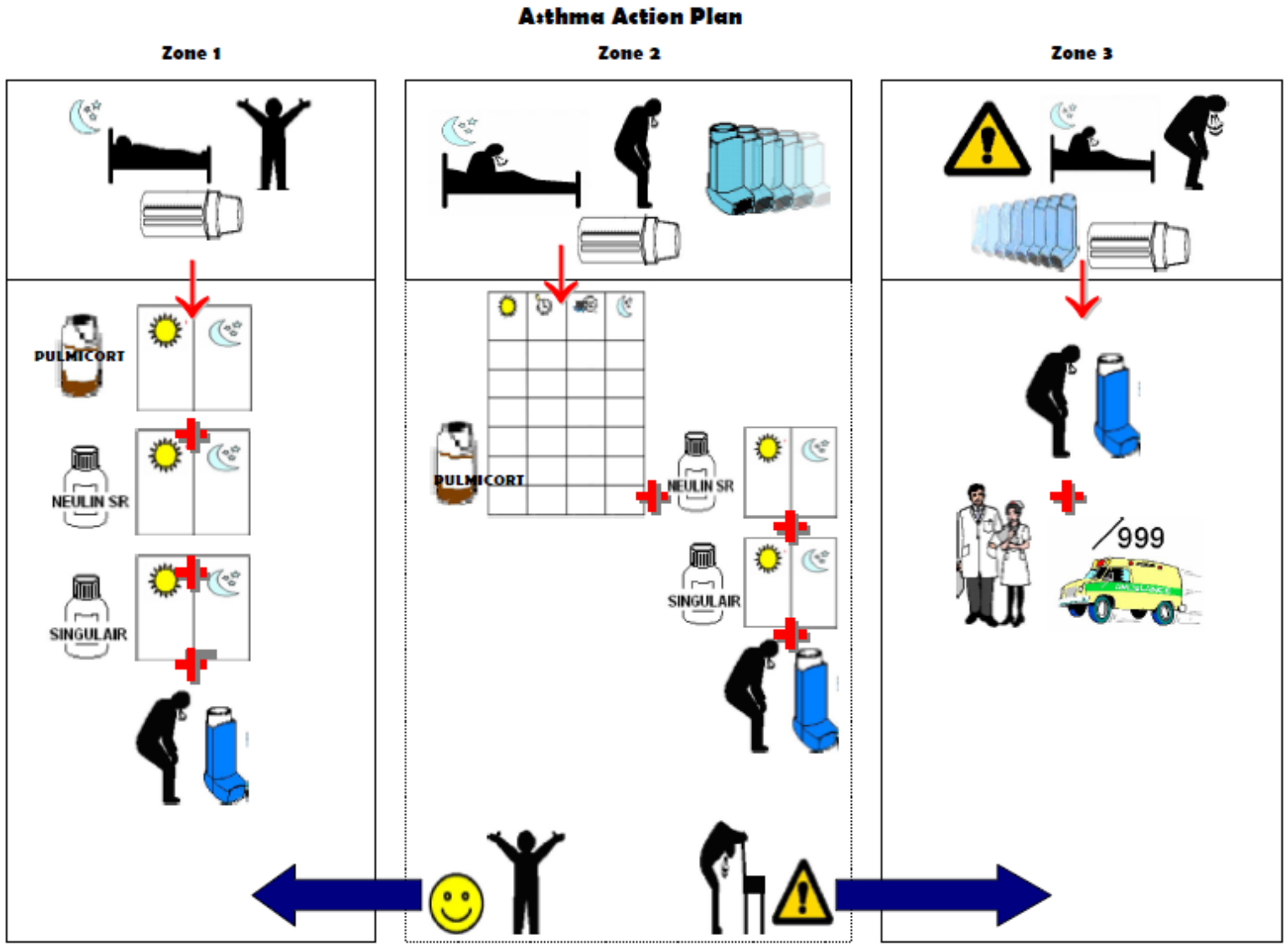
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
PULMICORT
NEULIN SR
SINGULAIR
PULMICORT
NEULIN SR
SINGULAIR
999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Zone 2
Zone 3
PULMICORT
NEULIN SR
SINGULAIR
PULMICORT
NEULIN SR
SINGULAIR
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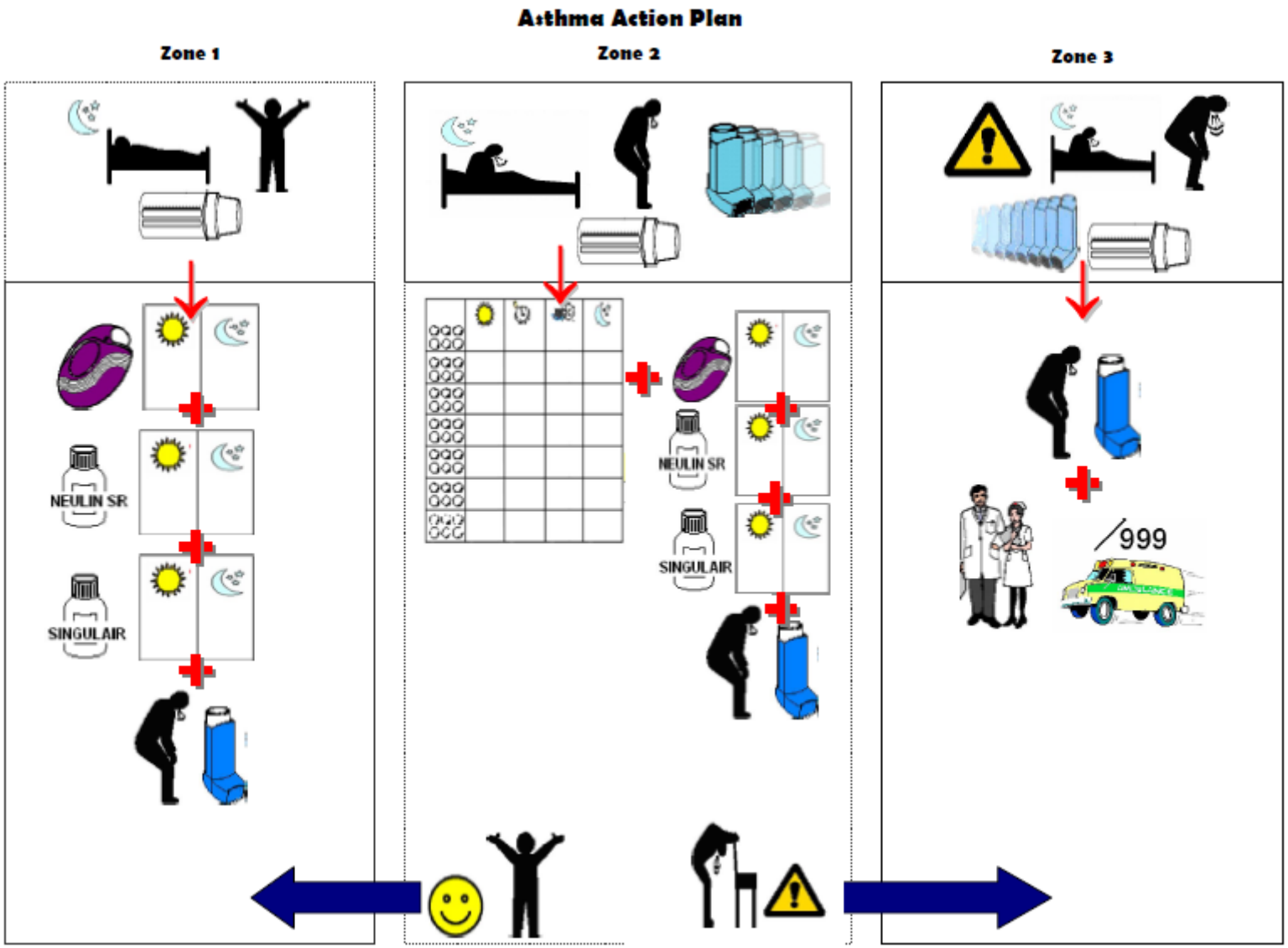
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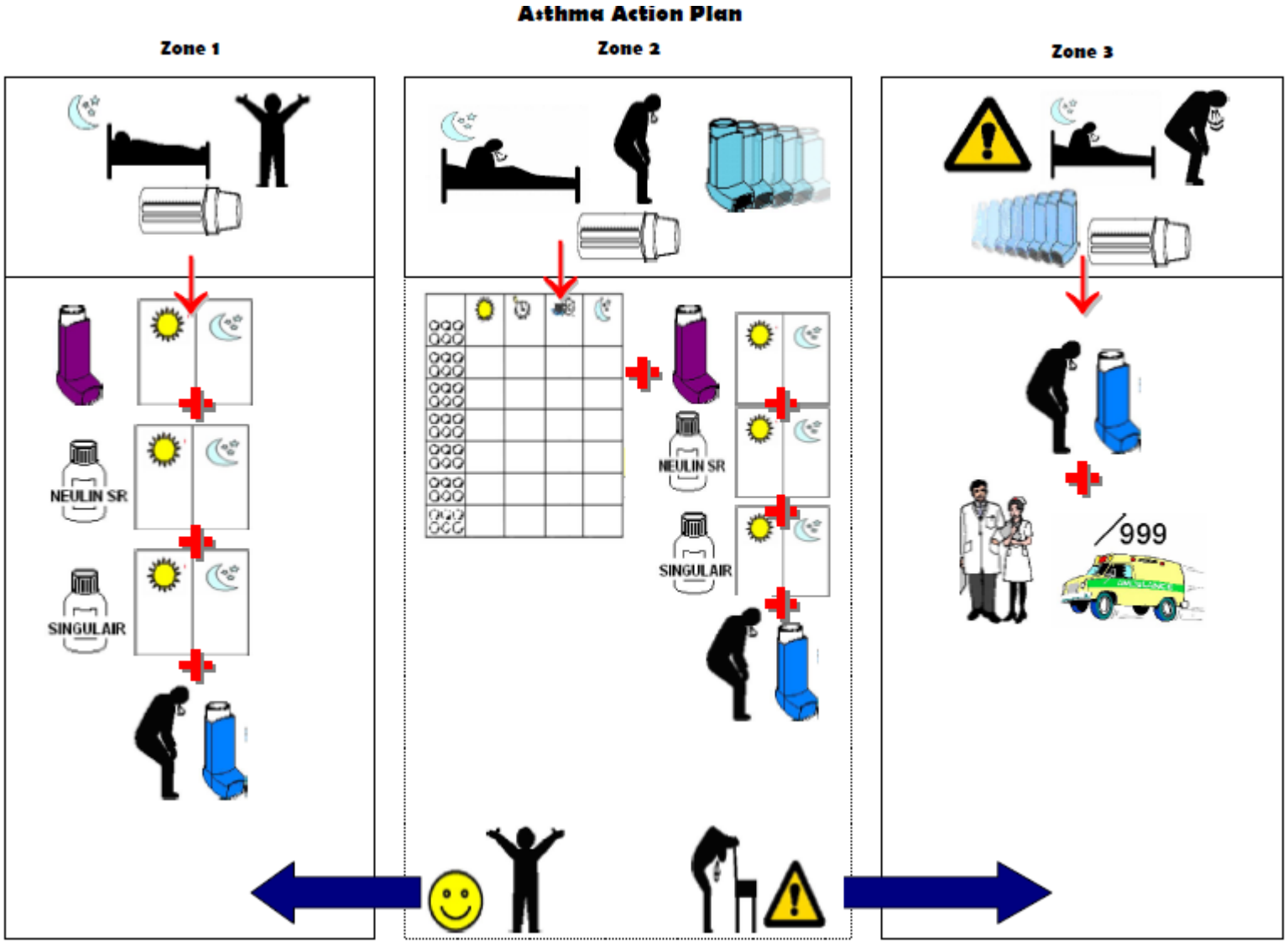
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999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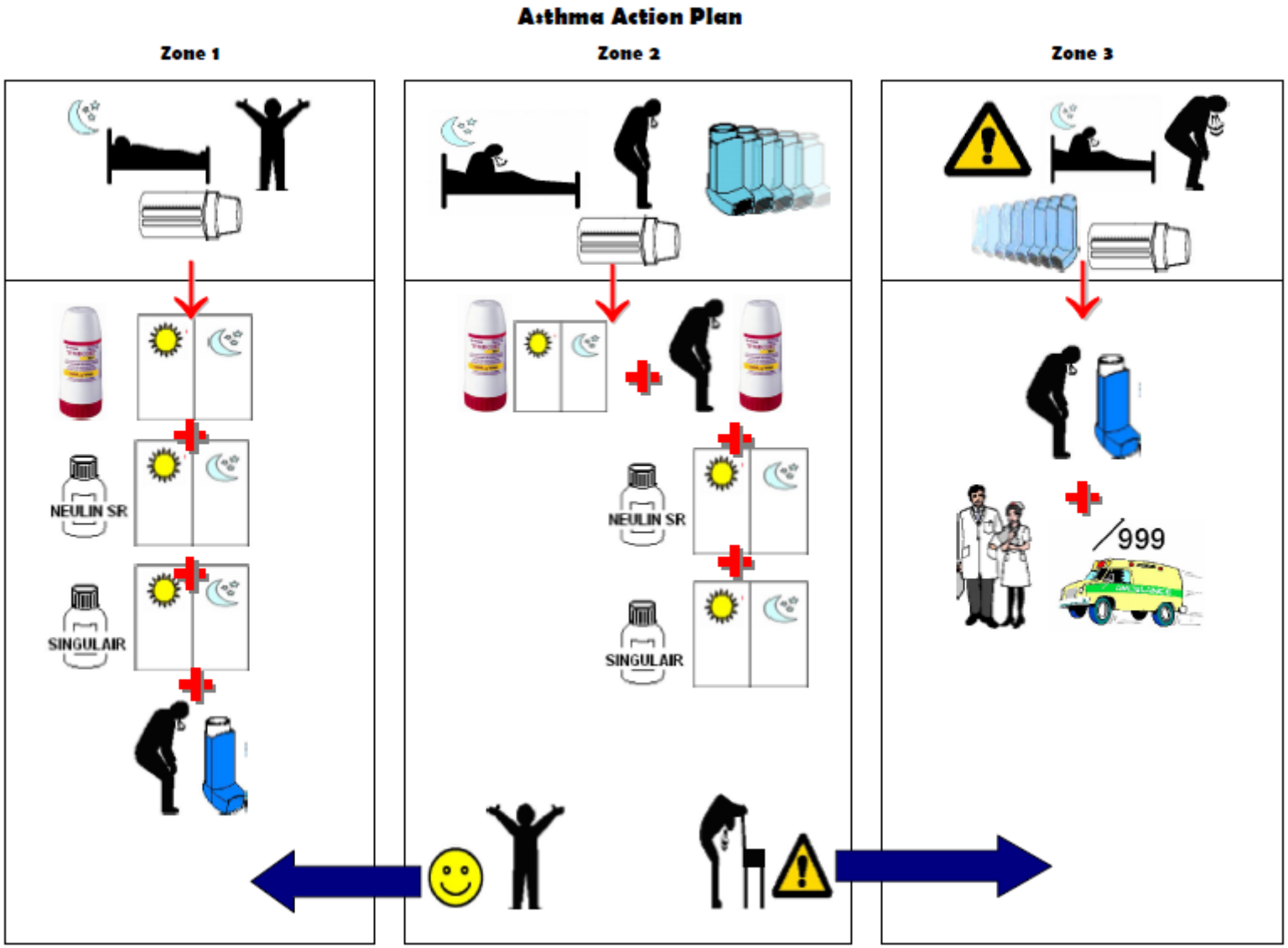
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999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Zone 2
Zone 3
NEULIN SR
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NEULIN SR
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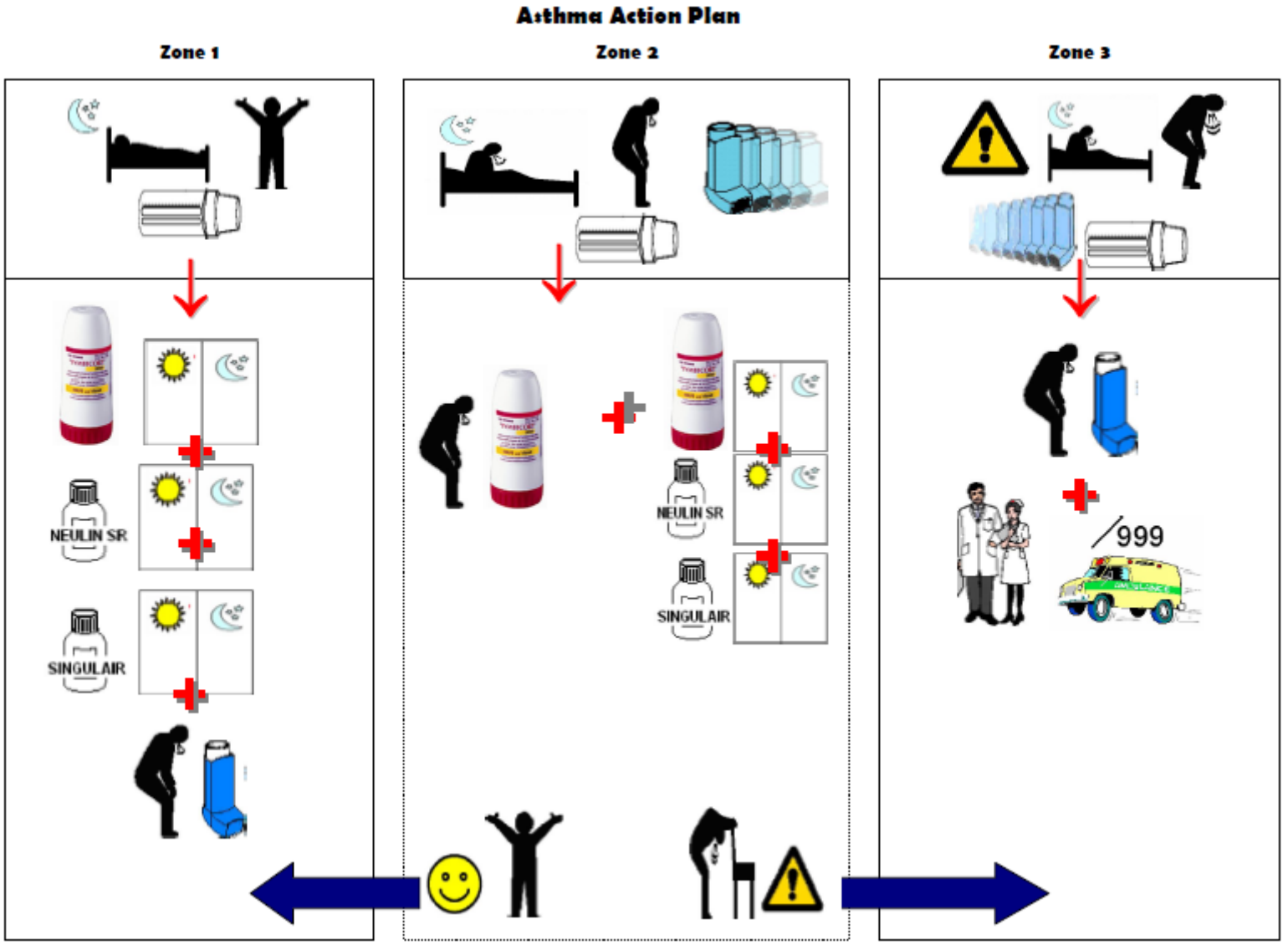
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Zone 3
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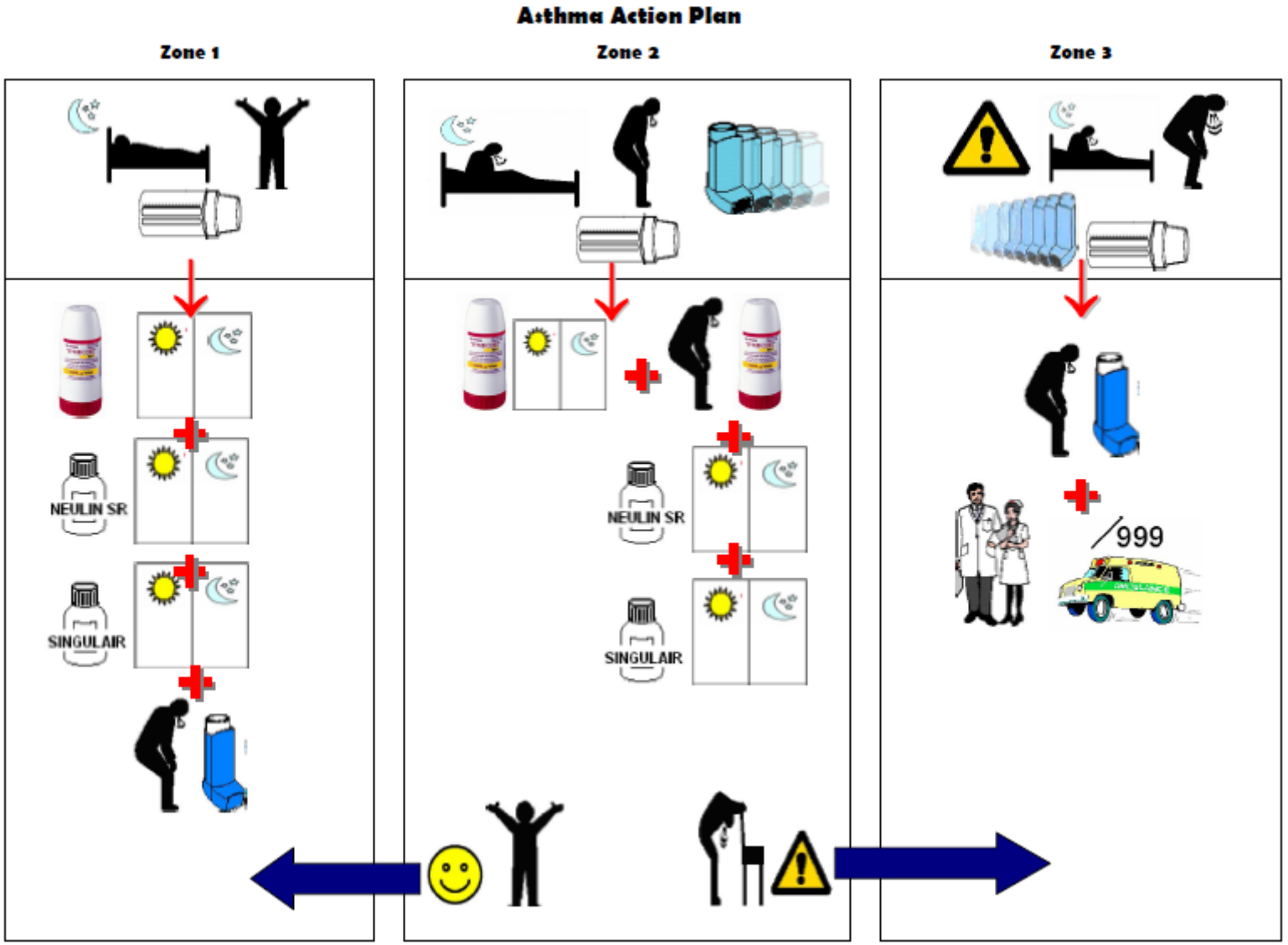
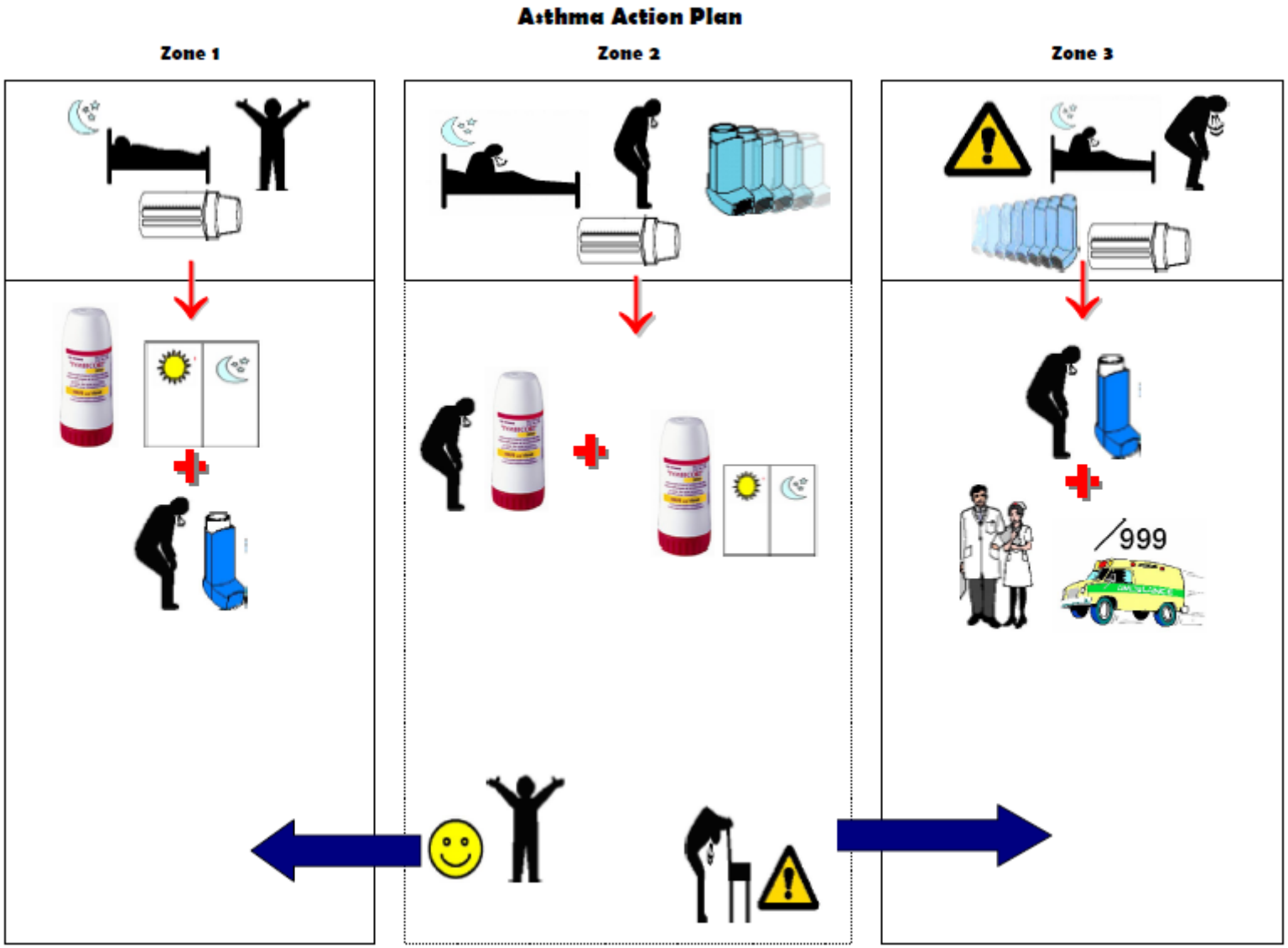
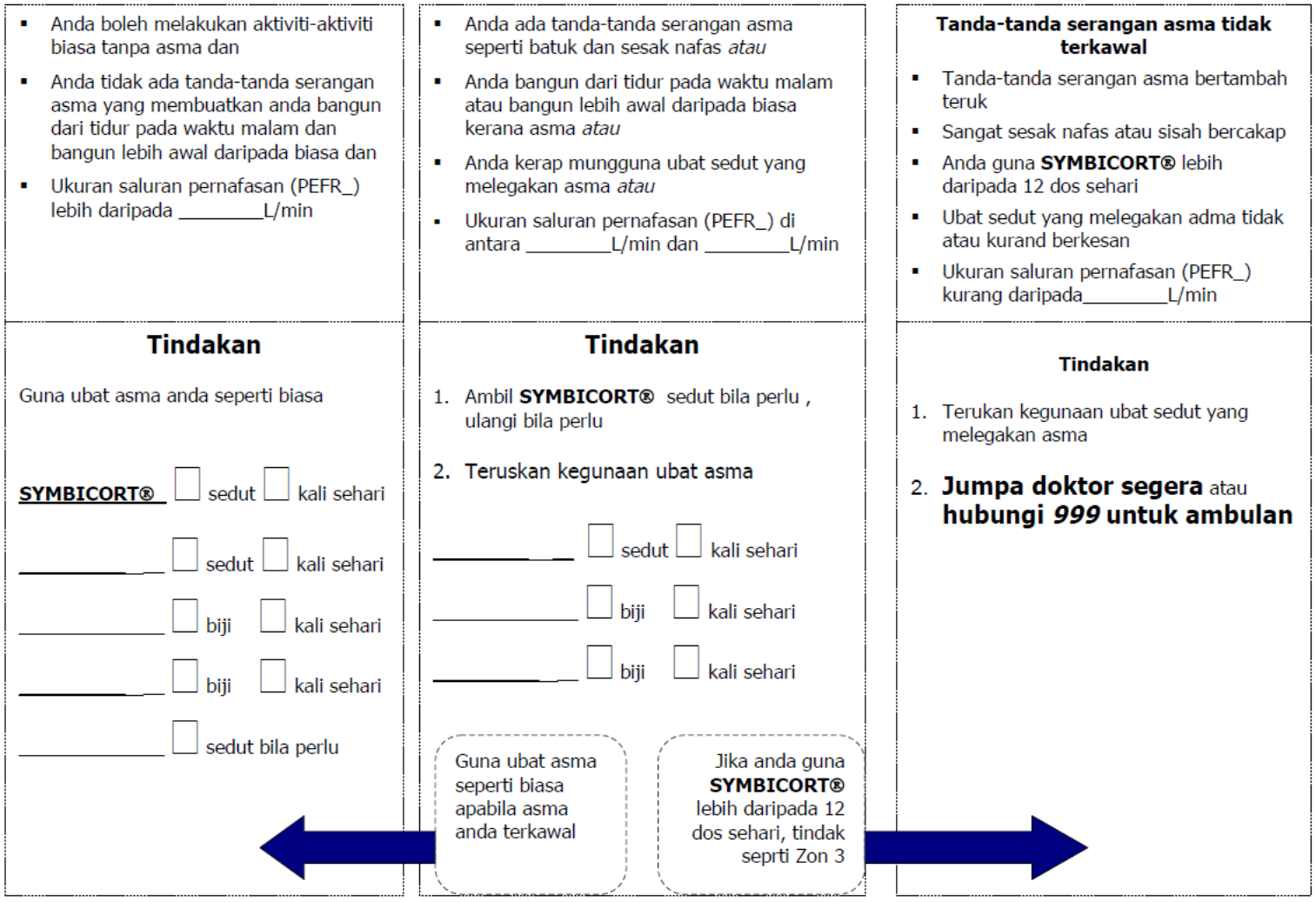

Asthma Action Plan
Zone 1
Zone 2
Zone 3
NEULIN SR
SINGULAIR
NEULIN SR
SINGULAIR
999


Asthma Action Plan
Zone 1
Zone 2
Zone 3
999

Appendix 6.9: Written Action Plan for use in Asthma Self-Management Training in Malaysia

Plan Rawatan Asma



Plan Rawatan Asma

Zon 1

- Anda boleh melakukan aktiviti-aktiviti biasa tanpa asma dan
- Anda tidak ada tanda-tanda serangan asma yang membuatkan anda bangun dari tidur pada waktu malam dan bangun lebih awal daripada biasa dan
- Ukuran saluran pernafasan (PEFR_) lebih daripada _____L/min

Tindakan

Guna ubat asma anda seperti biasa

_____ ☐ sedut ☐ kali sehari

_____ ☐ sedut ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ sedut bila perlu

Zon 2

- Anda ada tanda-tanda serangan asma seperti batuk dan sesak nafas *atau*
- Anda bangun dari tidur pada waktu malam atau bangun lebih awal daripada biasa kerana asma *atau*
- Anda kerap mungguna ubat sedut yang melegakan asma *atau*
- Ukuran saluran pernafasan (PEFR_) di antara _____L/min dan _____L/min

Tindakan

1. Ambil **Prednisolone 30mg (6 biji)** untuk **7-hari**
2. Teruskan kegunaan ubat asma

_____ ☐ sedut ☐ kali sehari

_____ ☐ sedut ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ biji ☐ kali sehari

Jika tanda tanda asma terkawal didalam 24 jam, sila guna Prednisolone untuk 7-hari sebelum *guna ubat asma seperti biasa.*

Jika Prednisolone gagal mengawal tanda-tanda asma didalam 24 jam, tindak seperti Zon 3

Zon 3

Tanda-tanda serangan asma tidak terkawal

- Tanda-tanda serangan asma bertambah teruk
- Sangat sesak nafas atau sisah bercakap
- Anda guna **ubat sedut yang melegakan asma** lebih daripada 8 dos sehari
- Ubat sedut yang melegakan adma tidak atau kurand berkesan
- Ukuran saluran pernafasan (PEFR_) kurang daripada_____L/min

Tindakan

3. Terukan kegunaan ubat sedut yang melegakan asma
4. **Jumpa doktor segera** atau **hubungi *999* untuk ambulan**

Plan Rawatan Asma

Zon 1

- Anda boleh melakukan aktiviti-aktiviti biasa tanpa asma dan
- Anda tidak ada tanda-tanda serangan asma yang membuatkan anda bangun dari tidur pada waktu malam dan bangun lebih awal daripada biasa dan
- Ukuran saluran pernafasan (PEFR_) lebih daripada _____L/min

Tindakan

Guna ubat asma anda seperti biasa

_____ ☐ sedut ☐ kali sehari

_____ ☐ sedut ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ sedut bila perlu

Zon 2

- Anda ada tanda-tanda serangan asma seperti batuk dan sesak nafas *atau*
- Anda bangun dari tidur pada waktu malam atau bangun lebih awal daripada biasa kerana asma *atau*
- Anda kerap mungguna ubat sedut yang melegakan asma *atau*
- Ukuran saluran pernafasan (PEFR_) di antara _____L/min dan _____L/min

Tindakan

1. Tambah do ubat pengawal asma

_____ ☐ sedut ☐ kali untuk **7-hari**

2. Teruskan kegunaan ubat asma

_____ ☐ sedut ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ biji ☐ kali sehari

_____ ☐ sedut bila perlu

Jika tanda tanda asma terkawal didalam 24 jam, sila guna dos tambahan untuk 7-hari sebelum *guna ubat asma seperti biasa.*

Jika dos tambahan gagal mengawal tanda-tanda asma didalam 24 jam, tindak seperti Zon 3

Zon 3

Tanda-tanda serangan asma tidak terkawal

- Tanda-tanda serangan asma bertambah teruk
- Sangat sesak nafas atau sisah bercakap
- Anda guna **ubat sedut yang melegakan asma** lebih daripada 8 dos sehari
- Ubat sedut yang melegakan adma tidak atau kurand berkesan
- Ukuran saluran pernafasan (PEFR_) kurang daripada_____L/min

Tindakan

1. Terukan kegunaan ubat sedut yang melegakan asma
2. **Jumpa doktor segera** atau **hubungi *999* untuk ambulan**

Asthma Action Plan

Zone 1

- You can perform normal physical activity without asthma signs and
- You do not wake up at night or in the morning because of asthma and
- Your peak flow rate is above _____ L/min

Action

Take your regular asthma medication every day

SYMBICORT® ☐ inhalation ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ inhalation when required

Zone 2

- You have increasing asthma signs (breathless, cough, wheezing) *or*
- You wake up at night or in the morning because of asthma *or*
- You are increased use of reliever *or*
- Your peak flow rate drop between _____ L/min and _____ L/min

Action

1. Take **SYMBICORT®** 1 inhalation when required, repeat if necessary
2. Continue taking regular medication asthma medication

SYMBICORT® ☐ inhalation ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ tablets ☐ a day

Resume to regular medication when asthma signs is controlled

If you have use more than 12 doses of SYMBICORT® in a day, please move to Zone 3

Zone 3

Signs of severe uncontrolled asthma

- Persistent worsening of asthma symptoms
- Extremely difficulty in breathing or speaking
- Use of **SYMBICORT®** more than 12 doses a day
- Little or no relief with use of reliever
- Peak flow drop rate below _____ L/min

Action

1. Continue taking your reliever inhaler when required
2. See **your doctor immediately** or **call 999 for ambulance**

Asthma Action Plan

Zone 1

- You can perform normal physical activity without asthma signs and
- You do not wake up at night or in the morning because of asthma and
- Your peak flow rate is above _____ L/min

Action

Take your regular asthma medication every day

_____ ☐ inhalation ☐ a day

_____ ☐ inhalation ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ inhalation when required

Zone 2

- You have increasing asthma signs (breathless, cough, wheezing) *or*
- You wake up at night or in the morning because of asthma *or*
- You are increased use of reliever *or*
- Your peak flow rate drop between _____ L/min and _____ L/min

Action

3. Increase your preventer to

_____ ☐ inhalation ☐ times for **7-day**

4. Continue taking regular medication asthma medication

_____ ☐ inhalation ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ inhalation when required

If signs controlled within 24-hour, continue for 7-day and then resume regular medication

If increase dose failed to control asthma signs within 24 hours, please act as according to Zone 3

Zone 3

Signs of severe uncontrolled asthma

- Persistent worsening of asthma symptoms
- Extremely difficulty in breathing or speaking
- Use of reliever more than 8 doses a day
- Little or no relief with use of reliever
- Peak flow drop rate below _____ L/min

Action

1. Continue taking your reliever inhaler when required
2. **See your doctor** immediately or **call 999 for ambulance**

Asthma Action Plan

Zone 1

- You can perform normal physical activity without asthma signs and
- You do not wake up at night or in the morning because of asthma and
- Your peak flow rate is above _____ L/min

Zone 2

- You have increasing asthma signs (breathless, cough, wheezing) *or*
- You wake up at night or in the morning because of asthma *or*
- You are increased use of reliever *or*
- Your peak flow rate drop between _____ L/min and _____ L/min

Zone 3

Signs of severe uncontrolled asthma

- Persistent worsening of asthma symptoms
- Extremely difficulty in breathing or speaking
- Use of reliever more than 8 doses a day
- Little or no relief with use of reliever
- Peak flow drop rate below _____ L/min

Action

Take your regular asthma medication every day

_____ ☐ inhalation ☐ a day

_____ ☐ inhalation ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ inhalation when required

Action

5. Take **Prednisolone 30mg** (6 tablets) once daily for **7-day**

6. Continue taking regular medication asthma medication

_____ ☐ inhalation ☐ a day

_____ ☐ inhalation ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ tablets ☐ a day

_____ ☐ inhalation when required

If signs controlled within 24-hour, continue for 7-day and then resume regular medication

If Prednisolone fails to control asthma signs within 24 hours, please act as according to Zone 3

Action

3. Continue taking your reliever inhaler when required

4. **See your doctor** immediately or **call 999 for ambulance**

Appendix 6.10: Asthma Control Test (ACT)

Ujian Kawalan Penyakit Asma

NAMA: TARIKH:

1. Sepanjang tempoh 4 minggu yang lalu , berapa banyakkah masa asma anda telah menghalang anda daripada melakukan aktiviti-aktiviti biasa di tempat kerja, sekolah, institut pengajian tinggi atau di rumah?
   - Sepanjang masa
   - Kebanyakan masa
   - Agak banyak masa
   - Sedikit masa
   - Tiada langsung

2. Sepanjang tempoh 4 minggu yang lalu , berapa kerapkah anda telah mengalami sesak nafas?
   - Lebih daripada sekali sehari
   - Sekali sehari
   - 3 hingga 6 kali seminggu
   - Sekali atau dua kali seminggu
   - Tiada langsung

3. Sepanjang tempoh 4 minggu yang lalu , berapa kerapkah simptom-simptom asma anda (seperti berdehit, batuk, sesak nafas, dada rasa ketat atau sakit dada) membuatkan anda bangun dari tidur pada waktu malam atau bangun lebih awal daripada biasa pada waktu pagi?
   - 4 malam atau lebih seminggu
   - 2 hingga 3 malam seminggu
   - Sekali seminggu
   - Sekali atau dua kali
   - Tiada langsung

4. Sepanjang tempoh 4 minggu yang lalu, berapa kerapkah anda telah menggunakan ubat sedut yang melegakan dengan cepat atau nebulizer anda (seperti Salbutamol, Terbutalin atau Fenoterol)?
   - 3 kali atau lebih sehari
   - 1 atau 2 kali sehari
   - 2 atau 3 kali seminggu
   - Sekali seminggu atau kurang
   - Tiada langsung

5. Bagaimanakah anda menilai kawalan asma anda sepanjang tempoh 4 minggu yang lalu ?
   - Tidak terkawal langsung
   - Kawalan adalah buruk
   - Agak terkawal
   - Terkawal dengan baik
   - Terkawal sepenuhnya

Asthma Control Test

NAME: DATE:

2. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

3. During the past 4 weeks, how often have you had shortness of breath?
   - More than once a day
   - Once a day
   - 3 to 6 times a week
   - One or twice a week
   - Not at all

4. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?
   - 4 or more nights a week
   - 2 or 3 nights a week
   - Once a week
   - One or twice
   - Not at all

5. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?
   - 3 or more times per day
   - 1 or 2 times per day
   - 2 or 3 times per week
   - Once a week or less
   - Not at all

6. How would you rate your asthma control during the past 4 weeks?
   - Not controlled at all
   - Poorly controlled
   - Somewhat controlled
   - Well controlled
   - Completely controlled

哮喘控制指數測試(ACT)

1. 在过 的4周内，在工作、学习或家中，有多少时侯哮喘妨碍您进行日常活动?
   - □ 所有时间
   - □ 大多数时候
   - □ 有些时候
   - □ 很少时候
   - □ 没有

2. 在过去的4周内，您有多少次呼吸困难？
   - □ 每天不止1次
   - □ 一天1次
   - □ 每周3至6次
   - □ 每周1至2次
   - □ 完全没有

3. 在过去的4周内，因为哮喘症状(喘息、咳嗽,吸困难、胸闷或疼痛)，您有多少次在夜间醒来或早上比平时早醒？
   - □ 每周4晚或更多
   - □ 每周2至3晚
   - □ 每周1次
   - □ 1至2次
   - □ 没有

4. 在过去的4周内，您有多少次使用急救药物(如沙丁胺醇)?
   - □ 每天3次以上
   - □ 每天1至2次
   - □ 每周2至3次
   - □ 每周1次或更少
   - □ 没有

5. 您如何评估过去4周内您的哮喘控制情况？
   - □ 没有控制
   - □ 控制很差
   - □ 有所控制
   - □ 控制很好
   - □ 完全控制

Appendix 6.11: Data Evaluation Form

DATA COLLECTION FORM: EVALUATION OF SELF-MANAGEMENT PLAN

Patient Name		
RN Number		
Contact Number		
Age	**Gender** Male / Female	**Race** Malay / Indian / Chinese / Others
Spoken Language		
Current asthma medication		**Remarks (Other medication/condition)**
History of training on asthma & medication **Training provided by**		Yes / No **Doctor/Pharmacist/Nurse/ Others_____**
Previous training on self-management **If yes, form of self-management training** **Availability of Peak Flow at home**		Yes / No Verbal / Written / Pictorial Yes / No

Details of 1st meeting	
Counseling provided	
Self-management training provided	
Action plan provided	
Type of action plan provided	Written (English) / Written (BM) / Pictorial
NOTE	

Predicted PEFR	**Predicted FEV_1**		**Predicted**	
DATE	1st assessment	2nd assessment	3rd assessment	4th assessment
Measured FEV_1				
Measured FVC				
Measured PEFR				
In the past 1 month **No of hospital admission** No of unscheduled GP visit No of days off work				
In the past 3 months **No of hospital admission** No of unscheduled GP visit No of days off work				
ACT score (max 25)				
Attempt of AP (Yes/No)				
Willingness to attempt **(yes/No)**				
Compliance				
Do you ever forget to take medicine?				
Are you careless at times about taking your medicine?				
When you feel better do you sometimes stop taking your medicines?				
Sometimes if you feel worse when you take medicine, do you stop taking your medicine?				

			2nd assessment	3rd assessment	4th assessment
		Have you implemented any of action according to action plan?			
Action Points					
Symptoms based Night time symptoms +/- Breathlessness		Use extra doses of reliever			
		Increase ICS dose			
		Increase ICS dose or taken prednisolone tablet + if symptoms persistent/ worsening e.g. breathless at rest or with daily activities, seek medical attention			
		Use of reliever has increased (more than 8 or less than every 4 hours), seek medical attention			
		Resume normal regimen if symptoms recovered			
PEFR based Night time symptoms +/- Breathlessness		Use extra doses of reliever			
		Measure PEFR to ensure >80%			
		Measure PEFR and if within 65-80% then Increase ICS dose or taken prednisolone tablet as appropriate			
		Increase use of reliever + measure PEFR and if 40-65%, seek medical help			
		Resume normal regimen if symptoms recovered			
Self-Management Skills Assessment					
Part 1 You woke this morning feeling perfectly well and spent the day doing your usual activities. At 7 o'clock in the evening you sit down to relax and you notice you are feeling a little wheezy and breathless. What would you do?		1) Take PEFR Reading (2)			
		2) Take prednisolone or increase dose as according to Action Plan (0)			
		3) Take extra beta agonist /reliever (2)			
		4) Increase dose of ICS (1)			
		5) Se**e doctor immediately (0)**			
Part 2 Over the next half-hour the wheezing and breathlessness get worse and you find it a little difficult to walk to the kitchen for a drink. What would you do?		1) Take PEFR Reading (2)			
		2) Take prednisolone or increase dose as according to Action Plan (6)			
		3) Take extra beta agonist (2)			
		4) Increase dose of ICS			
		5) Se**e doctor immediately (6)**			
Part 3 It has now been about one hour and your breathing continues to get worse and by 8 o'clock you are so wheezy and breathless that you find it difficult to speak or get up from your chair. What would you do?		1) Take PEFR Reading (0)			
		2) Take prednisolone or increase dose as according to Action Plan (3)			
		3) Take extra beta agonist (1)			
		4) Increase dose of ICS (0)			
		5) Se**e doctor immediately or call ambulance(7)**			

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