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A Study to Investigate the Uptake and Impact of Consensus Guidelines for the Management of Patients with Asthma in Primary Care

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ABSTRACT

FACULTY OF MEDICINE, HEALTH AND BIOLOGICAL SCIENCES
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A Study to Investigate the Uptake and Impact of Consensus Guidelines for the Management of Asthma in Primary Care on Quality of Life and Disease Control

by Martina Ann Dorward

This thesis addresses two key questions: Do patients who attend a practice, where the Primary Health Care Team follow the 1993 British Thoracic Society (BTS) guidelines have a better quality of life, and do they have better controlled asthma?

The study design was a cross sectional, observational survey of adherence to the BTS guidelines, symptom prevalence and quality of life in adults with asthma in Primary Care. Quality of life was measured using the St. Georges's Respiratory Questionnaire (SGRQ) and disease control was assessed from self-reported symptoms and serial peak expiratory flow measurements. Adherence to the BTS guidelines was judged in a variety of ways: by surveying the organisation, structure and facilities at practices using a questionnaire, by assessing General Practitioner's (GPs) self-reported behaviour using vignettes and examining prescribing from PACT data regarding inhaled corticosteroid and beta-agonist prescriptions (IHCS/β_2).

Associations were examined using correlation and multivariate regression analysis. By performing backwards, stepwise, regression analysis, the impact of practice organisation on the relationship between guideline adherence and outcomes was assessed.

The study included 1065 patients and 169 partners from 37 practices. Practices were well equipped to manage asthma according to the BTS guidelines and GPs' knowledge and reported adherence was good, with the majority of partners reporting management decisions consistent with recommendations in the guidelines. 'Medication taken on home visits' (p= 0.011) and 'the ratio of IHCS/β_2' (p= 0.037) were statistically significant predictors of improved quality of life: Data were presented as mean scores per practice, therefore, my results predict outcomes that would improve for the 'average' patient; however, in the clinical setting, not all patients would benefit. Practice organisation did not impact on the relationship between guideline adherence and outcomes.

The findings from this study have not convincingly demonstrated that guideline adherence translates into better patient outcomes. However, this is the first study to demonstrate an association between prescribing and patient outcomes in primary care. A better quality of life is observed in patients who attend practices with higher ratios of IHCS/β_2 prescriptions. This finding will be of interest to Health Authorities and Primary Care Trusts when planning performance indicators for the care of patients with asthma.

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Chapter Two:
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Chapter Three:
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The organisational changes that have occurred in general practice are presented and their impact on the management of patients will be discussed.

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Research Proposal:- Rationale for Project, Hypothesis and choice of Study Design
The rationale for further research is justified, the hypothesis is stated and the chosen study design and methodology are outlined.

Chapter Five:
Measurement of BTS Guideline Adherence
The methods to measure guideline adherence are introduced. The development of a novel tool to examine adherence to the 1993 British Thoracic Society (BTS) treatment guidelines for the management of asthma is described.

Chapter Six:
Outcome Measures
The chosen outcome measures used to assess quality of life and patients disease control is discussed.

Chapter Seven:
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The predictor variables to measure practice organisation is described. The development of a novel tool to measure aspects of practice organisation is presented.

Chapter Eight:
Statistical Methods and Sample Size Calculation
In this chapter the methods used to calculate the required sample size of patients and practices is presented. The procedures used to calculate the predictor and outcome variables are presented. Finally the process of data analysis is described.

Chapter Nine:
Study Setting and Methods
This chapter describes the setting for the study and gives the rationale for its selection. The procedures used for approaching and recruiting practices and patients are illustrated.

Chapter Ten:
Results
In this chapter descriptive data about the sample used are presented, along with the results of the analysis examining the relationship between guideline adherence and quality of life.

Chapter Eleven:
Discussion and Conclusion
This chapter draws together my conclusions and discusses the strengths and weaknesses of the study. I will discuss how results from this study have contributed to our understanding of the management of adult patients with asthma in general practice. The implications for practice is discussed and areas for future research will be highlighted.

Appendices

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"Not to know is bad; not to wish to know is worse"
African proverb

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Publications

The following publications and presentations are related to the work that is encompassed in this thesis.

Dorward, M.A., Corne, J. M., Smith, H. E., Low J. L., Holgate, S. T. "How Have Current Guidelines for the Management of Asthma Affected Clinical Practice?" (poster presentation), National Asthma Campaign conference, London, February 1998

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Dorward, M.A. Asthma Management in General Practice *Southampton Health Journal,* 1998, **14**, 40

Dorward, M.A. "The Role of the Practice Nurse in Asthma Management", *Southampton Health Journal*. 1995, **11**: No. 3: p8-10

Dorward, M.A. "The Role of the Practice Nurse in Asthma Management", (abstract/poster presentation). *Inspiration* (Quarterly Newsletter of RCN Respiratory Nurses), 1995,

CHAPTER ONE

CHAPTER ONE
THE DIAGNOSIS AND MANAGEMENT OF ASTHMA

1. Introduction

Despite improved understanding of the pathogenesis of asthma, the availability of effective asthma therapies and changes in service delivery, the reduction in the morbidity associated with this disease over the last decade has, at best, been moderate. Over the last 20 years, general practitioners (GPs) have become primary care specialists, with respiratory physicians as a resource for consultation (Charlton, 1997). Ninety per cent of patients with asthma are now managed entirely by their GP rather than a hospital consultant (Neville et al 1996; Charlton, 1997). Therefore, the primary health care team (PHCT) has the greatest responsibility and potential to improve outcomes for patients with asthma.

Primary care is considered the rational core of an equitable and efficient health service (World Health Organisation, 1978), and many features of primary care are particularly suited to meet the needs of patients with asthma. As the first point of contact, GPs often make the diagnosis of asthma. As family doctors, GPs take a holistic approach, which enables them to provide the necessary support required by patients and their carers. In this context in the last 20 years, there have been four major factors that have influenced the way patients with asthma are managed in general practice:

1. The development and implementation of treatment guidelines for asthma
2. The modification of general practice organisation through changes in contracting arrangements and the introduction of the chronic disease management programme
3. An increase in the use of patient education and self-management plans
4. The use of allied health professionals, especially practice nurses to co-ordinate and deliver patient care

The first of these changes, the development of guidelines for the management of patients with asthma, occurred in the late 1980s and was in response to the recognition of asthma as a *chronic* rather than *episodic* condition. This was accompanied by a shift in emphasis from *reactive* treatment of asthma symptoms, with drugs such as bronchodilators, to a more *proactive,* preventative approach using drugs such as inhaled steroids. At the same time, there were concerns regarding the rising numbers of asthma deaths and the recognition that around 80% of these deaths may be preventable. This focused attention on how to improve patient management in primary and secondary care (Cochrane and Clark, 1975; BTA, 1982; Eason and Markowe, 1987). To help clinicians improve their management of patients with asthma, the British Thoracic Society (BTS) first published guidelines in 1990 (BTS et al, 1990a and 1990b). These guidelines were reviewed in 1993 and again in 1997 (BTS et al, 1993 and 1997).

Although there has been widespread encouragement for doctors to manage their asthma patients according to the BTS treatment guidelines, there is limited evidence that the care of patients with asthma has improved. We do not know if patients have better controlled asthma and a better quality of life if they attend a practice where the GP and practice nurse follow the BTS treatment guidelines.

Whilst the main focus of this study was to explore the relationship between adherence to the 1993 BTS treatment guidelines and patient outcomes, it is recognised many factors may impact on this relationship; in particular aspects of practice organisation may be potential confounders. Therefore, this has been addressed in the study design and analysis.

1.1 Literature Review

The literature was reviewed:

- to gather background information on the importance of asthma and the current treatment and management for adults in general practice
- to examine the evidence base for the use of guidelines for the treatment of patients with asthma
- to review those organisational changes within general practice in the last 10 years, which may have impacted on the management of patients with asthma

Due to the breadth of the review, it was not possible to perform a systematic literature review for each subject. Instead, to obtain an over-view of what is currently considered good practice, "state of the art" reviews were used, including publications from the Cochrane Airways Group.

The literature was systematically reviewed to establish the evidence base of the 1993 BTS guidelines for asthma management in adults. Two *on-line* searches of the Medline and General Practitioner databases were conducted in 1995 and 1997. To maximise the amount of relevant articles found, the procedure recommended by Greenhalgh (1997) was followed. An experienced health services librarian advised on selection of appropriate medical subject heading (MeSH) terms. The searches were requested back to 1966, (the date of the earliest articles available from the computerised Medline database). Searching the MeSH term 'asthma', the subject headings were then "restricted to focus" using the sub-headings listed below.

1995

ASTHMA
Guidelines (Practice Guidelines)
British adj. Thoracic (for British Thoracic Society)
General practice (Family Practice, Primary/Community/Ambulatory Care)
Chronic Disease
Quality of Health Care
Quality of Life
St. George's Respiratory Questionnaire

The terms used for 1995 were repeated and the subject headings below were added for the 1997 search. From retrieved articles manual citation searches were also performed from the listed references ("daisy-chaining").

These are listed over-leaf:

1997

ASTHMA

Self-management

Patient Education

Prescribing (Treatment, Therapy, Prescribing Ratios)

PACT data

Other data bases searched using the same strategy were as follows:

(to earliest available articles)

- CINAHL - a nursing health data base (to 1982)
- Embase - medical database, including pharmacology related subjects (to 1980)
- British Nursing Index – nursing and allied professions database (to 1994)
- Cochrane database of reviews
- DARE database from the NHS Centre for Reviews and Dissemination

1.2 The Definition of Asthma

According to the Oxford Dictionary, the word *asthma* comes from the Greek *azo*, which means to breathe hard and is a noun for "a respiratory condition that is marked by wheezing".

Before the 1980s it was believed asthma was an abnormality of airway smooth muscle and that marked inflammation was only present in fatal asthma (Samet, 1987). However, the development of the fibre optic bronchoscope enabled scientists to study lung tissue from patients including those with mild disease. The recognition of inflammation as an important feature in asthma changed the fundamental understanding of the pathological processes involved and has led to changes in both definition and treatment.

The following definition of asthma (shown over-leaf) is from a publication produced by the Global Initiative for Asthma (GINA) in 1995, as a joint initiative with the National Heart, Lung and Blood Institute (NHLBI) of the USA and the World Health Organisation (WHO).

> "Asthma is a chronic inflammatory disorder of the airways. In susceptible individuals this inflammation causes recurrent episodes of coughing, wheezing, chest tightness and breathing difficulty. The inflammation also makes the airways sensitive to stimuli such as allergens, chemical irritants, tobacco smoke and cold air or exercise. When exposed to these stimuli, the airways may become swollen and filled with mucus, constrict and be hyper-responsive to stimuli. The resulting airflow limitation is reversible (although not completely in some patients), either spontaneously or with treatment. When asthma therapy is adequate, inflammation can be reduced over the long term, symptoms can usually be controlled and most asthma-related problems prevented (NHLBI, 1995)."

In this definition it is recognised that, although asthma cannot be cured, the underlying pathophysiological problem of airway inflammation can be effectively treated. Inhaled corticosteroids have been shown to be the most effective treatment with few side effects (Barnes, 1996). As inflammation may be present in the airways of patients with even mild asthma (Bousquet et al, 1990; Laitenen et al, 1993), anti-inflammatory treatment should be considered for all patients. Furthermore, a delay in taking adequate anti-inflammatory medication may result in the development of irreversible changes in airway function (Haahtela et al, 1991 and 1994; Dompeling et al, 1993; Selroos et al, 1994). Therefore, good management of asthma aims to suppress this inflammation and by early intervention prevent irreversible changes in lung function. (The treatment and management of asthma is discussed in more detail in sections 1.4 to 1.6).

1.2 1 Aetiology of Asthma

The factors that predispose an individual to asthma are complex. Genetic factors play an important role, it is more common in individuals with a parental history of asthma and a number of candidate genes have been proposed (Holgate, 1997). Also, asthma is strongly associated with a familial history of atopic diseases such as eczema and hay fever and it is also closely associated with high total serum IgE levels (Burrows et al, 1989). Despite new techniques for scanning genes, our

understanding of the genetic basis of asthma and allergy and the interaction with the environment still remains unclear. Asthma results from multiple interactions between the immune system and environmental factors acting on a genetic predisposition. It is likely there are different "asthmas" causing different symptoms. These different asthmas include a) atopic asthma, b) occupational asthma and c) aspirin-intolerant asthma. However, the exact mechanisms involved in the interaction between genetic and environmental factors are yet to be identified (Cogswell, 1992; Wilkinson and Holgate 1996).

The increasing prevalence of childhood asthma in developed and developing countries has prompted many to question whether this increase can be attributed to changing environmental factors (Seaton et al, 1994). There is an increasing body of evidence which suggests exposure to environmental factors and common allergens in early life may not only be a significant predisposing factor to its development, but may also exacerbate pre-existing asthma (Sporik et al, 1992).

Asthma is often associated with allergic diseases, especially in children, and there is evidence that the severity of asthma increases in relation to the level of allergen exposure (Platts-Mills et al, 1992a). The ubiquitous house dust mite (*Dermatophagoides pteronyssinus*) triggers attacks in many asthmatics and there is evidence that exposure to this common allergen in early childhood may strongly contribute to the development of the disease (Sporik et al, 1992). Other allergens known to trigger attacks are pollen, animal dander, moulds and feathers. Non-allergic triggers include exercise, cold weather, tobacco smoke and, particularly in children, upper respiratory tract infections (Johnston et al, 1995). The role these risk factors play in the development of asthma remains uncertain.

1.2.2 Pathophysiology of Asthma

The clinical symptoms of asthma - episodic cough, wheeze and breathlessness - were once considered to be the manifestation of a transient disorder of airway smooth muscle. Now it is known that the main pathological features of asthma also include inflammation, altered airway structure and function, and tissue remodelling. Implicated inflammatory cells include mast cells, eosinophils and neutrophils in the airway wall, as well as lymphocytes and plasma cells (Wardlaw et al, 1988;

Tattersfield and McNicol, 1987). Inflammation of the airways contributes to the bronchial reactivity and clinical manifestations of asthma through the release of chemical mediators including histamine and leukotrienes. Oedema of the airways, smooth muscle hypertrophy and excess mucus production that plugs the small airways are also features of asthma. Such changes in the airways may be present even in mild disease and can persist between exacerbations (Djukanovic et al, 1990). In the last 10 years, significant advances have been made in our understanding of asthma. However, despite intensive investigation the precise mechanisms involved in the aetiology and pathophysiology of this common disease have not as yet been identified (Holgate, 1997).

1.2.3 The Prevalence of Asthma

Asthma is a common chronic condition affecting all age groups and is the fourth most common condition treated by GPs in the UK (McCorick et al, 1995). It is estimated that at least 7-8% of adult patients and approximately 10% of children on a general practitioner's list will have a label of asthma (Gellert et al, 1990; Levy and Hilton, 1992; Jarvis et al, 1994). Most epidemiological studies demonstrate an increase in the prevalence of asthma over time despite the following limitations to the data:

- Clinicians differ in their diagnostic threshold for asthma.
- Data are derived from routine sources as there is no UK national register for patients diagnosed with asthma.
- Surveys may not be comparable as they use different case definitions for asthma.
- Prevalence surveys performed overseas may not be generalisable to the UK.
- There are difficulties extrapolating surveys that have focused on specific age groups or localities.

To estimate the prevalence of asthma in the population, studies have largely used a case definition based on symptoms. Much of this work has been performed with children and several studies have demonstrated an increased reporting of asthma symptoms and clinical diagnosis of asthma (Lee et al, 1983; Burney, 1986; Fleming and Crombie, 1987; Burney et al, 1990; Rona et al, 1995). At the same time,

increased hospital admission rates for children with acute asthma have been observed (Khot and Burn, 1984; Storr et al, 1988; Anderson; 1989).

The apparent increase of asthma in children may have been due in part to a shift in the labelling from chronic bronchitis to asthma. But the increase in asthma-specific symptoms, such as persistent wheeze, suggests there has been a real increase in the prevalence of the disease. One study that confirmed this was a population prevalence survey in the London borough of Croydon where questionnaires were sent to all the parents of children aged between $7^1/_2$ and $8^1/_2$ years old in 1978. The survey was repeated in 1991 to a similar, though smaller sample. These were large surveys including approximately 4700 children in the first, and 3700 in the second survey; in addition response rates were high (87% in 1978, 81% in 1991). Between the two surveys, reported "wheezing in the preceding 12 months" rose by 16%, from 11.1% in the 1978 survey to 12.8% in 1991 (Anderson et al, 1994).

There has also been an increased reporting of asthma in adults in the UK, particularly amongst 20-44 year olds (Burney et al, 1997). From information provided by the Office of National Statistics (ONS), of a population of over two million patients on the General Practice Research Database (GPRD), it was estimated in the period from 1994 to 1998, the overall prevalence of treated asthma increased from 6.6 to 7.2% in men, and 6.5 to 7.6% in women (ONS, 1998). Although these increases look relatively small they convert to statistically significant changes in the population that are unlikely to have occurred by chance (p = <0.0001). Even though these are of 'reported' cases of asthma and GPs may vary in the criteria they use to 'label' patients as asthmatic, this is too large an increase to be attributable to diagnostic shift alone. This size of increase over this four-year period, for the average practice of 10,000 registered patients would equate to an additional 80 being placed on the asthma register, which would mean a substantial increase in workload for members of the PHCT.

Recently, two international studies of respiratory disease have been published. These were very large studies using standardised methods and provide us with reliable estimates of asthma prevalence. These are the European Community Respiratory Health Survey (ECRHS) and the International Study of Asthma and Allergy in Childhood (ISAAC). The European Community Respiratory Health Survey (ECRHS) confirmed there was wide variation in the prevalence of symptoms in adults across Europe, with symptom prevalence tending to be higher in the North

than in Southern Europe. However, there were some exceptions. In Spain two areas reported high prevalence of wheeze: 16.2% in Galdako and 29.2% in Huelva (ECRHS, 1996). The ISAAC study confirmed that the UK has one of the highest rates of prevalence of asthma in the world. In the UK, it was estimated the prevalence of children "ever having asthma" was 20.9% with minimal geographical variation. This is based on data from a sample of 27,507 children aged 12-14 years (Kaur et al, for ISAAC UK, 1998).

Another more recent study of asthma prevalence in Belgian adults retrospectively surveyed the medical notes of 48,330 army conscripts. Information about reported asthma and objective measurements of airway hyper-responsiveness (reversibility to bronchodilator) was gathered. From 1978 to 1991 there was an increase of reported asthma from 2.4% to 7.2% and this was reflected in the relative proportion of subjects with bronchial hyper-responsiveness from 1.2% to 3.7% (Dubois et al, 1998).

So, despite the methodological problems associated with estimating asthma prevalence, there is consistency in the trends and it is widely accepted there *has* been a real increase in the disease in the UK and many westernised countries (Haahtela et al, 1990; Peat et al, 1992; Tirimanna 1996; Burney et al, 1997; Dubois et al, 1998; Kaur et al, 1998). In the UK, this created an increased workload for the Primary Health Care Team. From the weekly return service for the Royal College of General Practitioners (RCGP), consultations for asthma increased from 10-12 per 100, 000 in 1976 to 40-50 in 1994. More recently these figures have levelled out. This is probably due an increase in the number of patients seeing a practice nurse, rather than a GP.

1.2.4 Asthma Mortality

Asthma was the only one of the nine *avoidable* causes of death to rise between 1979 and 1987. It rose from a baseline of 5 to more than 6 deaths per 100, 000 in the UK (Acheson, 1989; DOH, 1995). However, it is difficult to be certain of figures reported from death certificates, as some uncertainty exists in distinguishing patients who have died "with" asthma as opposed to "from" asthma.

Part of the increase in recorded deaths is due to the changes in disease classification that occurred in 1979 and the coding of 'underlying cause of death' that was modified in 1984. The combined effect of these two changes increased the

recorded asthma deaths by more than one third (OPCS, 1989). The coding change alone meant that the number of recorded deaths among those aged over 75 was 15% higher in 1984. The increase in deaths among elderly people was due to changes in diagnostic and recording practices. In the 1980s, deaths were being recorded as 'due to asthma' that previously were attributed to other respiratory conditions. Therefore, after taking account of the coding changes the upward trend can probably be explained by a switch from other related headings, such as pneumonia or chronic bronchitis (DOH 1995).

From a confidential enquiry into deaths in the 1970s, it was estimated that approximately 86% of the deaths attributed to asthma could have been prevented if effective asthma management strategies had been followed (BTA, 1982).

In the mid 1990s it was estimated asthma mortality was falling by approximately six per cent each year in people aged 5-64 years and it was suggested this reduction could be attributed to improved management of the disease with prophylactic medication such as inhaled corticosteroids (Campbell et al, 1997). A more recent enquiry identified inappropriate medical care in only 28% of asthma deaths (Mohan et al, 1996). These changes are encouraging and may indeed be indicative of recent improvements in the management of asthma (Eason and Markowe, 1987; Campbell et al, 1997).

1.2.5 Asthma Morbidity

Asthma is disruptive and restricting and despite the availability of effective treatments continues to be sub-optimally treated (Wardman et al, 1985; Horn et al, 1990; Bauman et al, 1995; NAC, 1996). The associated morbidity (cough, breathlessness, night wakening) is widespread and it is estimated that between 23 and 57% of patients avoid certain activities, even between attacks (White et al, 1989; Janson et al, 1990; Jones et al, 1992a; Hilton et al, 1986).

The prevalence of night wakening is high. In a large survey conducted in general practice, of 7729 patients seen by 1199 GPs, 73% woke with asthma at least once a week and 39% woke nightly (Turner-Warwick, 1989).

Horn and Cochrane (1989) reported that of a community sample of 312 patients aged 16 to 83 with asthma, 52% (n=164) could recall at least one attack that required medical attention in the preceding 12 months and 47% had time off work. Twenty-

six per cent had a history of recurrent winter cough and over half of the patients felt their life was restricted in some way by their asthma. Jones and colleagues (1992a) found similar levels of morbidity. In their survey, 49% experienced wheezing or other respiratory symptoms at least once a week and 31% missed work or school (Jones et al, 1992a).

More recently, a major nation-wide survey found that of the 52,000 respondents:

- 27% felt that asthma had a major effect on or totally controlled their life
- 42% experienced respiratory symptoms every day or most days
- 44% were woken at night at least once a week by a cough, wheeze or breathlessness
- 81% of those between the ages of 12 and 17 years felt that exercise/activity had at least a moderate effect on their asthma and
- 13% had visited an accident and emergency department in the previous twelve months because of a severe attack of asthma (NAC, 1996).

Although this survey only represents self-selecting patients who voluntarily completed a questionnaire made available at their GP practice or community pharmacy, its cogency is compelling. The 52,000 people who took part in the survey may over-represent patients with symptoms, but they do emphasise the enormous burden of morbidity created by asthma.

1.3 Diagnosis of Asthma

> 'Diagnosis is the crucial process that labels patients, classifies their illness, identifies their likely prognosis and propels clinicians toward a specific treatment' (Sackett 1995).

Asthma is a common disease, so establishing the correct diagnosis is as important to epidemiologists as clinicians. Currently, the accepted clinical diagnosis is based on a characteristic pattern of symptoms. The epidemiologist however, needs further evidence from the results of objective tests. In the UK there is not a great emphasis on the use of objective tests to establish a diagnosis of asthma and this is at variance

with international guidelines. This makes the capturing of data for epidemiological studies difficult and some clinicians have proposed that this should be addressed (Taylor, 1997).

Indeed, for many years there have been concerns that asthma was under-diagnosed and the lack of a 'gold standard' physiological test may have contributed to this. This has been particularly evident in children (Speight, 1978; Speight at al, 1983; Jones, 1989; Jones and Sykes, 1990; Charlton et al, 1991b). In an early study Speight highlighted three factors that may act as barriers to the diagnosis of asthma in children in general practice:

- parents may not report symptoms accurately
- there is over-emphasis on the role of infection
- there is reluctance to use the word "asthma" (Speight, 1978)

The delay in diagnosis also arose from a failure to appreciate that asthma might present with symptoms other than wheeze, such as frequent cough (Konig, 1981). As a consequence, inappropriate or ineffective treatment may be given before reaching the correct diagnosis (NHLBI, 1995).

More recently Charlton and colleagues (1991b) reported a favourable trend in the diagnostic behaviour of GPs in the UK. However, this trend is based on a comparison with previous work in this area from another group. In the first study they estimated the time lag from onset of symptoms to diagnosis was approximately 40% of a child's age (Jones and Sykes, 1990). Charlton and colleagues estimated the median time from initial consultation to the diagnosis of asthma in children was 2.95 years, which is still a substantial delay. Both these surveys reflect the difficulty clinicians face in making the diagnosis of asthma. The diagnosis of certain illnesses like asthma may also be influenced by the 'latest fashion' and be influenced by pressures from society, parents and patients themselves. This difficulty in reaching a diagnosis has been reported in other chronic conditions, such as 'glue ear' (Black 1985).

To assess the possible under-diagnosis in adults, Frank and colleagues (1996) sent the European Community Respiratory Health Questionnaire (Burney et al, 1994) to 11,206 patients over the age of 16 registered at two practices in Manchester. The patients were also asked questions about family history and current smoking status.

Response rates were similar in both of the practices, 72.2 and 76.3%, and also responses to questions were similar. If there were four or more positive responses to questions about wheeze, cough, family and personal history about allergic disorders, the patients were deemed to have an asthma-like illness. The practice records were then examined to assess whether they contained information that corroborated the responses to the questionnaire. Of those who replied, 30.4% reported wheezing and 14.1% had been woken by breathlessness in the previous year. From the results it was estimated 13.8% had an asthma-like illness and of these, 6.6% had not been previously diagnosed and consequently had not received medication for asthma (Frank et al, 1996).

It is not only desirable to achieve control of symptoms for the patients' immediate well-being; there is also evidence that a delay in appropriate treatment may cause long term, irreversible airway damage (Haahtela et al, 1991 and 1994; Selroos et al, 1994). Unfortunately, establishing a diagnosis of asthma is hampered by the absence of a *gold standard* test that readily distinguishes asthma from other respiratory diseases.

Most national and international guidelines on asthma management suggest using objective measurements of *variable airways resistance*, such as forced expiratory volume in one second (FEV_1) or peak expiratory flow (PEF), to aid diagnosis (NHLBI 1995; RCGP 1993; CTS et al, 1996; NEADGP 1996).

In contrast, the British Thoracic Society guidelines for the management of asthma are vague about the use of diagnostic tests (BTS et al, 1990a, 1990b, 1993 and 1997). The 1993 guidelines cite the first aim of asthma management - *is to recognise asthma*; however, apart from a section on "clues to the diagnosis of childhood asthma", there is no specific advice about the use of diagnostic tests (Taylor, 1997). It could therefore be argued that the 1990 and 1993 guidelines did not adequately "guide" physicians in how to establish a correct diagnosis.

This omission has not been corrected in the subsequent revision. The opening paragraph of the 1997 guidelines reiterates that, *correct diagnosis of the condition is essential*, but the guidelines do not specifically recommend the use of objective, physiological tests to confirm the diagnosis of asthma (BTS et al, 1997).

1.3.1 Bronchial Challenge

Bronchial challenge is the diagnostic test considered to most accurately predict asthma and its severity. It measures the airways response to inhaled bronchoconstricting agents (Higgins et al, 1992) and the test and procedure were standardised by a panel of experts in 1975 (Chai et al, 1975). It requires patients to inhale doubling doses of either histamine or methacholine until their forced expiratory volume (FEV_1) reaches a level of 20% below their baseline reading. However, as this test is not available outside secondary care, it is not practicable for all patients to undergo bronchial challenge and in general practice the diagnosis of asthma is usually based on a history of symptoms and peak expiratory flow readings (Taylor, 1997).

1.3.2 Spirometry

A spirometer measures vital capacity, forced vital capacity (FVC) and timed measurements such as the forced volume of air that can be expired in one second (FEV_1). Measurements are easily obtained and with cheaper more portable spirometers this test can be performed in the community. A spirometric measurement of FEV_1 gives a highly accurate "snapshot" of severity. It is the most reproducible pulmonary function parameter and it is linearly related to the severity of airways obstruction. Therefore, it is a more sensitive indicator of long-term airway damage than PEF readings (Vaughan et al, 1989; Bye et al, 1992; Enright et al, 1994).

The measurement of FEV_1 is recommended for all patients in the American guidelines for asthma management to aid diagnosis and monitoring (Sheffer, 1991), and is an approach suggested for the UK by Taylor (1997). It could be argued that previously there was no real need to perform spirometry in primary care in the UK, as it was not a recommendation in national guidelines. Therefore in the past practices have been reluctant to purchase a spirometer as clinicians need to be trained how to perform spirometry and how to interpret results.

British guidelines on the assessment and management of asthma are currently based on peak expiratory flow measurements and symptoms and do not mention the use of FEV_1 measurements for diagnosis or monitoring This is at variance with international guidelines that emphasize the complementary roles of the two types of measurement. However, the British guidelines for the assessment and management

of Chronic Obstructive Pulmonary Disease (COPD), developed by the BTS Standards of Care Committee, are based on spirometric rather than peak flow measurements (BTS-SOCC, 1997). Therefore, it is likely spirometry will become an essential part of respiratory care for patients in general practice. Patients with asthma, COPD and other respiratory illnesses will also benefit, as clinicians will have more information on which to base their therapeutic decisions. This will also aid the epidemiologist in the accurate measurement of disease prevalence (Gibson, 1997).

1.3.3 Peak Expiratory Flow Readings

Due to their relatively low cost (about £10), portability and availability on prescription, peak expiratory flow meters remain the instrument of choice for monitoring patient's asthma in the community (Jones and Mullee, 1995a). They measure the fastest rate at which air can move through the airways, during a forced expiration, starting with fully inflated lungs.

The measurement of peak expiratory flow (PEF) can be used to establish the diagnosis of asthma and to monitor disease control. Peak expiratory flow measurements also enable patients to predict the onset of worsening asthma earlier than monitoring their symptoms alone (Harm et al, 1985; Sly et al 1985) and measurements are used to aid the diagnosis of asthma in one of three ways. In addition to a history of characteristic symptoms, in general practice a diagnosis is usually confirmed if one or more of the following are present:

- There is a significant increase in PEF (15% or greater) after inhalation of a short acting $beta_2$-agonist (referred to as *reversibility*).
- There is a 15% or greater decrease in PEF after exercise.
- There is a greater than 20% diurnal variability in PEF over a 24 hour period.

As well as being useful in establishing a diagnosis, PEF measurements are also used to monitor patients' disease in response to treatment and/or triggers. In poorly controlled asthma, the diurnal variation of PEF is usually 20% or greater. To examine the degree of diurnal variation, patients measure their PEF for one or ideally two weeks, morning and evening. The minimum and maximum readings are identified and the daily variation is calculated.

In clinical practice, a percentage is not usually calculated. Instead, observing the PEF measurements plotted on a chart usually assesses the degree and pattern of variability. In epidemiological studies an accurate figure is required and there has been some debate as to which index should be used.

In the 1980s, there were a variety of formulae to calculate PEF variability; this consequently produced different indices. Higgins and colleagues (1989) proposed the *amplitude percent mean* is the best variability index to use after examining serial PEF recordings from a community sample of 350 patients. On the whole, this index gives better distinction between asthmatic and non-asthmatic patients than other indices and is relatively easy to calculate (Higgins et al, 1989). The formula for *amplitude percent mean* is shown below.

$$\textbf{Diurnal variability (\%)} = \frac{\textbf{highest PEF - lowest PEF}}{\textbf{mean PEF}} \times 100$$

Peak expiratory flow variability has been shown to correlate well with bronchial reactivity to histamine (Ryan et al, 1982) and is widely used in epidemiological studies (Higgins et al, 1989). There is evidence that changes in PEF predict changes in FEV_1 (Dekker et al, 1992) and well-performed serial PEF measurements over a week have been shown to be more sensitive than a single spirometry reading in detecting changes in airway function (Enwright et al, 1994).

However, it has been shown that with repeated use, some peak expiratory flow meters may provide a less reliable measure of pulmonary impairment than FEV_1 (Vaughan et al, 1989; Shapiro et al, 1991; Miller et al, 1992).

1.4 The Aims of Asthma Management

Effective asthma management aims to achieve for the patient:

- minimal or ideally no symptoms, especially at night
- a normal level of activity (individually determined), including employment, schooling, sport, leisure activities etc.
- normal or best achievable FEV_1 (at least 80% of predicted)
- PEF diurnal variation of less than 20%, ideally less than 10%
- no exacerbations requiring nebulisation or rescue courses of oral steroids (Hargreave et al, 1990; Jamison and Mckinley, 1993; BTS et al, 1993).

Each patient with asthma is different. Their treatment requires tailoring to their individual needs, taking into account lifestyle, level of motivation, understanding of asthma and their educational attainment (Evans, 1993). Tattersfield and Holmes have proposed that effective asthma management is multi-faceted, with pharmacological and non-pharmacological components being interdependent upon each other (Tattersfield and Holmes, 1995).

1.5 Pharmacological Management of Asthma

When asthma was considered a disorder of airway smooth muscle, treatment focused on the relief of the symptoms of cough, wheeze and breathlessness with bronchodilators. Since recognition that the main physiological feature of asthma is inflammation, anti-inflammatory therapies have been added to the armamentarium of drug therapy. What follows is an overview of the most commonly used drugs in the management of chronic asthma.

1.5.1 Short Acting $Beta_2$-Agonists

Short-acting adrenergic agonists have been used to relieve the symptoms of asthma for more than sixty years. Over that time they have changed from non-selective agents (adrenaline) to beta-selective (isoprenaline) and more recently to $beta_2$-selective agents (salbutamol and terbutaline). This evolution of therapy has been accompanied by a reduction in the side effects of tachycardia and tremor.

The main advantage to inhaled short acting beta$_2$-agonists is their fast mode of action as bronchodilators. They provide almost immediate symptom relief and are often the only medication used by mild asthmatics. Until the early 1980s, treatment regimes advocated the use of beta$_2$-agonists three or four times a day. In contrast, it is now recommended beta$_2$-agonists are prescribed only for symptomatic relief.

Shepherd and colleagues conducted one of the earliest studies comparing regular versus symptomatic use of inhaled beta$_2$-agonists. In this study, 18 patients were prescribed salbutamol 100 μg two puffs four times daily or matching placebo, each for one week, in a cross-over trial. The patients taking salbutamol regularly only required 2.7 puffs of "rescue salbutamol", compared to 5.9 puffs in the placebo group. The evening PEF measurements (measured shortly after two puffs of salbutamol) for the patients in the "regular" group were higher, therefore the researchers concluded that regular treatment was preferable. From the results of this study of just two weeks therapy in 18 patients, regular treatment with salbutamol became accepted practice in the UK and elsewhere (Shepherd et al, 1981).

It was not until a significant increase in asthma deaths in New Zealand compared to the UK was observed early in the 1980s that treatment regimes using regular short acting beta$_2$-agonists were questioned (Sears et al, 1986). Evidence gradually emerged that *regular* use, whether as the only therapy or in conjunction with prophylactic medication, had a deleterious effect on the long-term control of asthma symptoms. The key study to support this thinking came from New Zealand where 64 asthmatics were followed up for one year in a double-blind, randomised, placebo-controlled cross-over study. Sears and colleagues demonstrated there was worse asthma control in the patients who received regular beta$_2$-agonist (fenoterol). Also, the number of exacerbations and their deleterious effect was not reduced, regardless of the dose of corticosteroid given and there were highly significant decreases in pre-bronchodilator FEV_1, morning PEF readings and increased PEF diurnal variation (Sears et al, 1990). The group also reported further data from this study a few years later. The patients who received regular beta$_2$-agonist had increased exacerbations, a significant decline in lung function and increased responsiveness to methacholine (Taylor et al, 1993).

Results from this work informed a change in practice early in the 1990s and clinicians were therefore encouraged to prescribe short-acting beta$_2$-agonist therapy

for symptomatic relief only "as and when required". Although Sears and colleagues showed that regular treatment with fenoterol resulted in worse control, results of other studies did not support this conclusion and debate around this issue has continued into the next decade (Wanner, 1995; Sears, 1995; Drazen et al, 1996; Dennis et al, 2000).

Two studies performed more recently have provided reassurance that regular use of inhaled $beta_2$-agonist (salbutamol) should not affect the exacerbation rate in patients with mild asthma. The first in 1996 by Drazen and colleagues reported no worsening of PEF readings in patients with mild asthma taking only regular $beta_2$-agonist (Drazen et al, 1996).

The second study was performed in 115 general practices in the UK with nearly 1000 patients. It was a randomised, double-blind, placebo-controlled study of the effects of regular use of inhaled salbutamol on the control of asthma. The majority (90%) of the patients in the study were taking inhaled corticosteroid and all continued to use their usual inhaled $beta_2$-agonist for symptomatic relief. There were no differences in morning PEF rate or the annual rate, timing or duration of exacerbations between the two groups. In the group receiving regular salbutamol, the use of reliever bronchodilator was also less ($p = <0.001$). Although it was found that the mean evening PEF and diurnal variation were greater ($p = <0.001$), this was not considered to be clinically relevant. The authors concluded that whilst regular use of inhaled short acting $beta_2$-agonist (salbutamol) of a normal therapeutic dose should not affect exacerbation rates, increased requirement indicated that the disease may not be optimally controlled and additional treatment should be used (Dennis et al, 2000).

This study demonstrates regular use of inhaled $beta_2$-agonist impacts minimal harm; however, it fails to show it is of benefit. Evidence from this study has not yet been incorporated into national and international guidelines. The majority of these were composed in light of evidence that regular use of inhaled $beta_2$-agonist has deleterious effects on a range of variables. Therefore the universal recommendation is that they should only be used for symptom relief and not regularly as maintenance therapy except for patients with severe persistent asthma (NEAGDG 1996; RCGP 1993; NHLBI 1995; CTS et al, 1996; BTS et al, 1997).

1.5.2 Inhaled Corticosteroids

Inhaled steroids are very effective at controlling inflammation in the airways of patients with asthma (Barnes 1995). They reduce hyper-responsiveness by modifying the inflammatory process and by acting on airway smooth muscle. Their main advantages are:

- reduction of both night-time wakening and diurnal variation in airway function (Wempe et al, 1992)
- enabling patients to stop taking oral steroids and subsequent reduction in the associated risks of systemic steroids (Reed, 1990)
- protection against inhaled allergens (Dahl and Johansson, 1982)
- suppression of bronchial reactivity both in the early and late response to allergens (Cockroft and Murdoch, 1987)
- reduction of the risk of fatal and near-fatal asthma (Ernst et al, 1992)
- prevention of long-term airway damage (Haahtela et al, 1991 and Haahtela et al, 1994)

There are some disadvantages to using inhaled corticosteroids (IHCS), but in short-term use the benefits tend to outweigh any disadvantages (Barnes 1995). For children and adults who require asthma treatment for many years, there remains concern about long-term effects.

The disadvantages of taking IHCS are:

- they need to be taken regularly
- at higher doses, systemic effects may be caused by the drug being ingested via the mouth or stomach
- there may be local side effects such as dysphonia, candidiasis, cough and throat irritation
- systemic absorption via the lung is variable and depends on the compound and delivery device. (In extreme cases this may cause adrenal suppression, osteoporosis or glaucoma)
- some thinning of the skin or bruising may be experienced
- the growth rate in children may be reduced in those taking higher doses of IHCS

The main concern regarding the long-term use of IHCS has been their systemic activity. When a patient uses a standard metered dose inhaler (MDI) only about 10-20% of the drug actually reaches the lung. Much of the dose is absorbed directly into the systemic circulation via the mouth or stomach if swallowed. Devices such as large volume spacers help filter out larger fast moving particles from MDIs and therefore optimise the amount reaching the lung, whilst decreasing gastrointestinal absorption. Until more is known about the long-term risks, the main objective has been to change the drug composition to ensure the inhaler devices deliver the optimum dose to the lungs whilst minimising systemic absorption.

Different IHCS are metabolised in different ways. The gastrointestinal tract poorly absorbs Fluticasone, so it carries a better risk to benefit ratio. Whilst systemic side effects will still be observed from absorption via the lung, fluticasone is estimated to be equipotent to half the dose of other inhaled steroids such as budesonide and beclamethasone (Barnes 1996).

1.5.3 Long-Acting Inhaled Beta$_2$-Agonist

Long-acting inhaled beta$_2$-agonists, such as salmeterol, have been shown to help by:

- maintaining bronchodilation over a 24 hour period (Ullman and Svedmyr, 1988)
- improving asthma symptoms and PEF readings in comparison to placebo and short-acting beta$_2$-agonists (Pearlman et al, 1992; Fitzpatrick et al, 1990)
- reducing a patient's requirement for corticosteroids when used as an add-on therapy (Wilding et al, 1997)
- giving prolonged protection against exercise-induced wheeze (Fitzpatrick et al, 1990)
- reducing nocturnal symptoms (Greening et al, 1994)

Due to the concerns regarding the regular use of short-acting beta$_2$-agonists (Sears, 1990; Taylor et al, 1993), it is currently recommended that long-acting beta$_2$-agonists are not used in isolation but as an "add-on" therapy (BTS et al, 1997). However, emerging evidence suggests if regular bronchodilation is required for asthma control, long-acting agents are to be preferred over short-acting beta$_2$-agonists (Pauwals et al, 1997).

1.5.4 Non-Steroidal Anti-Inflammatory Medication

Non-steroidal anti-inflammatory medications may be prescribed in addition to, or instead of inhaled steroids. Many paediatricians will give an initial trial of inhaled sodium cromoglycate before using inhaled steroids despite some unpredictability in its effectiveness. Approximately 70% of patients will notice some improvement in their asthma symptoms with sodium cromoglycate (Hargreave et al, 1990; Holgate 1996a).

Another non-steroidal preparation used is inhaled nedocromil sodium. As an add-on therapy for patients still experiencing symptoms with high dose IHCS, additional relief can be obtained (Wells et al, 1992; Clancy and Keogan, 1994; Holgate, 1996b). Nedocromil may also help reduce the requirement for high dose IHCS by 31% (Wong et al, 1993).

Sodium cromoglycate and nedocromil sodium must be taken four times a day, at least in the first few months of treatment. This regular dosing may be impractical for some patients. However for those patients who do not respond to $beta_2$-agonists, who need improved prevention of exercise-induced asthma, who cannot or will not take corticosteroids, non-steroidal anti-inflammatory medication has an important role (Barnes, 1995).

1.5.5 Oral Corticosteroids

Oral corticosteroids have been used for the treatment of asthma for over forty years (MRC 1956). Oral corticosteroids reduce the cells that are important in the pathogenesis of asthma, namely mucosal cells, T-cells and eosinophils (Robinson et al, 1993; Bentley et al, 1996). Oral corticosteroids significantly reduce patient's requirement for inhaled bronchodilator medication, reduce asthma symptoms and improve measurements of airway function including bronchial reactivity (Djukanovic et al 1996). They are of particular benefit in unstable asthma (Fiel et al, 1983) and are the recommended drug for "rescue therapy" in acute exacerbations (BTS et al, 1997). The main disadvantages associated with regular, prolonged oral steroid use are: osteoporosis, diabetes, hypertension, infection, obesity, and adrenal suppression. The development of the inhaled preparation beclomethasone dipropionate in 1972 has reduced the prevalence of these undesirable side effects in the routine treatment of asthma.

1.5.6 Theophylline

Theophylline is an effective bronchodilator, possibly with some anti-inflammatory properties (Barnes and Pauwals, 1994). Theophylline is given orally and is particularly effective in patients with persistent nocturnal symptoms (Barnes et al, 1982; Crescioli et al, 1996). There have been some concerns about its safety as it interacts with other drugs such as antibiotics and has a narrow therapeutic window. Nausea, vomiting and restlessness are well-recognised side effects. There have also been reports of increased acid secretion, gastro-oesophageal reflux and diuresis and with high serum concentrations patients may experience seizures and cardiac arrhythmias (Furukawa et al, 1988). There have also been concern expressed that theophylline, even at therapeutic concentrations, may lead to behavioural disturbances and learning difficulties in school children. The risk of side effects is minimised by sustained release preparations and monitoring of serum levels. British asthma guidelines recommend that theophylline and anticholinergic therapies (described below) should not be used alone, but to supplement IHCS and regular bronchodilators (BTS et al, 1997).

1.5.7 Anticholinergic Therapy

Ipratropium and oxitropium bromide are inhaled anticholinergic bronchodilators. They take longer to work than short acting $beta_2$-agonists (twenty to thirty minutes compared with five to ten) and have a fairly limited role in the treatment of asthma. Their main use is as an additional therapy in the treatment of an acute attack in children and they are useful for the treatment of adult patients who experience tremor with $beta_2$-agonists.

Anticholinergic drugs are possibly more effective at relieving the bronchoconstriction associated with COPD and are frequently prescribed to older patients. The main side effects from nebulised therapy are visual disturbances and glaucoma. Therefore, suitable precautions to shield patients' eyes are recommended during administration.

1.5.8 Leukotriene-Receptor Antagonists and Leukotriene Mediators

Although corticosteroids are one of the most potent anti-inflammatory agents available, there are a proportion of patients who do not respond despite administration of high doses; these patients require alternative medication regimes.

Leukotrienes, which are lipid mediators generated from the metabolism of arachidonic acid, play an important role in the pathogenesis of asthma.

Leukotriene production is increased in asthma and agents that block this have a unique mode of action as they have both anti-inflammatory and bronchodilatory properties. This suggests they play a key role in the treatment of asthma. They have complementary anti-inflammatory effects in asthma management and therefore offer additional clinical benefit in some patients.

Leukotreine synthesis inhibitors and leukotriene receptors antagonists are oral preparations that are currently prescribed as additional therapy to patients already receiving IHCS. Zileuton is the only leukotriene modifier currently available for clinical use. This is given once a day and has been shown to attenuate bronchial hyper-responsiveness to histamine (Fischer et al, 1995; Dekhuijzen et al, 1997).

Leukotriene antagonists are given twice a day, and in trials as a first line therapy have been shown to improve FEV_1 and symptoms (including night time) and reduce the requirement for $beta_2$-agonist in mild to moderate asthmatics (Spector et al, 1994; Fish et al, 1997; Barnes and Pujet, 1997). There is also evidence to support their use in patients who also have allergic rhinitis, in patients with exercise induced asthma, for aspirin-sensitive patients and those who have persistent asthma regardless of the severity (Drazen et al, 1999).

The leukotriene modifiers and antagonists are the first new drugs developed for the treatment of asthma in more than 20 years. Although IHCS are more effective with respect to the improvement of lung function, as oral agents leukotriene antagonists are expected to have increased patient compliance (Drazen et al, 1999). Some patients respond more to leukotriene antagonists than others and the reasons for this are not completely understood; this response may be genetically determined.

With evolving evidence, it will be possible to determine their efficacy and safety and also predict which patients will respond to these medications. The leukotriene modifiers and antagonists were not included in the 1997 BTS guidelines for the management of asthma and it remains unclear whether they can be used on their own or should be used in combination with IHCS. Until this has been confirmed it is not known whether they will be placed at either Step Two or Step Three of the guidelines.

1.5.9 Complementary Medication and Alternative Therapies

There is little evidence in favour of most complementary therapies, but patients commonly use them for treatment of chronic conditions, including asthma. Patients may also treat themselves with non-conventional medication such as 'Do-Dos' – a caffeine supplement available over the counter at pharmacies. According to a recent Cochrane review of the use of caffeine in asthma, it appears to improve airways function modestly for up to four hours but has side effects including headache and anxiety (Bara and Barley, 2000).

The use of complementary and alternative medicine has risen substantially over the last decade and it is estimated that 40% of general practices now offer access to at least one complementary therapy (Thomas et al, 1995). It is not clear why so many patients seek complementary and alternative medicine. It may be that their previous experiences of traditional medicine have not entirely satisfied their expectations. The public may perceive complimentary treatments as more successful than traditional approaches and patients may feel more in control of their illness by 'opting out' of conventional medicine. However, many of the therapies used by patients have little proven effect and, like caffeine, may even be harmful. Therefore, a brief summary of the evidence to date for various complementary therapies for the treatment of asthma is set out below.

a) Acupuncture

The evidence to date suggests that acupuncture has an immediate impact on airway obstruction, but its long-term efficacy has yet to be established. A recent review by the Cochrane airways group concluded there is no convincing evidence that acupuncture is a successful treatment for asthma (Linde at al, 2000).

b) Homeopathy

There are three different types of homeopathy- *single, complex* and *isopathic.* Isopathic homeopathy has so far proved to be the most successful. In this method, patients are administered dilutions of an allergen that causes symptoms related to exposure. It has been proposed that homeopathic immunotherapy (HIT) is beneficial to patients with rhinitis and asthma; however, to date there is insufficient evidence to be able to recommend homeopathy as a successful treatment for asthma (Linde and Jobst, 2000).

c) Nutritional Therapies

It has been shown that bronchial hyper-reactivity is related to the dietary intake of magnesium (Britton et al, 1994) and also sodium (Burney 1989). However, which have not been established as useful supplements or nutritional therapies as there have not been any prospective trials.

d) Herbal Medicine

A number of herbal medicines have been used in asthma and some have been evaluated in controlled trials. *Coleus forskholii* has been shown to increase intracellular levels of cyclic AMP and thus may have a bronchodilating effect (Baur, 1993). *Ginkgo biloba* is antagonistic to platelet activating factors (PAF), and hence it limits bronchial reactivity. Oral administration of this has shown to improve pulmonary function and protect against exercise-induced asthma (Wilkens, 1990). *Typholori Asthmatica* (an extract of *Typholori Indica*) has been shown to be of benefit in animal studies. However, between 17 and 53% patients experience adverse reactions with use of this herb (Shivpuri et al, 1972). This serves to remind us that 'natural medicines' are not always safe or free from harmful side effects.

In conclusion, a recent review of herbal remedies for the treatment of asthma no definitive evidence for any of the preparations emerged (Huntley and Ernst, 2000). Considering the popularity of herbal medicine with asthma patients, there is urgent need for stringently designed clinically relevant randomised clinical trials.

e) Yoga and Breathing Exercises

Most work examining the effectiveness of breathing exercise programmes for patients with asthma has examined their impact on patients with acute illness and a degree of fixed airways disease. Inspiratory muscle training in patients with asthma has been shown to be effective at improving symptoms and reducing the need for $beta_2$-agonist medication (Weiner et al, 1992).

There has also been some reported success with the use of *pranayama* or yoga breathing exercises. Nagendra and Nagarathna (1986) demonstrated significant reduction in patients' requirement for medication and also improvements in PEF

readings after a two to four week program of yoga exercises and breathing. Another program of exercise (also called the Pink City lung exercise) has been shown to improve objective measurements of airway reactivity, airway calibre, symptom scores and reduced medication use in patients with mild asthma (Singh et al, 1990).

The *Buteyko* breathing technique was originally developed in Russia and has had some evaluation in a group of 39 patients in Australia. Patients with moderate asthma were randomised to either the *Buteyko* or the 'control' breathing class for a period of four months. Patients in the *Buteyko* group had a significant reduction in their requirement for beta agonists ($p = 0.002$) and to a lesser degree inhaled steroids ($p = 0.06$). However, there was no improvement in objective measures of airway calibre (morning PEF, FEV1, end tidal carbon dioxide or resting minute volume); they did report better quality of life, although this did not reach statistical significance ($p = 0.06$).

Anecdotally, through personal contact with respiratory nurses it has been reported that by giving advice to patients to slow their breathing, some have been able to avert an attack. However, this has not been systematically evaluated and the whole subject of breathing exercises has received insufficient appraisal and this needs to be addressed by further research.

f) Environmental Control - Allergy Avoidance

The significant seasonal variations in asthma attacks are related in part to changes in exposure to different triggers. Modification of patient's environment to reduce allergen exposure can be beneficial. If individuals sensitive to house dust mite are moved to houses at high levels of altitude, (where house dust mite levels are considerably reduced), their symptoms resolve spectacularly (Boner et al 1985; Peroni et al, 1994). Similarly moving patients to allergy-free environments, such as a hospital, results in increased lung function and decreased medication use (Platts-Mills, 1992b; Harving et al, 1994). In practice allergy avoidance may be limited to regular vacuuming of carpets or mattresses rather than the more extreme measures of moving patients to a different environment.

Advising patients about allergy avoidance needs to be allergen-specific and patient-specific. Domestic pet allergens are usually inhaled in large quantities on

small particles, which penetrate deep into the airways. The reverse is true for the house dust mite allergen, *Dermatophagoides pteronyssinus*. Consequently, the onset of asthmatic symptoms associated with house dust mite sensitivity is usually more insidious in contrast to those experienced when patients come into contact with domestic pets. Patient's sensitivity to different allergens varies; a small amount of allergen may trigger a large reaction in some patients, whereas in others a greater amount is required to create the same degree of symptoms.

Air filtration units may be useful in reducing allergens from domestic pets such as cats and dogs, but not those produced by house dust mites. It has been shown that a clinically significant improvement may be achieved after six months of reduced levels of house dust mite; the same level of improvement may take longer to achieve following the removal of domestic pets as a reservoir of allergen remains in the home for many months (Wood et al, 1989).

Because of the varied response, the unreasonable commitment required by individuals and ineffective strategies, it has been difficult to transfer the results from allergen avoidance trials in the laboratory and "controlled" environments into patients' homes. A Cochrane review of randomised trials concluded in patients with asthma there was not convincing evidence that methods to reduce or control exposure to house dust mites (or their products) improve outcomes. Therefore, as these methods seem to be ineffective they cannot be recommended (Hammerquist et al, 2000).

g) Environmental Control - Tobacco Smoke

Cigarette smoke is a major irritant to patients with respiratory disorders. Asthma tends to be more poorly controlled in patients who smoke and this is reflected in their increased requirement for medication (Jindal et al, 1994).

The government has outlined its strategy to tackle the problem and one element of this is to provide smoking cessation programmes for the adult population (DOH 1998a).

There is also strong evidence for the use of nicotine replacement therapies, such as patches and chewing gum, in the general population (Tang et al, 1994; Silagy et al, 1994: Fiore et al, 1994). However, in the past, health education programmes regarding smoking cessation have not been specifically targeted to patients with asthma. The British Thoracic Society have addressed this with

advice for health professionals that advocates the use of education and nicotine replacement therapy (Raw et al, 1998).

1.6.1 Non-pharmacological Management of Asthma

It is a widely held view that effective management of asthma requires the use of non-pharmacological measures as well as medication and a shift towards increased patient education and self-management has been particularly apparent in the last decade (Hilton, 1993; Tattersfield and Holmes, 1995; Neville 1996). However, the evidence for the effectiveness of self-management and education remains poor.

The literature about patient education and self-management is extensive and is summarised in Tables One and Two on pages 37-39 and 46-47. In these tables, the evidence has been graded according to the criteria used by the North of England Asthma Guideline Development Group (NEAGDG, 1996). The levels of evidence are:

- Level I Well designed randomised controlled trials, meta-analysis, or systematic reviews
- Level II Well designed non-randomised prospective or retrospective controlled studies
- Level III Uncontrolled studies or consensus

In addition, the studies were assessed according to the level of evidence and the clarity of the described methodology and were graded A to C:

- A Directly based on level I evidence
- B Directly based on level II evidence, or extrapolated recommendation from level I evidence
- C Directly based on Level III evidence or extrapolated recommendation from level I or level II evidence

1.6.2 Evaluation of Education Programmes for Patients with Asthma

The need for education to help patients and their families manage their asthma effectively and live active lives is well recognised in clinical practice. The first part

of the International Consensus Report on the Diagnosis and Treatment of Asthma outlines patient education as:

> "A continual process designed to provide the asthma patient and his family with suitable information and training, so that the patient can keep well and adjust treatment according to a medication plan developed with the clinician" (NHLBI, 1995).

However, patient education alone is rarely successful in improving morbidity from asthma and there has been limited work to support the use of patient education programmes in general practice. Providing information in leaflets can help to inform patients with asthma about their disease. However, the material needs to be appropriate for all individuals and not above the average reading age of the target community (Bauman et al, 1989 and 1993; Smith et al, 1998). Patient information leaflets must also be up to date and congruent with current guidelines. In a recent study examining the accuracy of 168 different asthma leaflets stocked by practices in Wessex, 20% were found to contain inaccurate or misleading advice (Smith at al, 1998).

In a meta-analysis of 63 studies of education in the care of patients with chronic diseases, Mazzuca showed that programmes with a behaviour-orientated structure to facilitate a change in the patient's lifestyle and environment, were more effective than those purely providing information (Mazzuca, 1982).

A Cochrane review of the effects of limited patient education concluded health outcomes for adults with asthma are unlikely to be improved by the widespread use of information alone (Gibson et al, 2000a). In this review of 156 titles and abstracts, 53 studies were identified. Forty-two papers were excluded as they did not fulfil the methodological criteria, or because the interventions or outcomes measured were not appropriate. Twenty-four papers were excluded because they contained elements of self-management or behavioural change; these were included in a subsequent review of self-management by the Cochrane Airways Group. Eleven papers fulfilled all of the criteria set by the Cochrane collaboration and the reviewers. The outcomes that were examined are listed overleaf):

- hospitalisation
- visits to accident and emergency department
- contact with doctor (GP)
- lung function
- medication use
- symptoms

From the review, it was concluded limited asthma education programmes that only give information and make no attempt to influence attitudes, behaviour and self-management skills, do not improve patient's perception of the severity of their symptoms. Limited education may reduce the number of visits to Accident and Emergency departments in patients who were previously frequent attendees. Also, patients who present to an Accident and Emergency department with an exacerbation of their asthma may benefit from receiving written information. However, these improvements are not reflected if other outcomes are assessed. Limited patient education does not reduce hospitalisation rates, visits to the doctor, modify medication use, reduce the amount of time lost from work or improve lung function.

In order to give a taste of the types of interventions tested and the evaluative methods used, I have summarised the findings of 14 key studies (including the 11 evaluated in the Cochrane review). The studies are discussed in more detail below under separate headings of General Practice and Secondary Care.

a) Evaluation of Patient Education Programmes in General Practice

One of the first studies to assess the impact of education for patients with asthma in general practice was performed by Hilton and colleagues (1986). Patients were randomly assigned to maximum education, limited education or a control group. The maximum education group were given a booklet about asthma, a treatment card and quarterly follow-up appointments with their GP. The limited education group only received the booklet and card by post and the control group did not receive any additional materials or education. Outcome measurement included a questionnaire that assessed patients' knowledge and understanding of asthma (Hilton et al, 1982). After 12 months, 274 (80%) of the original 339 patients were reassessed. The group

receiving maximum intervention showed significant improvement in asthma knowledge (p=<0.05), patient satisfaction and emergency hospital attendance compared with the limited education and control groups. There was no significant improvement in self-management skills or morbidity (Hilton et al, 1986).

Two years later, Jenkinson and colleagues (1988) demonstrated that the use of an audiocassette tape was superior to a booklet in improving patients' knowledge scores about asthma; but patients found the booklet more acceptable!

More recently as part of the Grampian asthma study of integrated care (GRASSIC), Osman and colleagues (1994) examined the impact of an asthma education programme across four areas of Scotland. This was a pragmatic randomised, factorial trial comparing outcomes over 12 months between patients taking part in an enhanced education programme (four personalised booklets, sent by post) and patients receiving conventional oral education at outpatient or surgery visits. Patients were recruited into the study as they attended outpatient clinic for review between October 1989 and December 1990 and randomised to one of six groups. These were either integrated or clinic care, prescription of a PEF meter or no prescription, enhanced education or a control group.

The outcomes (morbidity and hospital admissions) of the intervention group were compared with a matched randomised control group who only received conventional oral education at outpatient visits. There was only a small reduction in morbidity (measured by night-time disturbance, extra visits to GP and days of restricted activity) for the intervention group compared with the control, and the changes in outcome were not statistically significant. After controlling for the length of time patients received education, the only outcome that significantly improved was the risk of admission to hospital. Patient in the intervention group had 54% fewer admissions than the control group (p=<0.05) (Osman et al, 1994).

The above studies focus on one-to-one education. Group education is an accepted method in promoting health in ante-natal patients and smokers. In the management of chronic diseases such as diabetes, there has also been some success in providing education to patients in groups (Ridgway et al, 1999). In asthma however, the evidence does not support group education. There have been two studies that have looked at this approach with patients in general practice. In a randomised controlled trial of individual education versus group education, both groups of 34 patients achieved similarly significant improvements in knowledge scores, but the individual

education took a total of 14.25 hours compared to 4.5 hours of health professionals' time for the group education (Thapar, 1994).

A recent large study of patients with asthma and COPD conducted in general practice concluded that on the whole, intensive, small group education with peer review was not effective in changing patient's health outcomes. This was regardless of age, severity and medication at baseline (Smeele et al, 1999).

Apart from these studies there has not been any other work published that compares the traditional approach of educating patients individually to group education for patients with asthma in general practice. Therefore, it cannot be recommended as better than the traditional one-to-one method.

b) Evaluation of Education Programmes in the Outpatient Setting

More research has focused on education provided in the outpatient department. These interventions have tended to target high-risk asthma patients, recruiting them after an acute attack requiring hospital admission or attendance at an accident and emergency department.

In an early study in the 1970s, Maiman and colleagues (1979) demonstrated that education of individual patients during Accident and Emergency room consultations improved knowledge and reduced the frequency of visits. They performed a randomised factorial, prospective, experimental study in 245 patients to assess the impact of different educational and motivational interventions, such as a book, an interview and a telephone follow-up on patients' asthma and self-management skills. The asthma nurse educator in the study was an asthmatic herself and this appeared to be the main factor that influenced the effectiveness of the education in reducing emergency room visits (p= <.05). There was no significant effect found for the booklet or the interaction between asthmatic nurse and booklet.

Ringsberg and colleagues (1990) observed a significant reduction in hospital admissions in a randomised controlled trial of education provided in an "asthma school" within an outpatient clinic. Thirty-eight eligible patients were identified from 121 approached. Self-administered questionnaires were used to assess patients' level of knowledge and quality of life at the start, after 5 and after 12 months of study. Lung function and reversibility were also assessed using spirometric tests. After 12 months, those who attended the "asthma school" had a

significant reduction in hospital admissions, had better quality of life according to the Nottingham Health Profile (a generic health measure) and also had increased knowledge of how to prevent attacks, compared to the control group. They did not report the results at 5 months (Ringsberg et al, 1990).

Three years later, Yoon and colleagues observed improvements in knowledge, psychological disturbances, behaviour, and symptoms after a brief education programme for patients recently discharged from hospital after a severe exacerbation of their asthma. However, there were no differences in average PEF readings or their daily variability (Yoon et al, 1993).

In the outpatient setting, there has also been work that has demonstrated structured patient education is cost-effective (Trautner et al, 1993). Trautner and colleagues showed a reduction in the overall costs associated with hospital admission for asthma (hospitalisation and lost productivity) over a three-year period following a five-day, *in-patient* education programme. The reduction in associated costs per patient was estimated to be 12,850 Deutschmarks overall. Of this, the health service saved 5,900 Deutschmarks per patient. These savings equate to approximately £4,000 in total and £2,000 to the health service over a three-year period. However, it is unclear if the patients were admitted especially for the five-day programme and also the precise cost of the programme was not reported, nor was it reported if the savings were sustainable over a longer period of time.

c) Do Patient Education Programmes for Asthma Improve Outcomes?

We would expect patient education programmes to improve outcomes. However, it has been evident for some years purely giving information to patients does not necessarily increase their adherence with medication regimes or encourage more healthy behaviour. There has been less work performed to assess the effectiveness of patient education programmes in primary care. The majority of data come from the outpatient setting and the existing evidence suggests that programmes are more effective in the outpatient setting, rather than in primary care.

This may reflect differences in the severity of the asthma managed in the two settings. Patients attending an outpatient clinic are likely to have more severe asthma and have more scope for improved outcomes than those managed in general practice. Also, it is likely the education of patients about asthma in general practice

varies according to individual clinicians' knowledge and experience and the information materials used (Smith et al, 1998).

Bradley and colleagues (1999), in a recent review of intervention development for trials, reminded us of the need to ensure that multifaceted interventions have a sound theoretical approach. Perhaps the development of more effective interventions in primary care will arise from closer collaboration between social scientists and educationalists.

Table 1. Studies Examining Education Strategies for Patients with Asthma (cont'd overleaf)

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Grading
Maiman et al ©	1979	Evaluation of effectiveness of educational and motivational intervention in A&E	(USA) Randomised, prospective study of factorial design with sequential introduction of interventions (nurse with or without 'shared characteristic of asthma', positive written material, interview or telephone follow up). 289 patients interviewed at end of A&E visit	The asthmatic nurse educator was generally more effective in achieving short-term reduction of emergency department visits. Although the usefulness of the positive written material increased when employed by the asthmatic nurse, there were no substantive independent effects of the written message on emergency department use.	I C
Moldofsky et al ©	1979	A videotape educational program for use in adults.	(Canada) Randomised controlled study to examine the benefits in 62 patients whose mean duration of illness was 17 years was assessed by comparing the level of knowledge of the experimental group immediately after viewing the tape with that of the controls	The experimental group scored significantly higher than the control group assessed after a mean interval of 16 months. The knowledge test score of the experimental group was found to have decreased to the level of the control group. The main areas in which the experimental group lost knowledge were self-care and drug therapy for asthma. The medical status of the two groups did not change appreciably over the period of the study.	I C
Hilton et al ©	1986	Structured education using a booklet, treatment card and regular review	(UK) Randomised, controlled study of morbidity and patient's knowledge about their asthma. 339 patients (aged 5 to 70) in OPD randomised to maximum or limited education	Re-assessed after 12 months (274 patients) maximum education group had significantly more asthma knowledge but this was not converted into self-management skills or improved morbidity. Education strategy may not have been appropriate for the wide age range (5 to 70)	I C
Jenkinson et al ©	1988	A specially prepared book and audiocassette tape	(UK) Randomised controlled trial in 177 patients in general practice. After a run in period of six months patients were randomly given the book, the tape, both the book and tape, or neither. Patients' knowledge of the use of drugs, perceptions of their disability, skill in using an inhaler, consumption of drugs, consultations with their general practitioners, morbidity (from patients' entries on diary cards), and use of the educational material were measured.	Knowledge about the use of drugs was significantly increased in groups who received the material after three months and persisted after 12 months. Patients who had been given the tape or the book and tape increased their scores of knowledge of drugs more than patients given the book alone. Patients in all groups given the material considered that their disability was reduced. Patients given both the book and the tape preferred the book.	I B

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Table 1. (cont'd) Studies Examining Education Strategies for Patients with Asthma (cont'd overleaf)

Ringsberg et al ©	1990	Multiprofessional asthma school	(Sweden) Randomised controlled trial to evaluate the benefit of OPD asthma school regarding knowledge, process and physiological outcomes	Re-assessed after 5 and 12 months. At 12 months compared to control, those who had attended the school had increased knowledge, quality of life (SF36) score and less admissions to hospital. 5 month outcomes not reported	I C
Mayo et al ®	1990	Rigorous medical regimen, use of spacer and educational programme to teach self-management	(USA) Randomised patient selection, with crossover. 104 patients identified with multiple hospital admissions, 47 randomised to intervention, 57 continued routine OPD review only. 19 patients from control crossed over to intervention group	Achieved significant reduction in hospital re-admission rates for the intervention group. No other outcomes reported. Minimal, not significant improvements in FEV_1	II C
Bolton et al ©	1991	Follow-up education programme for high frequency emergency room attenders	(USA) Randomised controlled trial of education (3 visits) given by specially trained nurse in OPD, followed up with telephone interviews. Outcomes measured - hospital visits and activity limitation	Mean monthly emergency room visits were significantly less for intervention group than control, intervention group also had less days of limited activity, demonstrated as reduced health service costs.	I C
Huss et al ©	1992	Computer education for adults with asthma	(USA) Randomised controlled trial in A&E	No effect seen in medication use	I C
Yoon et al ®	1993	Brief educational programme (2.5 to 3 hours), in small groups, on one occasion post admission to hospital	(Australia) Randomised controlled trial in 76 patients in OPD, using questionnaire, spirometry, home PEF monitoring; followed up at 5 and 10 months	Significant reduction in re-admission rate for intervention group. No difference in physiological airways measurements. Improved knowledge and self-management skills in intervention group	I B
Trautner et al ®	1993	5 day inpatient education programme	(Germany) Longitudinal cost effectiveness analysis of structured education for patients with asthma; followed-up at 3 years. Measured costs incurred by hospitalisation, number of visits and attacks and lost productivity	Significantly less attacks over the period of intervention than the year before and significant reductions in cost	III C

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Table 1. (cont'd) Studies Examining Education Strategies for Patients with Asthma

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Grading
Wilson et al ©	1993	Self-management education programme	(USA) Randomised, controlled study in OPD. Patients assigned to 1 of 4 groups; group education, individual education, workbook and control group. Outcomes measured - symptoms, bother rating, physician rated asthma status, activity, environmental control and MDI technique	All 3 education groups were associated with significant improvements in control of symptoms, MDI technique and environmental control practices. Small group education was also significantly associated with physicians evaluation of improved asthma status and activity levels	I B
Thapar et al ©	1994	Education of patients in small groups	(UK) Randomised controlled trial to assess improvement in knowledge about asthma. A specially designed questionnaire was used to assess knowledge and other variables before and after education. 34 patients in each intervention	Significant improvements in knowledge scores after both types of education. Group education took 4.5 hours for 34 patients, individual counselling took 14.25 hours for the same number. is acceptable to patients and takes much less time.	I C
Garrett et al ®	1994	Hospital based education programme	(New Zealand) Prospective controlled study in community health centre of high emergency room attendees	Intervention group had small improvements in morbidity but had more preventive medication, PEF meters, better knowledge and self-management skills than the control group	II B
Osman et al ©	1994	Personalised, computer supported education programme comprising of four booklets	(UK, Scotland) Pragmatic randomised trial in hospital OPD and general practice. Patients were randomised to enhanced education or control group receiving traditional oral advice only. Outcomes of morbidity, hospital admissions, consultations with GP, drug use, restricted activity and nocturnal symptoms	Intervention group had significantly fewer hospital admissions and less nocturnal wakening. No other differences were observed	I B

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1.6.3 Self-Management

Structured self-management plans (SMPs) aim to give patients greater control over their disease by actively involving them in making treatment decisions. Their use enables patients to monitor their response to medications and the impact of any triggers on their symptoms (Neville, 1996).

Some patients can judge the severity of their disease from their symptoms, but PEF measurements give some patients a more objective assessment of their asthma than symptom monitoring (Harm et al, 1985; Sly et al, 1985; Beasley et al, 1989; Charlton et al, 1990; Kendrick et al, 1993). Self-management plans are especially useful for patients who deteriorate rapidly, or those who tend to underestimate the severity of an exacerbation, often called "poor perceivers" (Sly, 1975; Rubinfeld and Pain, 1976; Burki et al, 1978; Barnes, 1992).

Until the recent systematic review produced for the Cochrane library was published, the evidence for the use of SMPs in primary care was inconclusive (Gibson et al, 2000b).

The objective of this review was to assess the effects of asthma self-management programmes, when coupled with regular health practitioner review, on health outcomes in adults with asthma. Twenty-five randomised trials of self-management education in adults over 16 years of age with asthma were included and self-management education was compared with usual care in 22 studies. Self-management education reduced hospitalisations (odds ratio 0.57, 95% confidence interval 0.38 to 0.88); emergency room visits (odds ratio 0.71, 95% confidence interval (0.57 to 0.90); unscheduled visits to the doctor (odds ratio 0.57, 95% confidence interval 0.40 to 0.82); days off work or school (odds ratio 0.55, 95% confidence interval 0.38 to 0.79); and nocturnal asthma (odds ratio 0.53, 95% confidence interval 0.39 to 0.72). However, measures of lung function were little changed.

The authors concluded self-management programmes that involved a written action plan showed a greater reduction in hospitalisation than those that did not (odds ratio 0.35, 95% confidence interval 0.18 to 0.68). People who managed their asthma by self-adjustment of their medications using an individualised written plan had better lung function than those whose medications were adjusted by a doctor. Training in asthma self-management which involves self-monitoring by either peak expiratory flow or symptoms, coupled with regular medical review and a written action plan

appears to improve health outcomes for adults with asthma. Training programmes, which enable people to adjust their medication using written action plans appear to be more effective than other forms of asthma self-management (Gibson et al, 2000b).

There has been a considerable amount of work examining the use of self-management plans and many of the studies consider educating patients how to 'self-manage'. There is a degree of overlap of studies included in both the Cochrane review of the effectiveness of patient education and self-management strategies. In Table Two I have included studies that mostly assess the impact of self-management. I have then discussed the work in this area in more detail below, under the headings of General Practice, Outpatient and Community Settings.

GREEN - WHAT TO DO IF WELL (no symptoms, PEF ≥ 80% of predicted) **Maintain treatment of regular preventer and reliever for symptoms**
AMBER - WHAT TO DO IF SYMPTOMS OCCUR (some symptoms, PEF ≥ 50% and less than 80% of predicted) **Double dose of preventer and take reliever every four hours**
RED - WHAT TO DO IF ILL (not responding to reliever, increased breathlessness, PEF less than 50% of predicted) **Start course of oral steroids and seek urgent medical help**

Figure 1. Example of a Patient Self-management Card (Beasley et al, 1989)

a) Evaluation of Patient Self-management in General Practice

It is recommended patients monitor their asthma using PEF readings (BTS et al, 1993 and 1997). The evidence for this recommendation in general practice is thin, but more convincing evidence is available from secondary care.

In general practice, Jones and colleagues failed to demonstrate any significant advantage in self-management plans over standard asthma management. In their randomised controlled trial in 25 general practices, they examined the use of a PEF

self-management programme and regular review by a GP or practice nurse, compared with review only. No significant differences were observed between the groups. The authors suggest that the lack of effect was due to the disease in their subjects being too mild to observe significant improvements. They suggested that rigid self-management strategies may not be appropriate for patients with mild disease as teaching self-management takes much longer than traditional review appointments and there is limited evidence for its effectiveness (Jones et al, 1995).

The Tayside Asthma Management Initiative group headed by Neville has made a major contribution to the evaluation of asthma management in UK general practice. They assessed the impact of self-management plans using 159 GPs who had previously taken part in a national audit of asthma management (Hoskins et al, 1996). Randomisation was at practice level. The intervention was a three-step, self-management plan, similar to that developed by Beasley and colleagues (1989), which was then tailored to the patient's past history of asthma. GPs from the intervention group identified patients who had experienced an attack in the previous three months and issued them with a self-management plan. These patients were compared with patients from the control practices who had also experienced an attack in the previous three months. In the recruitment process, GPs from intervention practices appear to have preferentially selected patients with greater morbidity. So, although there were significant improvements in the intervention group for all outcomes considered (reduced hospital admissions, primary care consultations, asthma symptoms, use of oral steroids and emergency nebulisers), the control group was not comparable (Hoskins et al, 1996).

Baldwin and colleagues (1997) evaluated the effect of written self-management plans administered in a general practice asthma clinic on morbidity, lifestyle and drug usage. The study was conducted in a two-partner practice. Fifty patients were randomised to either written or verbal self-management plans. Improvements in all outcomes were observed and patient's best PEF recording improved by over 50% in both groups. The sample used was rather small, but justified as the study was specifically designed to look at a 'naturally occurring' population that was indicative of an average general practice. The impressive improvement observed in morbidity scores emphasises the importance of appropriate structured management of patients with asthma in general practice, which prior to Baldwin's study had not been substantiated by the literature.

One of the early studies demonstrated that teaching patients about the importance of their symptoms and what to do if their asthma deteriorates may be more important in achieving improved patient care than PEF monitoring (Charlton et al, 1990). Charlton and colleagues (1990) performed a randomised study of self-management based on symptoms versus PEF guided self-management (using a plan adapted from Beasley and colleagues, 1989). The study population was 115 patients (adults and children) receiving prophylactic medication and attending a nurse-run asthma clinic. Both groups achieved improvements in all the outcomes measured: number of GP visits, oral steroids and emergency nebuliser use. This study highlights the importance of evaluating multifaceted interventions to ascertain which is the effective component.

b) Evaluation of Self-management in the Hospital Outpatient Setting

In the outpatient setting, Beasley and colleagues (1989) have shown that a management regimen based on regular objective assessment of airflow obstruction and adequate inhaled corticosteroid therapy is effective for adults with chronic severe asthma. Thirty-six patients between the ages of 14 and 60 had spirometry measured at monthly intervals. They were given a PEF meter and a self-management plan with instructions to increase or decrease their medication according to their PEF measurements. Patients were asked to assess their degree of breathlessness and record on a visual analogue scale the severity of symptoms. There was a substantial improvement in both subjective and objective measures of asthma severity. There was also a significant reduction in the requirement for oral steroids, night-time symptoms and the number of days lost from work together with significant improvement in patients' baseline lung function. However, this was a prospective, uncontrolled study; despite this, the authors believe the magnitude of improvement observed was much greater than could be achieved by a placebo effect alone. It is quite astounding that the results of this study have formed the basis of self-management plans used in primary and secondary care in the UK. Not only was this study relatively small (36 patients), it was not controlled and was performed in a group likely to have more severe asthma and therefore more scope for improvement.

In 1995, Ignacio-Garcia and Gonzalez-Santos published results of a prospective

controlled trial of PEF home monitoring to determine the usefulness of an objective measure of lung function in association with an education program and a medication self-management plan in reducing morbidity in adult patients with asthma. Thirty-five patients managed themselves, using PEF as the basis for the therapeutic plan and 35 control patients used symptoms and spirometric data for following physicians' treatment plans. After a 6-month study period, patients in the experimental group showed statistically significant improvements in morbidity parameters (days lost from work, acute asthma attacks, days on antibiotic therapy, physician consultations, and emergency room admissions for asthma), increases in FVC, FEV1, and FEV1/FVC, mean PEFR and mean morning PEFR, decrease in percentage of the mean PEFR amplitude, and a reduction in the use of inhaled beta-agonists, oral theophylline, and oral prednisolone. Although improvements in some of these parameters were also found in the control group, they did not reach the levels of significance obtained in the experimental group. Therefore, the authors concluded that personal use of an objective measure of lung function in association with a medication self-management plan leads to improvement in the patient's condition. However, it should be noted that the physician who assessed the patients was not blind to which group patients were allocated. Also, 24 (25%) of the original sample of patients dropped out (15 in the experimental and 9 in the control group) and a further 16 were excluded because of lack of PEF data (11 in the experimental and 5 in the control group). Although this was not a significant amount and the authors did not state it adversely affected the results, it demonstrates that to monitor PEF measurements for a long time is unreasonable and unrealistic for all patients.

Lahdensuo and colleagues (1996) compared the efficacy of self-management and traditional treatment in 115 patients with mild to moderate asthma in a prospective, randomised controlled trial. They compared the number of unscheduled hospital admissions and outpatient visits, days off work, courses of oral steroids and antibiotics and the quality of life of patients for a 12-month period. The intervention group received education and adjusted their anti-inflammatory medication according to their PEF measurements. This resulted in a lower mean number of visits, fewer courses of antibiotics and oral steroids and better quality of life scores (Lahdensuo et al, 1996).

c) Assessment of Self-management in the Community Setting

D'Souza and colleagues (1994 and 1998) performed a before and after intervention study in a rural community based asthma clinic. This six-month programme was developed in partnership with the Maori community; 69 patients aged 14-64 (55 female) were recruited after an eight-week run in period. The intervention was a guideline-based self-management plan using symptoms and PEF presented on a credit-card sized aide-memoiré. Patients were followed up at two monthly intervals. Significant improvements in mean PEF (p=<0.001), number of disturbed nights (p=<0.001) and "days out of action" (p=0.03) were achieved. A reduction in the requirement for acute medical treatment was also observed. When 58 of the original 69 patients were reviewed two years after completing the original six-month programme, it was shown this improvement in morbidity was sustained (D'Souza et al, 1994 and 1998).

d) Do Self-Management Plans Improve Patient Outcomes?

The answer to this question is yes, but the most convincing evidence for the use of self-management plans is from hospital outpatients and community clinics (Neville, 1996; Gibson et al, 2000b).

Although the evidence for the use of self-management plans was limited in the early 1990s, their use was recommended in the 1993 BTS guidelines and they were considered "best practice" in primary care and have subsequently become widely used. More research is needed about how to ensure SMPs are effective in primary care in the UK; but, as the use of self-management plans becomes more widespread, it becomes increasingly difficult to withhold the intervention and conduct randomised controlled trials.

Table 2. Studies Examining Self-management Strategies for Patients with Asthma (cont'd overleaf)

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Grading
Beasley et al ®	1989	Assessment of PEF in conjunction with self-management plan	(UK) OPD based study of 36 patients, aged 14-60 using a self-management plan. Open study design. Patients adjusted their medication according to PEF readings. Main message to double dose of inhaled steroids if PEF readings low (<70% predicted/best)	Significant improvement in all outcomes; lung function and symptoms. Open non-randomised, uncontrolled study. However, the degree of clinical improvement introduced the concept of stepping up and stepping down treatment according to PEF readings. Multiplicity of factors may have impacted on results.	II B
Charlton et al ©	1990	Comparison of symptoms only and PEF self-management plans	(UK) Randomised study based in General Practice, 115 patients (adults and children) all receiving prophylactic medication and attending a nurse run asthma clinic. Allocated to symptoms or PEF group using self m'ment plan adapted from Beasley (1989). Outcomes measured; number of consultations with GP, oral steroids and emergency nebulisers	Both groups achieved significant improvements in all outcomes measured. But no significant differences between the two treatment groups in number of GP visits, courses of oral steroids and nebulisers. No difference between adults and children. The use of PEF readings was not the key to improved morbidity.	I A
Dekker et al ®	1992	Assessment of inhaler technique and appropriate use of medication	(Holland) Observational study in General Practice of 150 patients to assess inhaler technique and appropriate use of asthma medication	44% had appropriate medications at home. 77% of those with inhalers made one or more mistakes in demonstrating their use.	N/A no intervention

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Table 2. (cont'd) Studies Examining Self-management Strategies for Patients with Asthma (cont'd over-leaf)

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Grading
D'Souza et al ®	1994& 1998	Credit card self-management plan for asthma	(New Zealand) Before and after intervention study. Rural community based asthma clinic, in partnership with Maori community. 69 patients aged 14-64, predominately female. Intervention of 16 week, guideline based self-management plan using symptoms and PEF introduced after eight week run in period	Significant improvements in mean PEF, number of disturbed nights and days incapacitated. Also a reduction in the requirement for acute medical treatment.	III C
Ignacio-Garcia and Gonzalez-Santos ©	1995	Asthma self-management education program by home monitoring of peak expiratory flow	A prospective controlled trial of home monitoring of PEFR to determine the usefulness of an objective measure of lung function in association with an education program and a medication self-management in adults in outpatients 35 patients managed themselves, using PEF as the basis for the therapeutic plan with educational intervention, 35 control patients used symptoms and spirometric data for following physicians' treatment plans.	After 6 months, patients in the experimental group showed statistically significant improvements in morbidity parameters (days lost from work, acute asthma attacks, days on antibiotic therapy, physician consultations, and emergency room admissions for asthma), increases in FVC, FEV1, and FEV1/FVC, mean PEFR and mean morning PEFR, decrease in percentage of the mean PEFR amplitude, and a reduction in medication.	I B
Jones et al ©	1995	PEF guided self-management plan	(UK) Randomised controlled trial comparing PEF self-management programme versus traditional care with planned visits for patients aged 15-40 years from 24 practices. 72 patients completed intervention data for 84 patients re: diary card. Outcomes measured, lung function, quality of life (Hyland et al, 1991) symptoms and days off work/school	No significant differences measured in PEF self-management group and control. Timing may have contributed - within six months of introduction of new contract. Also the practices that took part were well resourced and historically innovative, possibly less scope for improvement. Practices implemented self-management plans themselves after one briefing meeting. More structured guidance needed.	I (However intervention *could not* be recommended from this study)

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Table 2. (cont'd) Studies Examining Self-management Strategies for Patients with Asthma

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Grading
Lahdensuo et al ©	1996	PEF guided self-management and patient education in comparison to traditional management	(Finland) Prospective randomised controlled trial in 115 adult patients with >15% diurnal variation. Outcome measures; admissions to hospital, OPD visits (unscheduled), days off work, antibiotics, oral steroids and quality of life.	All measurement of outcome improved. Significantly less days off work, antibiotic prescriptions, courses of oral steroid and improved quality of life in the self-management group than control. The self-management group also had less OPD visits, but this was not significant.	II B
Hoskins et al ©	1996	Individually tailored self-management plans in comparison to traditional management	(UK) 159 GPs recruited patients to the study. These were GPs who had previously taken part in a national audit of asthma management. They were randomised into control and intervention practices. A three step-guideline based, management plan used, similar to Beasley et al (1989), with colour coding and individually tailored to patients asthma history was used. Patients were identified by an attack in the previous 3 months	There were significant improvements in the intervention group for all outcomes. hospital admissions, consultations, symptoms, oral steroids and emergency nebulisers. Selection bias possibly accounts for intervention group having higher morbidity than control at outset.	II B
Baldwin et al ®	1997	elf-management plans n general practice sthma clinic	(UK, Nottingham) Randomised trial of verbal and written self-management plans assessed using morbidity index	Fifty patients randomised to either written or verbal self-management plans. Both groups had significant improvements in all outcomes (except PEF). Group receiving verbal instructions were more severe at outset and improved to a greater degree.	II B

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1.7 The Role of the Practice Nurse in Asthma Management

In general practice, advice on lifestyle modification and self-management for patients with chronic diseases has become the practice nurses' responsibility. Nurses use an holistic approach to patient care and it is therefore appropriate for those working in general practice to have expanded their role in this way.

Prior to 1990, not that many practice nurses were involved in asthma management. A survey in the West Midlands found only 16% of 514 practice nurses were involved in asthma management (Greenfield et al 1987). Six months after the implementation of the new general practice contract in 1990, a survey in Glasgow found that already 39% of the practice nurses were involved in duties related to asthma control (Peter 1993).

Since 1990, the involvement of practice nurses in asthma management has continued to increase (Hibble, 1995). This has been as a direct result of the work of Greta Barnes, former director of the National Asthma and Respiratory Training Centre in Warwick (previously in Stratford-upon-Avon). Many practice nurses and GPs have attended courses run at this centre and her efforts have significantly increased professionals' awareness of asthma and its management in primary care.

My own survey of practice nurses conducted in South and South West Hampshire Health Authority in 1994 showed 82% of practice nurses reported being at least "moderately" involved in asthma management (Dorward 1994). In this survey, 71 practice nurses were sent questionnaires about their role in the care of patients with asthma and 51 (72%) valid questionnaires were returned. Using a scale to assess the level of involvement adapted from Pearson (1991), 41% had "maximum" involvement in the management of patients with asthma, 41% had "moderate" involvement, 11% had "minimal" and only 7% had no involvement.

Osman and colleagues (1995) also reviewed practice nurse involvement in the management and follow-up of adult asthma. They sent questionnaires to 163 practice nurses. Of the 148 (91%) returned, 23 (26%) described a "maximum role" and were fully responsible for running the review system, 68% had a "medium role" (shared responsibility with GP) and 6% participated in a system where patients always saw their GP ("minimum role") (Osman et al, 1995).

More recently, Robertson and colleagues have shown a positive association between practice nurse training and their enhanced role in the care of patients with asthma. Of 187 practice nurses in the Grampian area, one hundred and sixty-seven

(92%) nurses responded to a survey that demonstrated that nurses without advanced asthma training were less likely to provide or review patients self-management plans (p=0.01), to review PEF recording (p=0.01) or to discuss patients concerns (p =0.05) (Robertson et al, 1997).

But evidence of the value of practice nurse intervention remains at best moderate. Charlton and colleagues (1992) demonstrated that the introduction of a nurse-run asthma clinic in one general practice impacted favourably on morbidity. A significant reduction in the requirement for oral steroids, nebulisations and days lost from school and work (p=<0.01) was achieved. Also, there was a significant decrease in the number of GP consultations (p=<0.01). However, the subjects were not randomly selected and the resources required to achieve this improvement (45 minute nurse consultations) may not be routinely sustainable within a practice (Charlton et al, 1992).

To examine the impact of proactive nurse-run asthma care, Jones and Mullee conducted a controlled study in two general practices with similar demographic and practice characteristics. Patients from one practice received proactive nurse-run care and the other continued with "traditional reactive care". The proactive nurse-run care was over a period of 12 months but the exact components of the intervention are not reported. Despite the investment of considerable resources, none of the outcome measures (PEF readings, attitudes to asthma and interruption of daily activities) was significantly improved in patients from the intervention practice (Jones and Mullee, 1995b).

Nonetheless, there is some evidence to support the positive association of practice nurses with improved clinical outcomes (Neville et al, 1996). Neville and colleagues found that favourable associations of structure, process and clinical outcomes of care were associated with the employment of a nurse with a recognised qualification in asthma management. Practices with an asthma-trained nurse were more likely to have completed an audit and to have FHSA accreditation for a chronic disease management clinic for asthma. Patients from the practices that had all of these structures in place reported fewer days lost from work or school and hospital admissions for asthma (Neville et al, 1996).

It seems logical that well-trained and motivated practice nurses make a difference to the organisation and structure of asthma management in general practice and their intervention *should* be positively associated with favourable outcomes.

This view is echoed by Charlton (1997), who stated:

> "In the absence of scientific proof of their value, it has been suggested that practice nurses 'fill the cracks in the current system' and help with the systematic training of patients in self-management skills (Charlton, 1997)."

So why is there not more evidence for the effectiveness of intervention by practice nurses? The explanations proposed focus on nurses' training and their perceived ability.

Despite the increased number of nurses attending asthma-training courses, a significant number of them may lack adequate knowledge or expertise to perform their role. There have been concerns raised about practice nurse training in relation to the management of chronic disease (Stearn and Sullivan, 1993) and specifically the management of patients with asthma (Barnes and Partridge 1994). There may also be reluctance by some GPs regarding the evolution of practice nurses towards a more independent nurse practitioner, especially if it is perceived they do not have appropriate training (Greenfield et al, 1987; Georgian Research Society, 1991).

Practice nurses have not always used appropriate methodology to assess the effectiveness of intervention, and more qualitative research is required. In the past, many methodological problems have been encountered when attempts have been made to observe the impact of practice nurses on asthma management (Jones and Mullee, 1995b).

The methodological problems reported have been:

- identifying a control group (Modell et al, 1983; Charlton et al, 1991a)
- enthusiast bias by patients (Charlton et al, 1992)
- selection bias by GPs (Hoskins et al, 1996).

Perhaps more refined and rigorous trial designs will enable us to confirm the commonly held belief that practice nurses play an exceedingly important role in the management of patients with asthma. The rapidly developing discipline of health service research should be challenged with this evaluation, and should draw on

expertise from researchers from qualitative disciplines in order to comprehensively examine the role of the nurse in the care of patients with asthma in primary care.

1.8 Summary

In this chapter I have reviewed the array of current management strategies for patients with asthma. But, despite the development of effective medication, patient self-management plans, patient education and a multidisciplinary team approach to care, significant morbidity still exists. In response to persisting concern about the disease burden of asthma, national guidelines have been developed. In the next chapter I review the development of these guidelines for the management of asthma.

CHAPTER TWO

CHAPTER TWO
TREATMENT GUIDELINES FOR THE MANAGEMENT OF ASTHMA

2.1 Introduction

In this chapter, I will discuss treatment guidelines and the evidence for their use. The development of the British Thoracic Society (BTS) guidelines and local guidelines for the management of asthma will be described in detail. The impact of the BTS guidelines will be reviewed, concluding with proposed improvements.

2.2 Clinical Guidelines

The Institute of Medicine defines clinical guidelines as "systematically developed statements that assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field and Lohr, 1992). Clinical guidelines are an integral part of the NHS drive to improve performance. The NHS Executive (NHSE) is committed to the development and adoption of high quality national guidelines to improve clinical effectiveness (West and Newton, 1997) and has published proposals for the development, appraisal, and application of clinical guidelines (NHSE, 1996). The concept of quality improvement is borrowed from industry where guidelines provide a framework of identifiable key steps (Berwick et al, 1992). In the health care setting, the main advantage of using guidelines is to standardise clinical practice (Grol, 1992). Other advantages are listed below:

- to improve health service efficiency and reduce levels of inappropriate practice
- to facilitate the rapid and effective dissemination of information (Farmer, 1993)
- to encourage evidence-based practice (Grol, 1992)
- to assist clinicians and patients in making decisions about appropriate treatment for specific conditions and reduce variation in practice (Eccles et al, 1996)
- to raise the profile and provide optimum management for a particular condition (Conroy and Shannon, 1995a)
- to provide a framework for increased accountability (Newton et al, 1996)
- to provide evidence of competent practice (McGinn, 1988)
- to reduce the risk of litigation (Farmer, 1993)
- to control costs (Kibbe et al, 1994)

To ensure consistent messages across professions geographically, a national agency to oversee guideline integration and minimise duplication of work was proposed (Conroy and Shannon, 1995a). The recent government initiative, The National Institute for Clinical Effectiveness (NICE), will perform part of this remit providing information on the effectiveness of treatments and guidelines for doctors and nurses.

Guidelines for medical practice can contribute to improved care only if they succeed in moving actual practice closer to the behaviours the guidelines recommend (Lomas et al, 1989). This was demonstrated in a survey of obstetricians' rates of caesarean section in which a third of the doctors reported changing their practice as a consequence of advice in national guidelines. However, it also showed that knowledge of the guidelines' content was poor and that rates of caesarean section were actually 15 to 49% higher than those reported by the obstetricians. Ellrodt and colleagues (1995) retrospectively assessed adherence to guidelines for patient's discharge from hospital and found factors likely to negatively impact on physician's compliance with guidelines including:

- incorrect diagnosis leading to inappropriate guideline use
- changes in patient's clinical status affecting treatment decisions
- organisational difficulties and inefficiencies in health care systems.

Because of the complexities of treating and caring for individuals, they suggested guidelines should complement rather than be a substitute for clinical judgment and should not be imposed too rigorously (Ellrodt et al, 1995). Others have also suggested clinical guidelines should be used to educate rather than compel (McKee and Clarke, 1995).

Policy makers and the purchasers of health care in the UK view the use of guidelines as a possible way to control the behaviour of the medical profession (Farmer, 1993; Kibbe et al, 1994). However, the uptake and credibility of guidelines will not be maintained if they suggest ineffective or laborious procedures, or the reimbursement does not match expenditure (Mant and Fowler, 1990). In the United States of America (USA), there have been concerns expressed about the increased use of guidelines as some regard they limit autonomy, professional power and the clinical freedom to make decisions about patient

treatment (Woolf 1992). In the UK, similar concerns have been expressed by GPs (Siriwardena, 1995).

For guidelines to be effective, clinicians also require the knowledge, skills and motivation to change their practice. There needs to be adequate incentive to change practice or disincentive *not* to change. There should also be adequate representation of all relevant health professionals and patients in the development of guidelines in order to address profession-specific barriers (Thomas, 1998).

The potential for clinical guidelines to produce notable improvements in the quality of health care has been clearly demonstrated in well-conducted trials. In a systematic review of 59 published evaluations, it has been demonstrated that clinical practice can be improved by using guidelines (Grimshaw and Russell, 1993). Of 59 papers, 11 assessed the outcome of care and 7 of these reported significant improvements. This is a pivotal review that presented the evidence for using clinical guidelines. From this review, it was concluded the guidelines that prompted the greatest improvements in clinical care were the ones that used appropriate strategies in the following three key areas:

- development
- dissemination
- implementation.

For the full potential of clinical guidelines to be transferred to changes in practice, they need to be disseminated appropriately and presented in a format that is conducive to learning. For the non-specialist, who needs to be familiar with many conditions, this may be in the form of a brief printed summary (Williamson et al, 1989; McColl et al, 1998). According to Conroy and Shannon (1995a), any strategy for guideline implementation must have a positive impact at the following levels of:

1. professional knowledge
2. professional attitudes
3. professional behaviour
4. patient outcomes.

The impact of guidelines on these four levels is discussed below, taking examples from primary care.

2.2.1 General Practitioners' Knowledge of Guidelines

There has been limited work in this area. The published studies examining GPs' knowledge of guidelines have also looked at attitudes and are discussed in the other sections below.

Newton and colleagues (1996) performed a survey of GPs' knowledge, use, and beliefs about clinical guidelines. Three previously disseminated guidelines were selected, including the BTS guidelines for asthma management (BTS, 1993), the Royal College of Radiologists (RCR) guidelines for referral to radiology departments (RCR, 1993), and the Royal College of General Practitioners guidelines for the care of patients with diabetes (RCGP 1993). A postal questionnaire was sent to a random sample of 559 general practitioners in the Northern and Yorkshire region in March 1995. GPs were asked to rate their familiarity of the three guidelines on a five-point scale that scored one for 'never heard of' to five for 'very familiar with'. Questions were organized around the topics of: knowledge, use, practice change, beliefs, pressure felt to use the guidelines, and methods of implementation.

The study was conducted by members of the Department of Employment Studies, within the Faculty of Social Sciences at the University of Northumbria where Newton was the Head. Responses were received from only 300 doctors (54%), which was a fairly low response rate and may have been enhanced if a representative from General Practice had been part of the research team.

GPs were most familiar with the BTS guidelines - only 4 out of 300 (1.3%) had not heard of them. Knowledge and use of the three selected guidelines varied, but was generally towards the 'high' end of the scale. Doctors showed a high degree of homogeneity in their attitudes to guidelines, which were generally positive. Only single-handed practitioners varied from this pattern of responses. Most of the pressure to use the guidelines was felt to come from the Department of Health, and the least pressure from patients. Doctors felt that the methods of implementation that involved them in educational events and discussion with colleagues were most likely to have an impact on them. The authors concluded that GPs are generally receptive to guideline initiatives, and their views are in line with existing or

proposed implementation strategies. More investigation of the concept of 'use' is needed. Unfortunately, GPs' knowledge was not tested with clinical case studies or questions about the content of the guidelines.

2.2.2 General Practitioner's Attitudes Towards Guidelines

Siriwardena (1995) performed a questionnaire survey in Lincolnshire to examine the attitudes of GPs to guidelines. In 1994, a postal questionnaire on clinical guidelines was sent to all 326 general practitioner principals on the list of Lincolnshire Family Health Services Authority. The questionnaire consisted of 20 attitude statements, an open question on clinical guidelines, and questions about the characteristics and behaviour of respondents. Of the 326 general practitioners sent questionnaires, 213 (65%) replied. Most respondents (78%) reported having been involved in writing in-house guidelines. An even greater proportion (92%) reported having participated in clinical audit. Respondents were generally in favour of clinical guidelines, with mean response scores indicating a positive attitude to guidelines in 15 of the 20 statements, a negative attitude in four and equivocation in one. The majority of respondents felt that guidelines were effective in improving patient care (69%). Members (or fellows) of the Royal College of General Practitioners had a more positive attitude than non-members towards guidelines. They were also significantly more likely than non-members to have written in-house guidelines, as were those who had participated in audit compared with those who had not participated in audit. A substantial minority (over a quarter) of general practitioners were concerned that guidelines may be used for setting performance-related pay, or that they may lead to 'cookbook' medicine, reduce clinical freedom or stifle innovation. There was also concern that guidelines should be scientifically valid. The most common negative response to questions about guidelines expressed concern that practice guidelines should only follow scientifically proven evidence. Other negative views expressed in the Siriwardena survey were that guidelines try to force clinicians to 'pigeonhole' every patient and clinical situation and not allow adequate flexibility; this may *increase* the risk of litigation as people who have little knowledge of general practice may write them. Despite the negative views expressed, the author concluded that generally GPs believe that guidelines are useful in improving the delivery of care.

2.2.3 Changes in General Practitioner's Behaviour in Response to Guidelines

Studies to date examining the impact of guidelines on GPs behaviour in primary care have looked at their effect on specific processes of clinical care, such as referral for radiological investigation or specialist opinion. Elmslie and colleagues (1993) demonstrated that the use of guidelines improved the referral rate of infertile couples to a specialist and the use of guideline-based prompts has been shown to improve the recording of key variables associated with good care in diabetes and asthma (Feder et al, 1995). These results are encouraging but ultimately the changes in process must lead to improved outcomes for patients.

2.2.4 The Impact of Clinical Guidelines on Patient Outcomes

Knowledge, attitudes, and behaviour are all proxy measures for the ultimate aim of clinical guidelines to improve patients' health. The validity of clinical guidelines ideally should be judged by the degree that their implementation leads to anticipated changes in outcomes (Field and Lohr, 1992). There is some evidence that the use of clinical guidelines can improve the *processes* that reflect good care; there are fewer examples of improvements in patient *outcomes*. Examples of improved patient outcomes include:

- The use of computerised, guideline-based prompts has been associated with reduced diastolic blood pressure over a year in newly diagnosed hypertensive patients (McAlister et al, 1986).
- A guideline-based smoking cessation programme has been shown to increase the number of patients not smoking after one year (Wilson et al, 1988).

Worrall and colleagues (1997) showed significant improvements in patient outcomes in 5 out of the 13 (38%) studies of guideline implementation they reviewed. Although recognised to be a sound review, the NHS Centre for Reviews and Dissemination commented that, because not all the results were from randomised studies, the improvements in outcomes might not be solely attributed to the guidelines. Also, many of the guidelines reviewed were in existence prior to the advent of 'evidence-based guidelines', which may have affected their uptake and possibly their impact on outcomes. The many factors that either help clinicians adhere to treatment guidelines or act as a deterrent warrant further investigation.

2.3 Guidelines for the Management of Patients with Asthma

Rising morbidity and deaths from asthma prompted the development of the first guidelines for the management of adults with asthma, by a group of respiratory physicians from Australia and New Zealand in 1989 (Woolcock et al, 1989). Later that same year, guidelines for the management of asthma in children were published by an international group of paediatricians (Warner et al, 1989).

Many countries now have their own national guidelines for the treatment and management of patients with asthma. In the UK, national guidelines were first developed in 1990 by the BTS in conjunction with representatives from four other committees. Since then, some regions within the UK have also developed local guidelines. The development of the BTS and local guidelines are described below.

2.3.1 The British Thoracic Society Guidelines for the Management of Asthma

At the end of 1989, the British Thoracic Society (BTS), in conjunction with the National Asthma Campaign (NAC), the King's Fund Centre, the Thoracic Medicine Committee and the Research Committee of the Royal College of Physicians, set up a committee to produce a consensus statement on the management of chronic persistent asthma and acute severe asthma in adults. This statement was intended for publication in a non-specialist medical journal, for the guidance of general physicians and GPs.

One year later, the first guidelines were published in the British Medical Journal (BTS et al, 1990a and 1990b). The rationale for the guidelines was presented later in a series of background papers published in Respiratory Medicine (Barnes, 1991; Lane, 1991; Brewis, 1991; Bucknall, 1991; Neville et al, 1991).

The BTS guidelines were revised three years later because of the following:

- new treatments had emerged since 1990
- the care of children had previously been omitted
- the length and lack of user-friendliness of the 1990 version had been criticised
- a clearer description of what constitutes good asthma control was required
- guided self-management had not previously been emphasised (BTS et al, 1993).

The revision retained the step-wise approach to treatment introduced previously, but reinforced the importance of reducing treatment where appropriate. The guidelines were presented in summary charts that could be easily reproduced as cards or

posters for use in a variety of clinical settings (see appendix 1). Background papers did not accompany the 1993 revision, but areas of uncertainty were highlighted. The overall recommendations are listed below:

- to promote greater use of inhaled anti-inflammatory drugs, even in patients with apparently mild asthma
- to use objective monitoring of progress based on peak expiratory flow where possible
- to encourage greater participation of the patient or parents in the management of the condition.

2.3.2 The Impact of the British Guidelines for the Management of Asthma

The flow charts provided in the BTS guidelines give a clear and succinct overview of asthma management and the expected outcomes of treatment. This is presented using a stepwise approach, which is easy to follow (appendix 1). However, there has been limited work examining the use of the BTS guidelines in general practice; the studies are summarised in Table Three and discussed below using the levels proposed by Conroy and Shannon (1995a) of *knowledge, attitudes, behaviour* and *outcomes*.

2.3.3 General Practitioner's Knowledge of the BTS Guidelines

Two surveys of the same group of GPs and practice nurses in Norfolk were conducted in 1991 and 1992. The surveys examined the uptake and perceived value of local, national and international guidelines for the management of patients with asthma. The response rate for the second survey was higher and showed a considerable increase in the proportion that had received a copy of the BTS guidelines from 50% to 92% of the GPs (Harrison and Nichols, 1995).

A national survey of GPs showed that awareness of the BTS guidelines was high. Of the 206 GPs interviewed, 195 (95%) were aware of the guidelines, 78% were 'very' or 'quite' familiar and only 1% was not at all familiar (McGovern and Crockett, 1996). Of the 195, 70% claimed the recommendations influenced their prescribing habits and 66% felt that inhaled steroids were under-prescribed in adults and 63% in children; 88% wanted future revisions of the guidelines to include advice about self-management plans and nurse management of asthma patients.

Table 3. Studies evaluating the evidence for the impact of the BTS guidelines on the care of patients with asthma in primary care

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Evidence Level
Spelman	1993	Assessment of asthma guidelines on asthma management in primary care	(Ireland, Co. Wexford) 110 patients with active asthma surveyed using computerised search in a rural practice of 1883 patients > 16 years. 145 patients identified, (35 not active). Divided into β_2 or anti-inflammatory group and managed according to protocol following 1990 BTS guidelines. Followed up after one month.	49 patients (45%) using beta-agonist more than once a day required a change to their management. 28 (57%) of this group required either to increase or commence therapy; 17 (34.6%) needed advice or a large volume spacer; 4 (8%) were on maximum therapy and 41 (83.6%) reduced their beta-agonist requirement to once a day or less, within the study period.	III B
Harrison and Nichols	1995	Survey of asthma guideline use for the management of patients in primary care	(Norfolk) Two surveys of GPs and PNs re: value of local, national (1990 BTS guidelines) and international guidelines performed in 1991 and 1992.	Higher response rate in 1992. Only 21% overall in 1991. This increased to 77% of GPs and 60% of the PNs in 1992. Number who had received the BTS guidelines rose from 50% of GPs to 92%. Comments on the questionnaires confirmed the value of guidelines in production of practice protocols.	N/A no intervention
Pearson et al	1995	Survey of prescriptions to assess BTS step	(UK) Survey of 102 practices and 17,206 patients to identify amount of beta agonist collected by patients over a 12 month period.	At each step of the guidelines more than 50% of patients are receiving enough beta-agonist to justify a step up in therapy (not published in full).	N/A no intervention
Price et al	1995	Survey of GP prescribing patterns	(UK) Survey of 375 GPs and 750,000 patients to assess change in prescribing patterns for asthma medication comparing figures from 1991 to 1994.	Prescriptions for inhaled steroids have increased from 49 to 61% and almost doubled in 0-3 age group. Ratio of IHCS/β_2 has improved from 0.71 in 1991 to 0.83 in 1994. Results suggest GPs have changed their prescribing in line with guidelines but daily use of relief medication exceeds recommendations (not published in full).	N/A no intervention
Newton et al	1996	Survey of guidelines:- GPs' knowledge, use and beliefs	(Yorkshire) Postal questionnaire to a random sample of GPs to assess knowledge, use, practice change, beliefs and pressure to use guidelines (including 1993 BTS for asthma) and methods used for dissemination.	Only 4 (1.3%) of the doctors had not heard of the BTS guidelines (n=300). Results showed a degree of homogeneity across the doctors to respond favourably to the benefit of guidelines; with the exception of single partners who were more pessimistic in their beliefs regarding their benefit.	N/A no intervention
McGovern and Crockett	1996	Survey of GP and PN awareness and uptake of 1993 BTS guidelines	(UK) 200 GPs surveyed by a market research company, to assess degree that guidelines influenced prescribing and if habits reflected recommendations in guidelines.	195 (95%) of 206 GPs interviewed were aware of guidelines, 78% very or quite familiar and only 1% were not at all familiar. 70% of the 195 who were aware of the guidelines claimed their recommendations influenced prescribing habits. 66% felt that inhaled steroids were under-prescribed in adults and 63% in children. Showed need to improve review of patients taking more than once daily reliever medication.	N/A no intervention

2.3.4 Clinicians Attitudes Towards the BTS Guidelines

It is known from surveys that GPs generally have a positive attitude towards the BTS guidelines and find them useful (Harrison and Nichols, 1995; McGovern and Crockett, 1996; Newton et al, 1996). In the McGovern and Crockett survey, GPs had a positive attitude towards guidelines in general; nevertheless, although 83% of the GPs welcomed the advice offered in guidelines, they also admitted to deviating from their recommendations.

Newton and colleagues (1996) results are consistent with Harrison's (see section 2.21). In examining GPs knowledge, use and beliefs about three different clinical guidelines (including the BTS), doctors were most familiar with the BTS guidelines and were generally receptive to guideline initiatives, the majority of them responding positively to the following statements:

Guidelines help clinicians to -

- learn more about diagnosing and managing particular conditions
- improve the quality of care
- use the latest knowledge derived from research.

However, GPs who worked alone were more pessimistic in their beliefs about the value of the BTS guidelines (Newton et al, 1996).

2.3.5 Clinicians Behaviour in Response to the BTS Guidelines

Much of the work examining clinicians' behaviour has looked at prescribing habits (see Chapter 5). Spelman conducted a study that examined adherence to treatment recommendations in the 1990 BTS guidelines (Spelman, 1993). In his own practice, he conducted a survey to estimate which treatment step patients were on according to the medication they were prescribed and their frequency of use. The patients were then managed according to a guideline-based protocol. Forty-five percent of the patients (n=110) required a change in their management as their $beta_2$-agonist use exceeded the once a day recommendation, but no measure was made of the disease control achieved from changes in patient management in accordance with treatment recommended by the BTS guidelines.

There have been two other studies examining prescribing patterns. Price and

colleagues found that from 1991 to 1994 GPs prescription of inhaled steroids had increased from 49 to 61% of their asthmatic patients and almost doubled in the age group 0 to 3 years. The ratio of inhaled corticosteroid to beta$_2$-agonist (IHCS/β_2) had improved from 0.71 in 1991 to 0.83 in 1994, but despite this, the daily use of relief medication exceeded the recommendations in the guidelines (Price et al, 1995). In a similar study, it was found that 80% of the asthma population were at steps 1 and 2 of the guidelines. Of the 15,649 who could be allocated to a step according to their treatment, 1557 (10%) were outside of the guidelines and at each step more than 50% were receiving enough beta$_2$-agonist to justify a step up in therapy (Pearson et al, 1995).

In the survey conducted by McGovern and Crockett (1996), 70% of the GPs stated that their management of patients with asthma had changed as a result of the recommendations in the BTS guidelines. However, deviation from the recommendations was demonstrated in the responses to specific questions about prescribing. The BTS guidelines recommend that patients receiving reliever medication more than once a day should be prescribed some form of preventative medication; McGovern and Crockett found that more than 30% of the GPs stated that they were "happy" for their patients to take short-acting bronchodilators two to five times daily.

2.3.6 The Impact of the BTS Guidelines on Patient Outcomes

There is a widespread view amongst GPs and hospital doctors that guidelines have improved the management of asthma, but more work is needed to determine the optimal methods for determining their effects on outcomes (Harrison, 1996).

In other conditions, there is good evidence that adherence to clinical guidelines can improve patient outcomes, but it remains unclear if this is the case for the management of asthma. The efficacy in *individuals* of medications recommended in the 1993 BTS guidelines is undeniable. However, the evidence on which the recommendations are based is not always transferable into primary care as the clinical trials have been subject to rigorous control and not usually conducted in the community. Therefore, the effectiveness of the guidelines is reduced because of poor generalisability and this mismatch between the evidence base and the 'real world' decreases the value of the guidelines as a tool to promote good clinical practice. Clinicians' faith in their value is therefore diminished and compliance

with the recommendations is potentially reduced.

In summary, a positive impact has been demonstrated in three of the four levels associated with effective guidelines. It has been confirmed that GPs have positive attitudes towards the BTS guidelines and that their use and knowledge of their content has increased (Harrison and Nichols, 1995; Newton et al, 1996). It is also known that GPs have changed their prescribing habits towards the treatment regimes recommended in the BTS guidelines (Spelman, 1993; Price et al, 1995; Pearson et al, 1995). However, the true effectiveness of the BTS guidelines can only be confirmed if their implementation leads to improved outcomes and to date the impact of the BTS guidelines on patient outcomes in primary care has not been assessed.

2.3.7 Possible Areas for Improvement in the 1993 BTS Guidelines

Several of the recommended steps in the development and dissemination of guidelines were not followed in the production of the 1993 BTS guidelines for asthma management (Field and Lohr, 1992; North of England Study of Standards and Performance in General Practice, 1992; Grimshaw and Russell, 1993; Conroy and Shannon, 1995a; Thomas et al, 1998).

Features lacking in their development included:

- In the guideline development groups, other professional groups such as educationalists, psychologists and nurses were not key contributors.
- There was no clear definition of the end users.
- There was no clear definition of the strength of supporting evidence.
- There was no account of the development process.

Features lacking in their content/design included:

- Some of the information was not clearly laid out - especially regarding diagnosis and treatment of an acute attack.
- There is minimal detail regarding patient education and the use of self-management plans.

Features lacking in their dissemination included:

- They were originally published in a 'specialist journal'.
- There was no account of how they would be integrated into practice.
- There was no account of a programme of education.
- There was no account of a strategy to use the guidelines to change practice.

In the 1993 BTS guidelines, the concept of a 'partnership between the patient, his family and the health professional' is emphasised, but detailed advice regarding patient education or self-management is not provided and specific tools or diary cards are not recommended (BTS et al, 1993). The guidelines do specify the overall aims of asthma management but leave the practicalities of implementation to individual clinicians. Some have suggested the endorsement and promotion of well designed and validated, patient education and management plans would have been a valuable inclusion (Neville, 1996; McGovern and Crockett, 1996).
The possible areas for improvement to the BTS guidelines are discussed in more detail in the concluding chapters.

2.4.1 Local Guidelines for Asthma Management

There is evidence that guidelines may have reduced impact if they are devised by senior doctors away from the realities of daily clinical practice and if an impersonal or 'managerial' strategy is used for their implementation (Farmer, 1993; Newton et al, 1996). If asthma guidelines are developed by clinicians actively involved in the daily management of patients with asthma, there may be a greater sense of ownership that improves uptake and adherence. However, at a local level, there may not be the skills and resources to identify, assimilate and evaluate research findings in order to produce evidence-based guidelines (Eccles et al, 1996). There is evidence that most significant change in outcomes is achieved if clinicians devise their own guidelines (North of England Study of Standards and Performance in General Practice, 1992). The process of developing the guidelines and discussing the individual items may be of greater educational benefit than the guidelines themselves (Armstrong and Armstrong, 1994). This in turn may lead to all relevant personnel coming together to decide new strategies to improve the care of patients with asthma.

The evidence regarding the perceived value of local guidelines has been assessed by a survey of 94 GPs in Kent. A 26-item questionnaire was used to examine their opinions regarding local asthma guidelines. The 94 GPs represented a 59% response rate. Of the 26 items, the average GP thought 11.5 were 'obvious', 8.5 'useful' and 5.7 'controversial'. Considerable variability in GPs' views about the usefulness of different items was found and this was not associated with personal or practice characteristics (Armstrong and Armstrong, 1994).

Feder and colleagues (1995) examined the use of locally developed, guideline-focused and practice-based education for the care of patients with asthma and diabetes. In a randomised controlled trial, 24 inner city practices were given practice-based education programmes using guidelines. At the beginning of the study, practices created or updated disease registers for asthma and diabetes, using uniform diagnostic criteria. Three months after the start of the study, the practices were randomised into either the "asthma" or "diabetes" group and received guidelines and teaching sessions for one or other of the chronic diseases. Data were collected from the practices regarding both diseases, each practice acting as a control for the other disease. Analysis showed the size of disease registers for all the practices increased in proportion to list size (demonstrating increased case finding). The recording of quality of care variables (such as fundoscopy and PEF recording) increased in the intervention groups, but more so for diabetes than asthma.

One initiative in local guideline development that requires particular mention is the North of England Asthma Guideline Development Group (NEAGDG). This group used a very structured, multi-professional approach to the development of local guidelines and considerable care was taken to address all the key stages recommended for successful guideline development (Eccles et al, 1996). The identification and assessment of relevant literature was undertaken by a project team who set the criteria for papers to be included in the review and also the methods used for the development of the guidelines. The papers reviewed were graded according to the level of evidence as outlined in a previous chapter (1.6). Where guidance could not be derived from evidence, the project group consulted the current BTS guidelines (BTS et al, 1993) or formed their own consensus view. The guidelines were reviewed by three expert groups to review the methods used for their production, their content and clinical application.

The NEAGDG published a summary version of their guidelines that had the same sequencing of treatment as the 1993 BTS guidelines. Most of the main aspects of the NEAGDG guidelines were in fact similar to the 1993 BTS guidelines; therefore using the same evidence base, they had come to similar conclusions. However, the NEAGDG guidelines were wider in their scope than the 1993 BTS guidelines and in addition to treatment advice, included comments regarding peak flow measurement for the diagnosis and management of asthma and patient referral (NEAGDG 1996). They also fulfilled more of the recommended requirements for guideline development and dissemination as previously outlined than the BTS guidelines. The main differences were:

- The NEAGs (1996) were aimed only at the management of adult patients.
- They were produced by a locally focused group of clinicians and researchers.
- They were specifically produced to guide primary health care professionals.
- The project team was multidisciplinary.
- They were wider in scope than the BTS guidelines.
- Recommendations were based on the strength of supporting evidence.

Although national asthma guidelines are considered helpful by GPs and practice nurses, locally derived guidelines may be more accessible, acceptable and user friendly (Harrison and Nichols, 1995). The RCGP recommends that the first step in the development of local guidelines is to identify a valid national guideline (RCGP, 1995) and in several parts of the UK, the BTS guidelines have been used to produce local and regional asthma guidelines (Harrison, 1996).

We know that on the whole GPs have a positive attitude towards clinical guidelines and we also know the many advantages associated with their use in primary care. However the question "how effective have the BTS guidelines been in improving outcomes for patients with asthma" remains unanswered. The evidence base for most of the recommendations within the BTS guidelines was on the whole from studies in secondary care. When the guidelines were originally developed in 1990, they were an example of a guideline produced 'for', rather than 'with' members of PHCT. Members of the PHCT manage 90% of patients with asthma and therefore, it is in the community where there is potentially the greatest opportunity to have a positive impact in reducing morbidity and mortality.

CHAPTER THREE

CHAPTER THREE
THE ORGANISATIONAL CHANGES IN GENERAL PRACTICE

3.1 Introduction

Since 1990 there have been two changes that have impacted on the delivery of care for patients with asthma in general practice, namely, the remodelling of contractual arrangements and the introduction of the chronic disease management programme. These major organisational changes have occurred simultaneously with the introduction of the BTS guidelines for the management of patients with asthma. Therefore, when examining the impact of the BTS guidelines in primary care, the effects of these changes cannot be ignored.

The key studies examining the impact of the organisational changes on patients with asthma are summarised in Table Four, to be found towards the end of this chapter.

3.2 The 1990 Contract for General Practitioners

The new contract for general practitioners introduced in 1990 prompted many changes in the way care is organised in general practice (DOH, 1989). *Working for Patients* (DOH, 1989) has been one of the most innovative reforms to the NHS. The reforms offered opportunities for the previous professionally driven model of service provision to be replaced with a system that was more responsive to patients' needs. If practices chose to become fund holders, they could purchase services on behalf of their patients and this shifted the power base away from hospitals towards primary care (Glennerster et al, 1992). The new contract also brought health promotion and disease prevention within the responsibilities of all general practitioners.

In a survey of practices in Sheffield, the number and range of health promotion clinics provided in general practice grew exponentially in the twelve months after the introduction of the new contract. For example, between 1990 and 1991 the number of practices offering an asthma clinic rose from 10% to 42% (Hannay and Usherwood, 1992; Hannay et al, 1992) and similar increases in other health promotion clinics were apparent throughout the UK (Sefton 1991). However, for

patients with asthma, it remains unclear what impact these changes have had on their health and well-being.

3.3 The Chronic Disease Management Scheme

Further changes to the general practice contract in 1993 required practices wishing to be reimbursed for special Chronic Disease Management (CDM), to maintain a register of patients, work to an agreed practice protocol and define standards of care. In adjusting to these new requirements, many practices found it expedient to offer care in disease-specific clinics run by practice nurses. The most common clinics were for patients with diabetes and asthma. To prepare for the change in their role and increased responsibility, many practice nurses completed local and national training courses. The National Asthma and Respiratory Training Centre in Warwick (previously at Stratford-upon-Avon) is the most popular. Since 1990, 15,000 nurses have attended courses there and 11,000 have been awarded a Diploma in respiratory nursing.

With an average list size of 2000 patients, a full time partner will care for approximately 150 patients with asthma. In larger practices, a weekly asthma clinic was found to be the most convenient way to provide care (Barritt 1992). However, it is recognised that often those who attend clinics are least at risk from exacerbations and additional systems to target care towards those most in need were developed.

Jones and colleagues (1992b) showed those at risk can be identified by frequent non-attendance at clinic or through using a postal questionnaire about symptoms. In order to derive a simple morbidity index for use as a screening tool in primary care, 300 asthmatic patients aged 5 to 65 years were randomly selected from the repeat prescribing registers of three general practices in the Southampton area. Data were collected from patient interviews, lung function measurements, and general practice case notes. Reported morbidity was calculated using an index based on three questions (listed over-leaf):

- Are you in a wheezy or asthmatic condition at least once per week?
- Have you had time off work or school in the past year because of your asthma?
- Do you suffer from attacks of wheezing during the night?

The outcomes used were mean forced expiratory volume in one second and mean peak expiratory flow (over a seven day period), diurnal variation in peak flow, and the relation of the morbidity index to lung function. The sample was quite young (mean age 22.8 years) and data were collected for 296 patients (164 men). Mean forced expiratory volume in one second was 67% predicted (SD 18.4), mean peak expiratory flow was 80% predicted (SD 18.9), and mean diurnal variation was 10% (SD 7.7). Seventy-six subjects were classified as having low morbidity, 95 medium, and 125 high. The morbidity index was significantly associated with forced expiratory volume in one second, mean peak expiratory flow rate, and diurnal variation ($p = >0.05$); nevertheless, it was not significantly associated with inhaler technique or use of prophylaxis. Jones and colleagues concluded that in these three well-resourced practices there was a large burden of persisting morbidity, across all ages of patients diagnosed as asthmatic (Jones et al 1992b).

The level of morbidity demonstrated in Jones' study was similar to the results of studies performed some years previously (Hilton et al 1986; White et al 1989; Turner-Warwick et al 1989). Furthermore, the use of a morbidity index may help to target those asthmatic patients who need more attention by concentrating on those most likely to be at risk, who report medium to high morbidity (Jones et al, 1992b). More recently the predictive value of this tool has been assessed and reviewed and is a very pragmatic instrument for use in primary care (Jones et al, 1999).

It is a widely held opinion that systematic care (disease registers, regular review) and dedicated clinics benefit patients with asthma. It was this belief that led to accreditation of general practices for Chronic Disease Management (CDM) payments and banding for health promotion in 1992. Through these changes, Family Health Service Authorities (FHSAs) were empowered to monitor asthma care by inviting bids from practices to run CDM clinics. The need to quickly

establish a new system and the lack of routine data on patient outcomes resulted in the FHSAs adopting an accreditation system based on process of care.

The accreditation for FHSA CDM payments and approval for band three health promotion services have subsequently been accepted as measures of good asthma management. However, accreditation *per se* has not been found to be associated with favourable clinical outcomes (Neville et al, 1996). Nevertheless, Band III health promotion status *has* been shown to be associated with some proxy indicators of quality, such as the ratio of IHCS/β_2 prescriptions (Naish et al, 1995).

A further requirement for eligibility for CDM payments was the performance of annual 'process' audits. Systematic collection and analysis of data provided practices with additional insight into the morbidity within their patient population and help focus attention on areas of need. Often Medical Audit Advisory Groups (MAAGs) collated such information to provide a district wide perspective on asthma care. Some MAAGs extended the data collected to include information about outcomes. A comprehensive audit of asthma care that collects data about outcomes as well as process measures qualifies as an 'extended primary care audit' which entitled practices to claim for an extra payment under the CDM scheme.

The CDM programme has encouraged increased recording of information and more systematic care, but it is not known if these changes have contributed to achieving the goal of all health professionals - improved health in their patients.

3.4 Audit of Asthma Care

One of the aims of the BTS guidelines was to stimulate audit and provide a standard against which to measure asthma care. Whilst the guidelines may have catalysed activity in secondary care, the widespread audit activity in primary care was largely prompted by contractual change.

Asthma audit in general practice frequently focuses on the process of care alone, for example by recording the frequency of PEF measurements or noting smoking status. Such measurements of process might improve without any change in patient well-being. This is nicely illustrated in the study by Martys, which involved auditing the impact of setting up an asthma clinic. There was no

detectable improvement in objective measures of disease control after the advent of the clinic, but there were marked improvements in the completeness of recording relevant data in patient notes (Martys, 1992).

A study published in 1997 demonstrated how participation in audit might be associated with improvements in the management of acute asthma. Unfortunately, the GPs in the study were not a representative sample. They were all members of the GPs in Asthma Group (GPIAG) and thus more likely to be motivated to change their practice than GPs without a special interest in asthma (Hoskins et al, 1997).

Some audits have been accompanied by improvements in patients' well-being and the process of audit has precipitated the introduction of a new intervention. For example, following an audit in a two-partner practice in Shropshire in 1984, a check-list for patient care and a patient booklet were introduced. In a follow-up audit three years later, significant improvements in asthma symptom scores were demonstrated (Barrit and Staples, 1991).

Neville and colleagues demonstrated that participation in audit was associated with improved clinical outcomes. In this study, questionnaires were sent out to participating practices that collected data from 30 randomly selected patients. It was shown that accreditation to participate in the CDM scheme *per se* was not favourably associated with the outcomes measured of symptoms, hospital admissions and days absent from work or school. However, 143 practices (64%) had completed some form of audit of their asthma care and the 4259 patients in this sample had more favourable outcomes than the 2473 patients from practices who had not participated in audit.

Even though 225 practices took part in the study and all parts of the UK were represented, the authors recognise the findings may have been subject to participant bias. It was concluded that, although the process of audit itself may not decrease morbidity, it facilitates decision making about how asthma care in general practice should be organised, monitored and remunerated (Neville et al, 1996).

3.5 Shared Care

Shared care in asthma is the joint management of patients and their families by health care professionals from primary, secondary and tertiary care. The

diagnosis and management of asthma occurs across the three sectors and patients may require the services of some or all of these health professionals as their disease changes throughout their lives (Charlton et al, 1994; Levy et al, 1997).
Hickman and colleagues (1994) identified the following taxonomy for the shared care of chronic disease; they identified six types:

1. *community clinics* where the specialist undertakes a clinic in general practice
2. *basic* where communication comprises the regular exchange of letters or standardised record sheets
3. *liaison* where the hospital team and GP meet to discuss and agree the management of patients under shared care
4. *shared care record cards* where the exchange of information is made through a booklet or "co-operation" card kept by the *patient*
5. *computer-assisted shared care* where a circuit of information is established between GP and hospital specialist based on data collected at each visit and mediated through computer generated summaries
6. *electronic mail* where hospital specialist and GP both have access to the same data on patients.

The importance of good communication between primary and secondary care is well recognised (Charlton et al, 1990). Some health authorities have established nurse specialists who have a responsibility to liaise with primary care and smooth the transition from hospital to home; others use a co-operation card to facilitate the exchange of information. But despite the NHS research and development initiative identifying 'shared care' as an area that requires further research, it is difficult to provide and there have only been modest advances in the care of patients across this divide in any of the chronic diseases.
There is one study that has demonstrated the benefits of shared care for patients with asthma. The GRASSIC group in Scotland is one of the only groups to have formally evaluated a different approach to care across the primary/secondary care interface. They established an integrated care programme for patients with asthma to help standardise the flow of information between hospital and primary care. They used a computer-based package to develop the patients' plans. In this

randomised trial, the intervention group had significantly fewer hospital admissions and less nocturnal wakening (GRASSIC, 1994).

The care of patients with asthma across the primary/secondary care interface has received little attention and further research is required to explore the cultural and political factors that may present as barriers to the development of strategies that improve patient outcomes (Evans, 1996; Levy et al, 1997).

3.6 The Impact of Practice Organisation on Patients with Asthma

Eastwood and Sheldon (1996) performed a systematic review examining organisational aspects of asthma management. They included 27 studies, 9 of which were randomised controlled trials. The studies reviewed included a broad range of different types of organisational structure and processes that have been adopted in the care of patients with asthma and were as follows:· 4 evaluated asthma clinics (2 with GPs and 2 with practice nurses).

- 3 examined modifications to the GP consultation (using prompts etc.).
- 6 looked at community provision of asthma services (with various health care professionals).
- 6 looked at outpatient provision (all used respiratory nurse specialists).
- 1 study examining shared care (GRASSIC 1994).
- 3 looked at care in accident and emergency departments.

Eastwood and Sheldon stated in their review that there was little evidence to support the widespread assumption that asthma clinics lead to sustained reduction in morbidity. They also concluded that community-based clinics (e.g. outreach clinics) may be successful if targeted at specific groups using true specialists. It may be that the knowledge and interest of who actually delivers the care is more important than their 'job description', or the organisational framework in which they work.

The numerous studies exploring the impact of different aspects of the organisation of asthma care on patient outcomes are summarised in Table Four. Many of the studies are methodologically weak, but one is worthy of further discussion (*vide infra*).

Neville and colleagues (1996) performed a survey to explore whether FHSA accreditation of asthma clinics, based on measures of structure, is associated with improvement in measures of process or clinical outcome. Using a large national sample (225 practices, 6732 patients) it was shown practice audit and employment of a nurse with an asthma diploma were associated with favourable patterns of clinical outcome as well as structure and process. However, as the authors state one needs to cautious when inferring clinical outcomes from a series of associations. In Neville and colleagues' study, the practices volunteered their participation; therefore, the results are subject to recruitment bias from more enthusiastic participants. Also, this was not a controlled study and a series on a large number of variables makes statistical significance likely regardless of clinical importance. Of course practices that employ nurses with an asthma diploma, or that participate in audit may achieve favourable clinical outcomes in ways unrelated to the variables examined in the Neville's study. However, this study does highlight the areas of uncertainty that exist about what outcome measures are appropriate in asthma care and also raises questions about the organisation of asthma care in general practice and how it should be monitored and remunerated (Neville et al, 1996).

Table 4. Studies evaluating the impact of practice organisation on the care of patients with asthma in general practice (cont'd overleaf)

First Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Level of Evidence
Modell et al	1983	Consensus management at spontaneous asthma consultation	(UK, London) Group practice of 1300 patients, 8 GPs. Before and after case study examining PEF, symptoms, attitudes and knowledge over 12 months.	Minimal change in patient satisfaction and knowledge. Most improvement achieved in children - this result was possibly influenced by parents.	III C
Usherwood and Barber	1988	Asthma mini-clinic for children after school at 2 to 12 weekly intervals	(Scotland) Controlled assessment, outcomes were medication, absenteeism, parental reported symptoms. Children from neighbouring practice acted as controls, matched for age and sex.	Minimal difference post intervention. Some decrease in absenteeism, GP consults, home and out of hours visits. No description of consulting patterns between practices. Absenteeism not necessarily due to asthma.	III C
Barrit and Staples	1991	Repeat audits in one general practice in 1984 and 1987	(UK, Shropshire) 192 patients to examine asthma knowledge, use of PEF monitoring and inhaler technique.	General improvement in knowledge, improved scores for symptoms.	III C
Charlton et al	1991a	Practice nurse run asthma clinic	(UK, Norfolk) Comparison of process and outcome measures for 115 patients before and after introduction of PN run asthma clinic.	Improvements not all positively attributed to the PN. Improved org. of care, reduced GP consults, more appropriate prescribing. Some subgroup numbers very small.	III C
Charlton et al	1992	Practice nurse run asthma clinic	(UK, Norfolk) Comparison of attitudes and morbidity for 105 patients before and after introduction of PN run asthma clinic.	Potential enthusiast bias of those attending. Significant reduction in morbidity and time off school and work.	III C

Table 4. (cont'd) Studies evaluating the impact of practice organisation on the care of patients with asthma in general practice

Author	Year	Intervention	Study Design, Setting and Population	Results and Comments	Level of Evidence
Martys	1992	Pre and post audits of a GP run asthma clinic	(UK, Derbyshire) 6 monthly visits with education, PEF and diary card. Also monitored smoking and medication.	Increased prevalence from 4% to 6%. Improved organisation able to identify asthma patients more easily. Practice could not cope with increased volume of patients with 6 monthly checks. Difficult to assess clinical improvement in patients.	III C
Bryce et al	1995	Assessment of an audit facilitator	(UK, Scotland) Controlled study using opportunistic review of children. Used asthma chart, reminder letter for review. Measured prescriptions, hospital visits and cost to health services.	Increased consultations. Increased prescriptions for prophylactic meds and PEF meters. Increased use of asthma stamp. Increased primary care costs (reduced secondary care costs?). Poorly controlled patients and same GPs therefore increased asthma awareness.	III B
Jones and Mullee	1995	Nurse-run asthma care in general practice.	(UK, Southampton) Prospective study for the assessment of proactive nurse-led care in 2 matched practices. 200 patients, (randomly selected?) 100 each control (traditional care) and intervention groups. The intervention group received nurse-run pro-active care.	141 patients completed study (71 I, 70 C). In the intervention group only 33 patients received at least one consultation with the nurse. Not strictly a control group? To establish baseline all patients reviewed before start of study. Published as a discussion paper.	III C
Neville et al	1996	Asthma care in general practice. Observation of structure, process and clinical outcomes	(UK, National) 225 practices. A total of 6732 patients of any age, (30 randomly selected by each practice) had primary and secondary care variables measured re: asthma attacks, disease control, emergency treatment and hospital attendances over a 12 month period.	Symptoms and hospital admissions were better in patients from practices that had recently participated in audit and employed a practice nurse trained in asthma management. Association with CDM accreditation FHSA and structure and process but not clinical outcomes.	II B

3.7. Summary

In summary, the contractual changes in general practice over the last ten years have led to numerous changes in the organisation of care for patients with asthma (Levy et al, 1997). Most changes have been instigated with the belief that these interventions are beneficial, but most are not evidence-based. Many changes to organisation and delivery of asthma services to patients in general practice have been made due to changes in contractual and financial to arrangements. Eastwood and Sheldon stated in their review of the organisation of asthma care:

> "There is a lack of good quality research evaluating organisational aspects of the delivery of asthma care and more attention should be paid to looking at complete packages of treatment rather than specific interventions (Eastwood and Sheldon, 1996)."

They suggest that previous studies may not have paid sufficient detail to the impact of organisational factors such as location, personnel and structure on patient's well being (Eastwood and Sheldon, 1996). In primary care, there are many features of asthma management that have become accepted practice; for instance the increased participation of practice nurses and the annual review of patients' asthma. Also, the many modifications that have occurred in general practice make the evaluation of any feature of asthma management in isolation problematical. It is difficult to examine one feature without looking at the impact of 'the whole package' delivered by a particular practice.

Therefore, in examining the impact of the BTS guidelines it is difficult to know whether guideline-based treatment alone can improve patient outcomes. It is also not known whether some changes to practice organisation and service delivery enhance guideline adherence, or act as potential barriers to the provision of effective treatment. This will be explored further in the study described in the next chapter.

CHAPTER FOUR

CHAPTER FOUR : RESEARCH PROPOSAL

4.1 Introduction

In this chapter the rationale for conducting further research that examines asthma management in general practice is explained. A summary of the three key areas that need addressing is set out, the hypothesis is stated and the justification for the chosen study design for the project is discussed. The outcomes that will be used to assess the impact and validity of the BTS guidelines in general practice are outlined. Finally, the independent variables to measure guideline adherence are described.

4.2 Rationale for the Project

Asthma is a major health care problem in the UK affecting approximately three million people and members of the PHCT manage the majority of patients with asthma.

Although there is no cure for asthma, effective medication for symptom control is available and its use has increased. The number of prescriptions for asthma preparations dispensed in England doubled in the decade 1983 to 1993 from 16 to 32 million (DOH, 1995).

The treatments for asthma are expensive and in 1995 the financial burden created by NHS health care, sickness and invalidity benefits was estimated to be almost 672 million pounds per annum (PSSRU, 1997). It is sobering to note that, despite the increasing use of medication and resources, many patients do not experience optimum management and many peoples' lives are adversely affected by asthma. Asthma is an inflammatory condition of the airways and patients require the appropriate medication to control the inflammation, and like other conditions they require advice about lifestyle and guidance to self-manage.

There is good evidence that adherence to clinical guidelines for some conditions can improve patient outcomes, but it remains unclear if this is the case for the management of asthma. The efficacy in *individuals* of prophylactic medication such as inhaled corticosteroids recommended in the 1993 BTS guidelines is undisputed. However, the evidence comes from clinical trials, which are controlled situations, where patients are seen regularly and compliance with therapy is rigorously monitored. Poor

generalisability of the evidence base potentially reduces the value of the guidelines.

We know that GPs are generally receptive to guideline initiatives but the "use" of asthma guidelines in general practice management of the condition requires further investigation (Newton et al, 1996). In a climate of finite resources, it is imperative that we have more information about the impact of these guidelines, which recommend the prescription of expensive medications (Tattersfield and Holmes, 1995; Conroy and Shannon, 1995a; Grol, 1992; Grol, 1993; Siriwardena, 1995; Eastwood and Sheldon, 1996). The question 'how effective have the BTS guidelines for asthma management been in improving patient outcomes?' remains unanswered (Harrison, 1996).

It seems reasonable to expect that clinicians and practices that adhere to the BTS guidelines and provide optimum management will be able to demonstrate better outcomes in their patients than practices that do not (Grol 1992; Conroy and Shannon, 1995b). The desired outcomes for patients with asthma are laid out on flow charts incorporated in the 1993 BTS guidelines (appendix 1). It is implicit in the guidelines, that patients, who attend a practice where the GPs follow the recommended treatment regimes, should achieve improvement in these outcomes. It is this assumption that I wish to explore in this study.

Nevertheless, in chronic disease such as asthma, the majority of patients lead lives that are characterised neither by good health, nor by severe impairment. The intermittent and subtle impairment in health caused by asthma is not always detected by measuring conventional clinical outcomes such as peak expiratory flow rates. Therefore, other methods have been devised to assess disease severity, monitor progress and quantify treatment effects. These methods of health assessment were devised to capture information that is more relevant to the concerns of patients, than measurements of lung function. Also, measurements of lung function do not always fully reflect all the disease processes that occur in asthma. In mild-moderate asthmatics, who constitute the majority of patients with this disease in primary care, standard physiological measurements do not tell the whole story (Jones, 1991b; Marks et al, 1993; Juniper et al, 1993). Therefore additional measurements of health are required to complement the existing physiological measures and these have become known as disease-specific quality of life questionnaires. A more comprehensive outline of these measures is presented in chapter 6.

Although the main focus of this study is the impact of BTS guideline adherence on patient well-being, attention will also be paid to the influence of practice organisation.

Many changes have occurred in general practice in the last decade making it difficult to evaluate the impact of the BTS guidelines in isolation. It is unclear whether guideline-based treatment alone can improve patient outcomes, or whether changes to practice organisation and service delivery are synergistic in the provision of effective treatment. Aspects of practice organisation will therefore be documented in this study as potential confounders to guideline adherence.

In summary there are three key areas that need addressing; these are:

1. the extent of BTS guideline adherence in general practice
2. the relationship between adherence to BTS guidelines and patient well-being
3. how aspects of practice organisation may act as potential confounding factors to guideline adherence.

The study that follows intends to add to our knowledge of asthma management in general practice. It informs us about GPs adherence to the BTS guidelines by examining their knowledge, behaviour and prescribing habits in relation to important patient outcomes, including quality of life and disease control. In the analysis, organisational characteristics of the practice are examined and assessed as potential confounders to guideline adherence.

4.3 Hypothesis

The original hypothesis to be tested was:

Patients with asthma who attend a practice, where the PHCT follow the 1993 BTS guidelines, have improved quality of life and improved disease control.

Within this hypothesis there is an assumption that disease control and quality of life are inextricably linked. Nonetheless in the previous section I have demonstrated that in asthma this may not be the case. Therefore, it could be argued that there are two hypotheses to be explored that look at the impact of BTS guideline adherence on disease control and quality of life separately. This has therefore been acknowledged and the two hypotheses are: (listed over-leaf)

1.Patients with asthma who attend a practice, where the PHCT follow the 1993 BTS guidelines, have improved quality of life.

2.Patients with asthma who attend a practice, where the PHCT follow the 1993 BTS guidelines, have improved disease control.

4.4 Study Design

A cross-sectional, observational study design was selected. The choice of this method for epidemiological research is supported by Altman (1992), who states it is not practical to randomise subjects to factors that cannot be controlled by investigators, in this case adherence to the BTS guidelines.

Many aspects of asthma management in primary care have become accepted practice (such as the increased participation of practice nurses); therefore it would have been difficult to find sufficient practices providing "traditional" asthma care to act as a control group. Many have commented on the methodological difficulties in examining organisational interventions in the management of patients with asthma in primary care. Jones and Mullee noted:

> "In the current climate of enthusiasm for proactive asthma care, a formal, randomised controlled trial - the gold standard of quantitative evaluations would be almost impossible (Jones and Mullee 1995b)."

Therefore, a pragmatic approach was taken to test the hypotheses. This study exploits the natural variation in primary care practice. It seeks not to change practice but to examine to what extent guideline adherence affects patient outcomes and to investigate how aspects of practice organisation may or may not enhance this effect.

4.5 Guideline Adherence

Guideline adherence can be measured at four levels; these are listed over-leaf:

1. increased *knowledge* and awareness of the guidelines by clinicians
2. improved *attitudes,* so that clinicians agree with and accept the recommendations as a better standard of care
3. improved *behaviour* and clinical practice, so there is conformity with the guidelines
4. improved *outcomes*, patient health and quality of care (Conroy and Shannon, 1995).

To test the hypotheses in this study, it was necessary to devise a method to assess GPs adherence to the BTS guidelines. As the BTS guidelines are far ranging in their recommendations, the method devised combined several approaches and used routine and bespoke data collection methods. The variables measuring guideline adherence are listed below and expanded in Chapter Five.

- GPs' use and knowledge of the guidelines was assessed using direct questioning.
- GPs' behaviour - this was captured as self-reported behaviour in response to clinical scenarios.
- Practice equipment and facilities - the BTS guidelines make recommendations concerning availability of PEF meters, equipment and medication. The availability of these resources was self-reported by the practice in a questionnaire.
- Patterns of prescribing concordant with the BTS guidelines. The Prescription Pricing Authority (PPA) in Newcastle upon Tyne collects data on all prescriptions dispensed in England and Wales. This routinely collected data is analysed and summary statistics are available to researchers and practices as PACT data (prescribing analysis and cost).

4.6 Practice Organisation

As aspects of practice organisation may act as potential confounding factors to guideline adherence, it was intended to capture information about the different ways used to deliver asthma care in general practice. It was planned to collect information about organisational structures in place and examples of innovative practice. The variables are summarised in Table 5, on page 84.

4.7 Patient Outcomes

The validity of clinical guidelines is ultimately assessed by how much their implementation leads to positive changes in outcomes. These improved outcomes may include positive changes in clinicians' behaviour (such as prescribing) that result in positive changes in patient outcomes (Field and Lohr, 1992). The following are traditionally used to assess the impact of asthma interventions:

- Patients' symptoms and the frequency of acute attacks.
- Patients' requirement for reliever medication.
- Limitation of patients' activities.
- Necessity for emergency visits to hospital.
- Physiological measurements (percentage predicted FEV_1, PEF readings and diurnal variation).
- Health status measured by quality of life measurements.

To date, there have been difficulties comparing the impact of different interventions on asthma control due to a lack of universally accepted outcome measures (Usherwood and Barber, 1988; Barrit and Staples 1991). Hospital admission rates have been associated with the quality of asthma management in general practice (Griffiths et al, 1997a), but their use is flawed because of disparity across regions regarding the availability of resources and differing admission policies for acute asthma (Shelley, 1996). Also the use of hospital admissions as an outcome measure has limited relevance to community-based studies where the proportion of patients admitted to hospital is very small (Hyndman et al, 1994).

Morbidity in asthma can be assessed by symptoms recall and the manner in which they impact on daily life. Interestingly, "subjective" measurements of symptoms and well-being are not always reflected in the physiological measures of disease control. In the absence of an ideal outcome measure, this study used a range of outcome measures to assess quality of life and improved asthma control. Quality of life was chosen to be the primary outcome (measured by the St. George's Respiratory Questionnaire). The secondary outcomes measured were percentage predicted FEV_1, diurnal variation in peak expiratory flow (PEFDV) and symptoms. The rationale for selection, methods and tools used to gather outcome data and to measure BTS guideline adherence is described further in Chapters Five and Six.

4.8 Plan of Analysis

The association of quality of life with BTS guideline adherence was assessed at practice level using the *mean* values from patient outcome data within each practice. To look for any *association* between the independent variables and outcomes, it was intended to perform correlation analysis. To assess whether any aspects of guideline adherence *predict* quality of life, it was intended that a multivariate regression model would be constructed. Variables measuring practice organisation would then be added to the model to assess their impact as potential confounders to guideline adherence.

The analysis is described in full in Chapter Nine. The patient and practice level variables used are summarised in Tables Five and Six. An overview of the dependent and independent variables is presented in Figure Two (page 87).

Table 5. Patient Level Variables and Variable Type for Anlalysis

Measurement at Patient Level	Variable Type		
	Dichotomous	**Ordered Categorical**	**Continuous**
DEMOGRAPHY			
Age			18-45
Gender	Male/female		
Social Class		I-V	
Education			9 to 18 yrs
House Tenure		5 categories	
QUALITY OF LIFE			
(SGRQ)			0-100%
DISEASE CONTROL			
a) Symptom Score		0-15	
b) PEFDV			0-100%
c) FEV_1			0-150%

Table 6. Practice Level Variables and Variable Type for Analysis (cont'd over leaf)

	Variable Type		
Measurement at Practice Level	**Dichotomous**	**Ordered Categorical**	**Continuous**
BTS ADHERENCE			
a) GP use	Use or Not		
b) GP Knowledge		0 to 3	
c) Behaviour			
Stepping up treatment		0 to 11	
Use of rescue medication		0 to 8	
Management of acute attack		0 to 11	
Equipment in consulting room		0 to 6	
Equipment taken on home visits		0 to 6	
Drugs taken on home visits		0 to 8	
d) Practice Equipment		0 to 14	
e) Practice Structure			
Practice Protocol		0 to 10	
Self-management Plan Use			0 to 100%
f) **Practice Resources**			
Practice Nurse Experience		0 to 10 yrs	
e) Prescribing (PACT)			
Ratio of inhaled corticosteroids To $Beta_2$ -agonist prescriptions		0 to 2	

Table 6 (cont'd) Practice Level Variables and Variable Type for Analysis

	Variable Type		
Measurement at Practice Level	**Dichotomous**	**Ordered Categorical**	**Continuous**
PRACTICE LIST SIZE			
a) number of patients registered			0 to 21, 000
b) number of partners		1 to 11	
PRACTICE ORGANISATION			
a) participation in audit		0-2	
b) asthma register			0 to 15%
c) asthma clinic		0-2	
d) system for recall and review		0-3	
e) computerisation		0-3	
f) treatment compliance		0-6	
g) use of generic prescribing	Yes or No		
h) availability of spirometer	Yes or No		
i) skin testing	Yes or No		

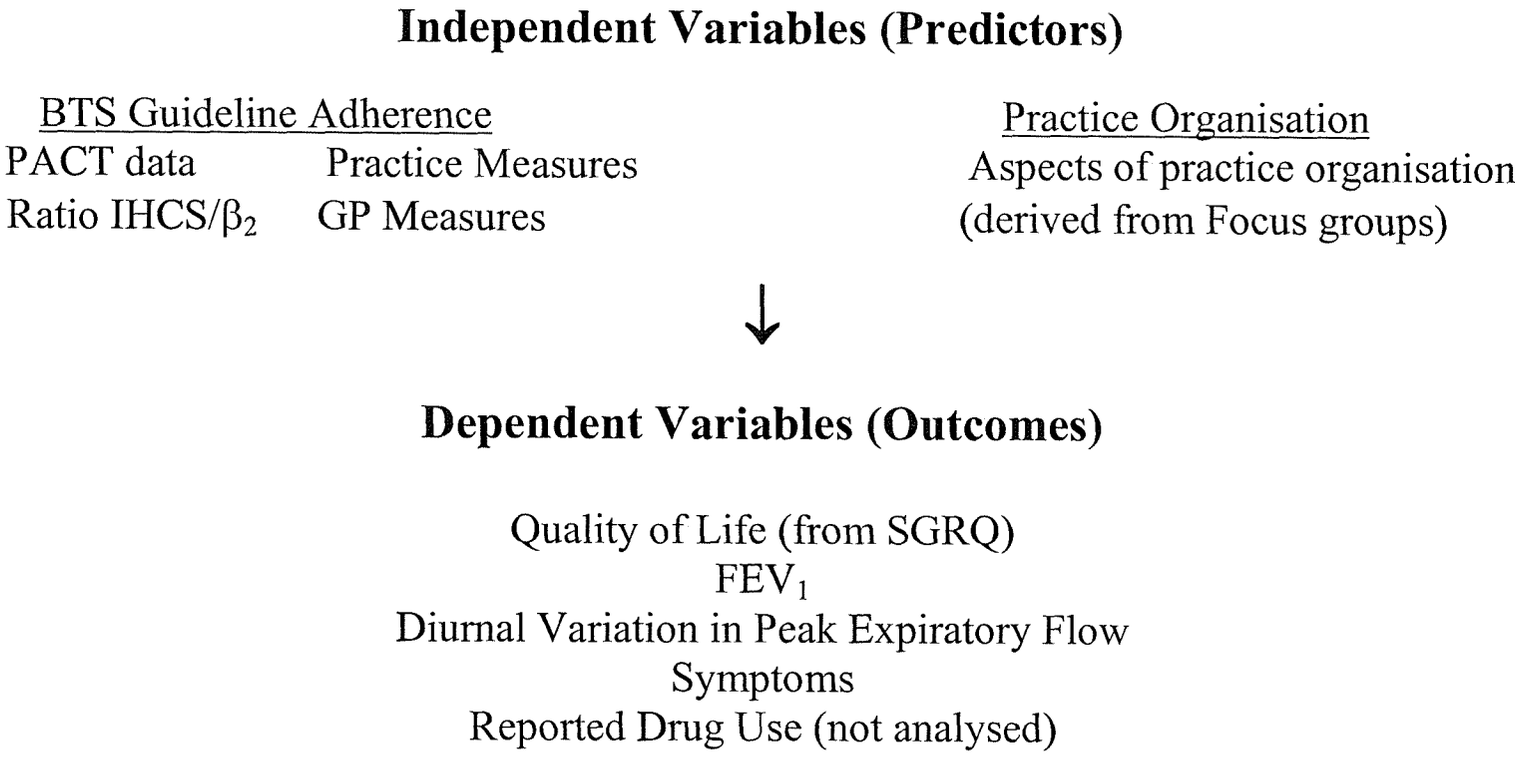

Figure 2 Hierarchical Diagram of Dependent and Independent Variables

CHAPTER FIVE

CHAPTER FIVE:
MEASUREMENT OF BTS GUIDELINE ADHERENCE

5.1 Introduction

In this chapter the methods used to measure adherence to the 1993 BTS guidelines are introduced. In the absence of a pre-existing instrument to measure guideline adherence, a series of measures were designed to assess general practitioners' knowledge and behaviour, availability of appropriate practice equipment and facilities. A bespoke scoring system provided a single score for each practice. The same questionnaire also captured data about aspects of practice organisation. The construction of the questionnaire and its piloting is presented in Chapter Seven.

5.2. Measuring BTS Guideline Adherence with Respect to Organisation of Care and Facilities

Two key recommendations in the BTS guidelines are:

- To use objective monitoring of progress, based on PEF readings wherever possible.
- To encourage greater participation of the patient or parents in the management of the condition (BTS et al, 1993).

In this study, direct questioning was used to assess the use of objective monitoring through PEF measurements and the use of self-management plans.

To manage asthma according to the BTS guidelines, certain equipment needs to be available at the practice. So as well as asking about the equipment kept at the practice, information was also sought about equipment kept in individual GPs' rooms and taken with them on home visits. The availability of the appropriate equipment and medication was assessed using closed questions. Although these items are 'resources', their presence was considered to demonstrate guideline adherence.

To assess the second recommendation of the BTS guidelines, information was required about the use of PEF diary cards for monitoring patients' progress and the use of self-management plans. The BTS guidelines also state that the education of patients with asthma may be shared with other health care personnel such as nurses. Therefore,

information was sought about the training and involvement of practice nurses in the care of patients with asthma.

5.3. Measuring BTS Guideline Adherence by Assessing Self-Reported Behaviour

Behaviour was assessed using vignettes. The first step in the development of the vignettes was to examine the 1993 BTS guidelines. In the BTS guidelines, the recommended treatment regimes are summarised using five treatment 'steps'. The guidelines advise matching each patient to the step most appropriate for their needs. Explicit recommendations are made when to 'step' patients up to the next level of treatment. The "vignettes", or mini-case studies each contained an indication for an imaginary patient to receive increased medication or move up a therapeutic step according to the recommendations in the 1993 BTS guidelines.

Asking about awareness of guidelines or knowledge of their factual content may-over estimate the impact guidelines have on clinical practice. It is recognised that self-reported behaviour may not be truly reflective of what happens in clinical practice; however, observation of clinicians' behaviour was not considered in the original study design. The questions pertaining to particular aspects of guideline adherence are outlined in the sections below, and summarised at the end of the chapter in Table 10.

5.4. Clinician's Use and Knowledge of the BTS Guidelines

Clinicians were asked whether they used a practice protocol, local or national guidelines to inform decisions about asthma management (see question Six, Table 5). Use of the BTS guidelines was considered the only correct answer. Practice protocols and local guidelines may not be based on the BTS guidelines and, at the time, local guidelines had not been developed in all areas. Therefore, if BTS guidelines were used to decide patient management the response scored 1, any of the others scored 0. GPs were asked how familiar they were with the BTS guidelines (see question Seven, Table 5). The scores to these responses were ranked from 0 for 'not aware, not heard of them (BTS)' to 3 for 'know what the guidelines recommend for *all* aspects of asthma management'.

5.5. Appropriateness of Clinician's Behaviour

The BTS guidelines emphasise the sensitivity of nocturnal symptoms as an indication of poor control; therefore, responses to a question about nocturnal wakening were ranked 2 points for 'always enquire about nocturnal symptoms', 1 for 'sometimes' and 0 for

'never' (see question 13, Table 8a). The 1993 BTS guidelines also stress the importance of checking patient compliance and inhaler technique prior to stepping up treatment. Therefore, in the vignettes (see questions 12, Table 8a and questions 14 and 15, Table 8b), discretionary points were given if some comment regarding compliance/technique/device check was made as well as the correct selection of treatment. Responses were ranked according to the appropriateness of the selection according to the recommended treatment steps of the BTS guidelines. In the guidelines, a specific treatment is recommended at each step but there is some flexibility to allow for the selection of alternatives.

The scoring was therefore ranked with 2 points given to the optimum selection according to the BTS guideline step and 1 point for alternatives, 0 points were allocated if the treatment selected was not recommended in the guidelines or not appropriate at that step. Data were collected in 1996 and 1997 and it was anticipated the 1995 review of the guidelines would be published imminently. GPs who had started to change their management in anticipation of the revised guidelines were not penalised if they reported *anticipated* rather than current recommendations.

5.6. Clinicians' Behaviour (equipment available in their rooms)

To manage asthma according to the BTS guidelines, the PHCT need a PEF meter, a height measure and either tables, a *normagram* or a wheel to calculate the percentage predicted peak expiratory flow (BTS, 1993, S8 and S9). These should be readily available in treatment and consulting rooms. The responses to each of the items in the questions that enquired about equipment were given 1 point if present and 0 if not. Discretionary points were also allocated if relevant 'other' items were mentioned that reflected use of the BTS guidelines; for example, if clinicians mentioned they had a copy of the BTS steps in their room, a point was added (see question eight, Table 8c).

Table 7. Questions Assessing Clinician's Use and Knowledge of the BTS Guidelines

Section 3	Aspect of Guideline Adherence
Question 6 *(management decisions)* **Do you use any of the following when deciding the management of asthmatic patients?** a) British Thoracic Society Guidelines b) Local Guidelines c) Practice protocol d) other?	Clinicians' use
Question 7 *(familiarity with BTS)* **How familiar are you with the BTS Guidelines for asthma management?** a) Not at all, you have not heard of them b) You have heard of them but are unsure of their content c) You know what the guidelines recommend for **most** aspects of asthma management d) You know what the guidelines recommend for **all** aspects of asthma management	Clinicians' knowledge

Table 8a. Questions Assessing the Appropriateness of Clinicians' Behaviour

Section 3	Aspect of Guideline Adherence
Question 12 *(vignette)* **What would be your preferred management for a 36-year-old male patient recently diagnosed with asthma, taking 200mcg beclomethasone twice daily who is getting nocturnal symptoms?** a) prescribe oral theophylline b) prescribe inhaled long-acting $beta_2$- agonists c) increase his dose of beclomethasone d) prescribe ipratropium bromide e) none of the above f) other?	appropriateness of treatment
Question 13 **Do you enquire about nocturnal symptoms due to asthma?** a) always b) sometimes c) never	appropriateness of management

Table 8b. Questions Assessing the Appropriateness of Clinicians' Behaviour (cont'd)

Section 3	Aspect of Guideline Adherence
Question 14 *(vignette)* **A 27 year old female patient whose usual treatment is high dose inhaled steroids, via a large volume spacer has developed a cold and over the last two days has required short acting beta$_2$-agonists several times a day. Her inhaler technique is satisfactory but her peak expiratory flow readings are below 50% of her best.** **What would be your preferred management for this patient?** a) prescribe oral theophylline b) prescribe inhaled long-acting beta$_2$-agonists c) prescribe a rescue course of oral steroids d) prescribe a broad spectrum antibiotic e) other	appropriateness of treatment
Question 15 *(vignette)* **You have made arrangements for an asthmatic adult to be taken to hospital. The patient is cyanosed and has a respiratory rate of 30 per minute.** **What management would you consider for this patient, who is particularly distressed, whilst waiting for the ambulance to arrive?** a) intravenous sedation b) intravenous aminophylline c) intravenous steroids d) nebulised beta$_2$-agonist e) nebulised ipratropium bromide f) nebulised steroids g) 40 puffs of a beta$_2$-agonist via a large volume spacer h) peak expiratory flow measurements i) other?	appropriateness of treatment

Section 3	Aspect of Guideline Adherence
Question 8 (equipment in consulting room) **Which of the following do you have <u>in your room</u> for the assessment of patients with asthma?**	
a) peak expiratory flow meter b) peak expiratory flow meter for low readings c) predicted values (for PEF) d) height measure e) other?	Appropriateness of behaviour

Table 8c. Questions Assessing Behaviour (equipment available in room)

5.7. Clinicians' Behaviour (appropriateness of the drugs and equipment taken on home visits)

Patients with asthma may need to be seen at home and therefore practices need portable equipment and appropriate medication in their emergency bags. The BTS guidelines do not make specific recommendations for equipment required for home visits, so the basic equipment and medications recommended for the management of uncontrolled asthma were used. The guidelines recommend a peak expiratory flow meter, some means of estimating a patient's percentage predicted value and a nebuliser or a large volume spacer. The medications recommended are a $beta_2$-agonist (available for administration via inhaler plus a nebuliser or spacer device) and oral prednisolone (BTS, 1993, S22). The responses to each of the items in the questions that enquired about equipment and medication were given 1 point if present and 0 if not (see question nine, Table 8d).

Table 8d. Questions Assessing Behaviour (appropriateness of the drugs and equipment taken on home visits)

Section 3	Aspect of Guideline Adherence
Question 9 *(equipment taken on home visits)* **Which of the following items of equipment do you routinely take with you on home visits?** a) peak expiratory flow meter b) peak expiratory flow meter for low readings c) predicted values (for PEF) d) spacer device e) portable oxygen f) nebuliser (inc. mask and tubing) g) other	Appropriateness of behaviour
Question 10 *(drugs taken on home visits)* **Which of the following drugs do you routinely take with you on home visits?** a) beta$_2$-agonist metered dose inhaler b) oral steroids c) steroids for injection d) adrenaline for injection e) salbutamol for nebulisation f) other?	Appropriateness of behaviour

5.8. BTS Guideline Adherence at Practice Level (equipment, structures and resources)

There are features of asthma management that are recommended in the 1993 BTS guidelines as 'good practice' and are described in greater detail below (and shown in questions one, two, three, five, six and nine in Table 9). BTS guideline adherence at *practice level* was assessed from the following:

- The presence of a practice nurse trained in asthma management.
- An asthma protocol based on the BTS guidelines.
- The use of self-management plans.
- The frequency of inhaler technique checks.
- Equipment available at the surgery.

a) The presence of a trained practice nurse

According to the BTS guidelines, the education of patients with asthma should be shared with nurses. To assess practice nurse training and experience as a resource, a question was included about certificated training courses completed in an academic institution. To assess the experience of nurses at each practice, the number of years since completing asthma training was ascertained and expressed in years since completion. If more than one nurse had a qualification in the care of patients with asthma, the longest time since completion of training was used.

b) An asthma protocol based on the BTS guidelines

The practice protocols were checked for the inclusion of ten items mentioned in the BTS guidelines. These ten items were selected after consultation with experts in the field of respiratory medicine and an arbitrary score of 1 was given for each one present in the practice protocol. Therefore, the potential score for this question was ten, and the higher the score the greater the adherence. The ten items are listed over-leaf:

1. The use of self-management plans.
2. The emphasis on prophylactic medication.
3. Introducing anti-inflammatory medication if $beta_2$-agonist required more than daily.
4. Patient education.
5. Selection of the correct device and teaching/monitoring technique.
6. Teaching patients how to recognise signs of asthma worsening.
7. Recognition and avoidance of triggers, especially cigarette smoke.
8. Monitoring with peak expiratory flow measurements.
9. Adjusting medication in accordance with needs.
10. The use of rescue medication (oral steroids).

c) The use of self-management plans

The use of self-management plans (SMPs) is recommended in the 1993 BTS guidelines. Therefore, a greater number of patients receiving SMPs, at a practice indicated greater adherence to that aspect of the guidelines. Practices were asked to estimate the proportion of patients given self-management plans and this was expressed as a percentage.

d) The review of inhaler technique

The BTS guidelines stress the importance of checking patients' inhaler technique. Questions were asked about who assesses this, how often and by what method. A point was given if the GP, and/or the practice nurse checked inhaler technique and two points if both checked this. I estimated the minimum frequency for checking inhaler technique was annually and this was given one point, more frequently or according to the patient's requirements was given two points.

e) Equipment available at the surgery

To manage asthma according to the BTS guidelines, practices need equipment such as peak expiratory flow meters, *normagrams* of predicted values, inhaler and spacer devices for patient teaching, height measure and a nebuliser. A score of 1 was given for each one present. Some procedures and equipment were not included in the BTS guidelines (e.g. Skin prick testing and spirometry) and therefore by implication were not recommended in the guidelines. These data were captured as examples of 'innovative practice' and are presented in Chapter Seven.

Table 9. Questions Assessing BTS Guideline Adherence at Practice Level (cont'd overleaf)

Section 2	**Aspect of Guideline Adherence**
Question 1 *(experience of practice nurses)* **a) Do any practice nurses take a special interest in asthma?** **b) How many?** **c) Have any of the nurses completed asthma training?** **d) How many?** **e) Dates** (Expressed in years since training)	practice resources
Question 2 *(asthma protocol)* **a) Does the practice have an asthma protocol?** **b) Is the protocol based on any asthma guidelines?** (10 key points checked)	practice structure
Question 3 *(self-management plans)* **a) Are self-management plans used?** **b) Which ones?** **c) What percentage of patients are given them?**	practice structure
Questions 5 and 6 *(inhaler technique checking)* **5.a) Is inhaler technique assessed for patients with asthma?** **b) Who usually assesses inhaler technique?** GP, Practice Nurse or Both **c) How is inhaler technique checked?** i) Using a written checklist ii) Using a "mental " checklist iii) Other, e.g. Ames **6. How often is inhaler technique assessed?** a) monthly b) six monthly c) annually d) according to individual requirements e) other	practice structure

Table 9. (cont'd) Questions Assessing BTS Guideline Adherence at Practice Level

Section 2	Aspect of Guideline Adherence
Question 9 *(equipment)* **Which of these facilities does your surgery have for the care of patients with asthma?** a) nebuliser (please specify availability of nebuliser) i) treatment room ii) for loan by patients iii) for home visits b) spirometer c) peak expiratory flow meters d) peak expiratory flow meter, for low readings e) selection of inhaler devices for teaching f) spacer devices for teaching g) height measure h) means of estimating patients predicted values i) diary cards Symptoms PEF j) skin testing kit	practice resources

5.9.1. Measuring BTS Guideline Adherence by Examining Prescribing Patterns

The PPA publishes quarterly reports of drugs prescribed and their cost. Prescribing analysis and cost data (PACT) is available at three levels:

- Level 1 data contain total prescribing costs for individual general practices, summarised under the chapter headings from the British National Formulary (BNF)
- Level 2 data are about prescribing by subsections of the BNF
- Level 3 data give more detailed information about individual drugs

All GPs routinely receive level 1 PACT data and can request levels 2 and 3. Health authorities are also provided with PACT data from the PPA enabling the authority to compare their performance with other health authorities, monitor general practice spending and allocate prescribing budgets.
However, PACT data have certain limitations:

- They cannot be linked to demographic or clinical data.
- They exclude prescriptions written but never dispensed.
- They exclude private prescriptions.
- The number of items prescribed may not reflect the amount of drug prescribed.
- The information is limited to prescriptions from general practice and it does not include those dispensed from hospital pharmacies for patients seen in outpatients, or on discharge from hospital (Majeed and Voss 1995; Bateman 1996; Majeed et al, 1997).

Despite the above limitations, PACT data are derived from routinely collected information, are readily available and the most efficient way to collect information about GPs prescribing patterns (Currie et al, 1997).

5.9.2 Defined Daily Doses

The analyses of volumes of drug prescribed have previously been limited by their presentation as 'prescriptions' or 'prescribed items', which do not allow for the quantity or strength of each drug. This limits the potential value of PACT data to researchers and managers. The calculation of Defined Daily Doses (DDDs) has gone some way to

address the mismatch between the items and amount of drug prescribed. A method was devised by the World Health Organisation (1991) to enable the conversion of prescribed drugs into equivalent units of a standard defined volume. The formula to calculate DDDs gives each drug a value that is within its recognised range of possible doses. It is an arbitrary unit of measurement and does not represent a real or recommended dose, but purports to represent the average daily maintenance dose prescribed when used for its main indication in adults.

DDDs for commonly used drugs in primary care were agreed in a joint project with the Nordic Council on Medicines and the World Health Organisation (WHO) Centre for Drug Collaboration Statistics (1991). The values allocated to some substances were thought to be inappropriate for UK general practice so the formulae were reviewed with the intention of calculating UK DDD values.

5.9.3. Defined Daily Dose Values for the UK

To ascertain the appropriateness of DDD values for the UK, the Prescribing Research Unit (PRU) at Leeds University compared prescribing data for the UK and Ireland with the values assigned by the WHO.

Carbon copies of prescriptions (FP10s) written by 1250 English general practitioners in 1992 and 1993 provided the data used in this development work. These English Prescribed Daily Doses (PDDs) were then compared with the WHO DDDs and the percentage difference calculated:

$$\% \text{ difference} = \frac{(\text{PDD minus DDD})}{\text{DDD}} \times 100$$

The percentage differences were in fact small and The PRU concluded the vast majority of the WHO DDD values would probably be acceptable for use in the U.K. (Prescribing Research Unit, 1995). In October 2000 an expert panel consisting of members of the Prescribing Support Unit in Leeds, the pharmaceutical industry, the Prescription Pricing Authority and the editor of the British National Formula published further work regarding the development of the English equivalent of the WHO DDDs. Average Daily Quantities for medications in 27 therapeutic areas have now been developed. However, these need to be constantly monitored on an annual basis to ensure new drugs are included, the

values proposed reflect changes in licensed doses and actual prescribing patterns (Prescribing Support Unit, 2000).

Work carried out prior to the commencement of this study showed that DDDs could be a more reliable indication of drug volume prescribed than using items or cost as the unit of measurement.

Maxwell and colleagues performed a study comparing the prescribing habits of a group of fundholding practices and a group of non-fundholding practices in northeast Scotland. Prescribing habits and costs for the practices were calculated by converting each prescription using the WHO DDD mechanism. Over the two years that data were collected, both groups of practices reduced the volume of their prescribing for the classes of drug analysed. Using this method it was demonstrated that although prescription costs per patient rose, the volume of drugs prescribed actually fell. The overall rise in costs was explained by the rise per unit costs of the drugs. Therefore, the authors concluded that the doctors had responded positively to requests for them to prescribe at generally lower volume levels. From this, it was suggested that the DDD method could be used to calculate more meaningful cost per volume figures than simply using items or "cost per patient per year" as an assessment of practice prescribing habits and that the DDD method to assess drug volume gives a more accurate assessment of prescribing habits which may not be well recognised if total drug costs alone are observed (Maxwell et al, 1993).

5.9.4. The Ratio of Inhaled Steroids and Bronchodilator

One of the main recommendations in the BTS guidelines is for increased use of inhaled anti-inflammatory drugs, even in patients with mild asthma. It has been suggested that the patients of doctors who prescribe more prophylactic medication may experience less morbidity (Hay and Higgenbottam, 1987; Horn and Cochrane, 1989; Gellert et al, 1990; Neville et al, 1991).

The ratio of prophylactic s (inhaled steroids and cromoglycate) to $beta_2$-agonists has been proposed as a "surrogate quality marker" of asthma management in general practice (Naish et al, 1995; Sturdy et al, 1995; Griffiths et al, 1996; Shelley et al, 1996; Aveyard, 1997). The key studies in this area are described below.

Naish and colleagues (1995) examined GPs' prescribing behaviour in practices that demonstrated indicators, characteristic of good asthma management, namely:

- Approval for asthma surveillance.
- Band Three health promotion.
- Vocational training.

The practices with these indicators of good asthma management had on average higher ratios of prophylactic to bronchodilator treatment and significantly higher asthma drug costs than other practices.

Other studies have examined the relationship between the ratio of inhaled corticosteroid and beta agonist (IHCS/β_2) prescriptions and hospital admissions. Griffiths and colleagues (1996) demonstrated an association between asthma prescribing and hospital admissions. Practices with higher ratios had lower hospital admission rates.

However, Shelley and colleagues (1996) failed to show a significant relationship between admission rates for asthma and prescribing ratios. The results of the Shelley study were in direct contrast to the results of the work by Griffiths (1996), but there are aspects of Shelley's study that may be criticised:

- The inclusion of hospital admission rates for all ages when it is recognised that the diagnosis of asthma is least secure at the extremes of age.
- The failure to define admissions - it was not clear whether re-admissions were included in their data (Griffiths et al, 1997b).

A study by Aveyard (1997) compared hospital admissions with prescribing ratios and process measures associated with favourable asthma control (taking deprivation into consideration). A high rate of admissions in practices was correlated with deprivation of the patients, in the form of a practice Townsend score ($r = 0.33$, $p = 0.003$), and also with poorer prescribing, measured by the preventer-reliever ratio ($r = -0.38$, $p = 0.001$). Regression analysis showed that the relationship between good prescribing and low admission rates was not explained by confounding variables. Only 32% of the variation in admission rates between practices was explained by the regression equation. It was concluded that prescribing, as measured by the preventer-reliever ratio, and hospital admission rates may have limited usefulness. Whilst it is encouraged in the guidelines to

prescribe high amounts of corticosteroids per patient, in Aveyard's study it was associated with higher admission rates. This may be explained by the following:

- Corticosteroids may be prescribed, but not taken by patients.
- Corticosteroids may have been prescribed in the wrong dose.
- Corticosteroids may have been prescribed, but in the wrong way using the wrong device.
- Corticosteroids may have been prescribed, but have been ineffective in some patients.

To date the value of the ratio of IHCS/β_2 as an indicator of good asthma management has only been judged using hospital admissions as the outcome measure. Hospital admissions are a rare event and may represent poor asthma control, or replicate the severity of the disease in a particular population. This study provided an opportunity to examine the relationship between prescribing habits and patient outcomes.

Clinicians' prescribing patterns were assessed from PACT data from the Practice Prescribing Authority. The data for the total items of inhaled steroids and the total items of bronchodilators were presented as Defined Daily Doses. The ratio of IHCS/β_2 was calculated thus:

$$\textbf{ratio} = \frac{\textbf{inhaled corticosteroid}}{\textbf{beta}_2\textbf{-agonists}}$$

The different aspects of guideline adherence measured in the study are summarised overleaf in Table 10.

Aspect of Guideline Adherence	Measure	Range of Score
practice resources	Presence of trained practice nurse. *(Section 2 - question 1)*	0 to 10
practice structure	Asthma protocol. *9Section 2 - question 2)* Self-management plans. *(Section 2 - question 3)* Checking inhaler technique – who. *(Section 2 - question 5)* Checking inhaler technique –frequency. *(Section 2 - question 6)*	0 to 10 0 to 100% 0 to 5 0 to 3
practice equipment	Presence of nebuliser, peak expiratory flow meters, inhaler and spacer devices, height measure, predicted values and diary cards. *(Section 2 - question 9 (not b and j))*	0 to 14
Clinicians' use of guidelines	Management decisions. *(Section 3 - question 6)*	0 to 1
Clinicians' knowledge of guidelines	Familiarity with BTS. *(Section 3 - question 7)*	0 to 3
Clinicians' behaviour (treatment and management)	Vignette *(Section 3 - question 12)* Nocturnal symptoms. *(Section 3 - question 13)* Vignette *(Section 3 - question 14)* Vignette *(Section 3 - question 15)*	0 to 11 0 to 3 0 to 11 0 to 8
Clinicians' behaviour (equipment)	Equipment in room. *(Section 3 - question 8)* Equipment taken on home visits. *(Section 3 - question 9)*	0 to 6 0 to 6
Clinicians' behaviour (drugs)	Drugs taken on home visits. *(Section 3* *questions 10 and 11)*	0 to 8
Clinicians' behaviour (prescribing)	Ratio IHCS/β_2 (DDDs)	0.0 to 1.0

Table 10. Measurement of Guideline Adherence

5.10. Summary

In this chapter, three ways to measure BTS guideline adherence have been introduced:

- By assessing self reported behaviour.
- By examining the organisation of care and resources.
- By examining prescribing patterns.

This study presented an opportunity to examine BTS guideline adherence using specifically designed measures and to assess the impact of adherence on patient outcomes. The validity of the ratio of inhaled steroid to $beta_2$-agonists as an indicator of quality asthma management is not proven and this study also provided an opportunity to examine the PACT data for practices and compare the ratio of IHCS/β_2 (expressed as DDDs) with patient outcomes.

The outcomes used are described in chapter six.

CHAPTER SIX

CHAPTER SIX
OUTCOME MEASURES

6.1 Introduction

Traditionally, measuring success of medical treatments has relied upon clinical assessment of the patient and laboratory tests. In asthma, bronchial challenge testing, spirometry and PEF measurement have been widely used. However, achieving "physiological perfection" may not necessarily equate with the patient's own sense of well-being. The realisation that patients' opinions are important in the assessment of their health care has resulted in the development of instruments to measure subjective well-being as an adjunct to traditional outcome measures. In this chapter, I review the outcome measures feasible in a community-based project and the rationale for those selected for use in this study.

6.2 Measuring Quality of Life in Patients with Asthma

Instruments to measure patient-assessed health outcomes may be generic or disease-specific. There are many standardised generic measures that have been subjected to substantial validation and are widely used, including the Sickness Impact Profile (SIP) (Bergner et al, 1976), the Nottingham Health Profile (Hunt and McEwan 1980) and the Short-Form 36 (SF-36) (Ware and Sherbourne 1992). The SIP is one of the longest and most comprehensive measures and is often used as the "gold standard" to which others are compared. The SIP has been shown to be a valid measure to quantify general health impairment in patients with Chronic Obstructive Pulmonary Disease (COPD), but is insufficiently sensitive for patients with FEV_1 greater than 50% of predicted (Jones et al, 1989b). The majority of patients with asthma fall into this latter category. To facilitate the assessment of quality of life in patients with mild and moderate asthma, several disease-specific quality of life questionnaires have been developed. These are summarised in Table 11.

Table 11. Quality of Life Instruments in Asthma

Author	Year	Questionnaire	Specifity	Administration	Validation
Juniper et al	1992	**The Asthma Quality of Life Questionnaire**	Asthma-specific, 32 items, designed for use in clinical trials	Items are in four domains: symptoms, emotions, environmental exposure and activity limitation. Each item has seven possible responses, and the patient personally identifies 5 of the 11 activities. Both versions (interviewer and self-administered) take 10 minutes to complete (Juniper et al 1993). In my own experience it also requires some 5 minutes preparation time, prior to its administration for explanation and organisation of the coloured cards that accompany the package.	In validation studies it has demonstrated good responsiveness and longitudinal construct validity (Juniper et al, 1993; Rowe and Oxman, 1993), in addition to its good discriminative properties with an intra-class coefficient of 0.92 (Juniper et al, 1993; Malo et al, 1992)
Marks et al	1992	**The Asthma Quality of Life Questionnaire (AQLQ)**	Asthma-specific self-administered containing 20 items in 4 domains: - breathlessness/physical restriction, mood disturbance, social disruption and health concerns.	It takes about 5 minutes to complete and there is a scale of five points for each response. The items have been selected using psychometric techniques that reflect what is important to patients.	It has good discriminative properties with an intra-class correlation coefficient of 0.80 and it has good cross-sectional and longitudinal construct validity (Marks et al, 1993)
Hyland	1991	**The Living With Asthma Questionnaire**	Asthma-specific self-administered 68 item instrument containing 11 domains.	The items for inclusion were identified from comments at 6 patient focus groups. The original questionnaire, the AQ1 had 12 domains and 101 items. These were subsequently refined through standard psychometric techniques using a total of 783 patients. It uses a 3-point scale for responses. It is estimated to take 15 minutes to complete (personal communication).	It has been shown to have predictive validity (40 patients) demonstrated by its relationship to PEF (r= -0.44) and the prescription of steroids (r=0.35) (Hyland, 1991). It has also been used to demonstrate improved quality of life in comparison to placebo in a double blind, placebo-controlled trial of 425 patients administered 'salmeterol' (Palmer and Hyland, 1991).
Jones	1991b	**St. George's Respiratory Questionnaire (SGRQ)**	Not asthma specific, standardised, self-completed 76 item questionnaire.	It was designed to allow comparative measurements of health between patient populations and to quantify changes in health following therapy (see appendix 4). The questionnaire was developed for patients with chronic airflow limitation, whether caused by chronic bronchitis, emphysema, COPD or asthma. It has 3 domains of symptoms, activity and impacts.	It has been validated as an assessment tool and its components are well-correlated with physiologic measures (symptoms and FEV_1). It has good repeatability when tested in stable asthmatics. Repeated at 2 weeks intra-class coefficient was 0.91 and coefficient of variation was 19% (Jones et al 1992c).

6.3 The St. George's Respiratory Questionnaire (Jones, 1991b)

To ensure patients' own experience of their disease was represented in the outcomes measured in this study a disease specific quality of life measure was sought. From the quality of life measures reviewed (see Table 11), the St. George's Respiratory Questionnaire (SGRQ) was selected. The availability of personal contact with the author (Professor Paul Jones) was very valuable. This allowed discussion about the administration and analysis of the questionnaire. The two major factors that influenced selection of the SGRQ were:

- The ease of its administration was considered a particular advantage in a community-based study with limited time available to see a large volume of patients.
- The simplicity of its analysis would allow direct comparison between patients physiological disease outcome and guideline adherence in their practice.

The SGRQ has been validated and has good repeatability when tested in stable asthmatics (Jones et al 1992c). To assess repeatability, the total scores of the SGRQ questionnaire administered on two occasions to the same sample of patients a fortnight apart were compared. The coefficient of variation was 19%, which compares favourably with reported repeatability of other respiratory quality of life questionnaires (Guyatt et al 1985).

With repeated testing, after 12 months with 122 out of an original sample of 152 patients, correlation was found between changes in the SGRQ total score and a range of other measures of disease activity, such as FVC, the six minute walking test and the frequency of anxiety and wheeze (Jones et al, 1992c).

The SGRQ has also been shown to have good reliability with an intra-class correlation coefficient of 0.91 and good cross-sectional correlation with the SIP, anxiety, depression and the 6-minute walking test. More recent studies have successfully used the SGRQ to measure quality of life in patients with asthma (Osman et al, 2000). It has also been used as a predictor of hospital re-admission for patients with COPD (Osman et al, 1997), to examine the relationship between quality of life and age in a sample of the general population over 45 (Renwick and Connolly, 1996) and to compare guided self-management and traditional treatment of asthma (Lahdensuo et al, 1996).

The SGRQ was developed for patients with chronic airflow limitation, whether caused by chronic bronchitis, emphysema, COPD or asthma. It is a standardised, self-completed 76-

item questionnaire designed to allow comparative measurements of health between patient populations and to quantify changes in health following therapy (see appendix 4). In the SGRQ, responses to the majority of statements are either true or false, but some have 4 or 5 frequency or severity options. For example, Part A of the SGRQ contains questions about *how much chest trouble you have had over the last year* and rates its severity:

1) Over the last year I have coughed -	Most days a week?
	Several days a week?
	A few days a month?
	Only with chest infections?
	Not at all?

Part B, section 2 of the SGRQ requires the respondent to complete statements about *what activities usually make you feel breathless these days:*

11)	Sitting or lying still	True or False?
	Getting washed or dressed	True or False?
	Walking around the home	True or False?
	Walking outside on the level	True or False?
	Walking up a flight of stairs	True or False?
	Walking up hills	True or False?
	Playing sports or games	True or False?

The SGRQ has the following 3 domains:

- **"Symptoms"** concerned with respiratory symptoms, their frequency and severity
- **"Activity"** concerned with activities that cause or are limited by breathlessness
- **"Impacts"** which covers a range of aspects concerned with social functioning and psychological disturbance resulting from respiratory disease.

A score for each domain, or component and an aggregate score can be calculated using weightings. These weightings were empirically derived from 140 patients of varying ages, with different severity of asthma from 6 different countries. Factors such as

nationality, age, spirometry and duration of asthma were found to have minimal effect on the weights (Quirk and Jones, 1990).

In this study, mean scores for all three domains of symptoms, activity and impacts were calculated for each patient, as well as the total mean score. As the unit of analysis in this study is the general practice a quality of life score for each practice was calculated by taking the arithmetic mean of the SGRQ scores for the patients from each practice.

a) The SGRQ Component Scores

To calculate the score the weights for all the positive responses are added together. The summed weights are then divided by the maximum possible weight for that component the result is expressed as a percentage. The range of possible values is from 0 to 100 and a higher score indicates a worse quality of life; the formulae for the calculations are set out below (Jones, 1991b).

$$\textbf{Score (\%)} = 100 \times \frac{\text{Summed weights from } \textbf{positive} \text{ responses}}{\text{Sum of } \textbf{potential weights}}$$

b) The SGRQ Total Score

The total score is calculated in the same way by aggregating the scores from the three components and expressing this as a percentage. The sum of the weights given in the guidance notes are presented below:

- Symptoms 662.5
- Activity 1209.1
- Impacts 2117.8
- Total 3989.4

c) Missing Values

If the response to a question was missing, the weight for that question is subtracted from the maximum possible weight to give a new divisor. It is recommended the maximum number of missing values tolerated in the calculation is no more than 10.

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6.4.1 Measures of Disease Control

Good asthma management aims to achieve:

- Minimal or ideally no symptoms, especially at night.
- Being able to carry out normal levels of activity.
- Normal or best achievable FEV_1 of at least 80% of predicted.
- PEF diurnal variation of less than 20%, ideally less than 10%.
- No exacerbations requiring nebulisation or rescue courses of oral steroids (Hargreave et al, 1990; Jamison and Mckinley, 1993; BTS et al, 1993).

So, in addition to measuring quality of life as the primary outcome, I also chose to include some secondary outcome measures of disease control from the above list. Symptoms, diurnal variation in peak expiratory flow and percentage predicted FEV_1 were chosen as they provide a good range of measures and are reasonably pragmatic in a large community based study.

6.4.2 Symptoms

In this study, patients recorded their symptoms on a diary card that was completed over a 14-day period: (see appendix 13)

- Symptoms on waking.
- Daytime symptoms.
- Problems with daily activities attributed to chest problems.
- Night-time wakening.

Using the following 0-3 scoring system (0 for no symptoms, 1 for mild, 2 for moderate and 3 for severe), patients rated their symptoms (see appendix 13). This gave a range of symptom scores from 0 to 12 per day, with a higher symptom score representing greater morbidity. The assessment of severity is obviously dependant on patients' own subjective judgement of what constituted mild, moderate or severe for them as individuals. Nocturnal wakening is a sensitive marker of poor asthma control, therefore to ensure this was obvious in an individual score, the frequency of wakening was entered into the total and not categorised as mild, moderate or severe as the other symptoms.

If scores were interrupted, or missing for a whole day, only the total of complete days were used to calculate the mean score for that individual patient*. A practice symptom score was calculated as the mean of the individual patient symptom scores (see formula below):

$$\textit{Individual mean} = \frac{\text{Total Symptom Score}}{\text{14 (or total of complete days if fewer)*}}$$

$$\textit{Practice mean} = \frac{\sum \text{individual means}}{\text{number of patients per practice}}$$

6.4.3 Measurements of Physiological Disease Control

In epidemiological studies of asthma, it is recommended that some combination of tests be performed to establish the severity of asthma (Siersted et al, 1996; Taylor, 1997). In this study, peak expiratory flow measurements and spirometry were also performed.

6.4.4 Diurnal Variation in Peak Expiratory Flow (PEFDV)

Peak expiratory flow (PEF) is a useful indicator of variability in airway calibre, which correlates with the changes in FEV_1 and with airway hyperresponsiveness (BTS et al, 1997). Serial PEF measurements taken in the morning and evening are considered one of the most reliable measures to assess the level of asthma control (Enwright et al, 1984; Taylor, 1997). An average reading can be calculated for a given period, usually 2 weeks. This reading can be compared with a predicted "normal" standardised for sex, age and height.

The use of diurnal variation in peak expiratory flow (PEFDV) is popular in the monitoring of asthma patients and it is estimated some 85% of patients are willing and able to record their PEF rate satisfactorily at home (Jamison and McKinley, 1993; NHLBI 1995).

Peak expiratory flow variability has been shown to correlate well with bronchial reactivity to histamine and is widely used in epidemiological studies (Ryan et al, 1982; Higgins et al, 1989). There is evidence that changes in PEF predict changes in FEV_1 and well-performed serial PEF measurements over a week, have been shown to be more sensitive than a single spirometry reading in detecting changes in airway function (Dekker et al, 1992; Enwright et al, 1994).

Portable PEF meters are widely used in practice for the diagnosis and monitoring of asthma in primary care. Nonetheless, there are some associated problems with using PEFDV for monitoring asthma; these are described below.

a) Cumbersome calculations: Diurnal variability in peak flow has been included in asthma guidelines for many years, however, doctors in primary and secondary care settings rarely use it, because of the cumbersome calculations involved. Also, several alternative equations may be used. The most common are the following:

- amplitude percentage mean {(maximum–minimum)/mean}
- amplitude percentage maximum {(maximum–minimum)/maximum}

Determining the amplitude percentage mean from just one week's twice daily peak flow readings is complicated and tedious. Furthermore, the calculations take too long for a standard medical consultation in primary care. Electronic recording and computerised processing of peak flow data are still prohibitively expensive for general practice.

b) Number of daily observations and impact of timing: Most asthma guidelines state that diurnal variability should be calculated from two sets of peak flow readings each day taken in the morning and afternoon/evening. However, since completing the work for this study there has been some debate regarding the accuracy of calculating "true" diurnal variability with just two readings per day. If patients record only two peak flow sessions per day, the time at which peak flow is recorded may have a major impact on the estimated diurnal variability. However, asking patients to record peak flow measurements in the middle of the day is generally impractical. Clinical trials often specify time "windows" within which peak flow measurements should be performed. Doing this may, however, introduce more error, because the timing of the peak flow *acrophase* appears to be determined by the time at which the patient wakes on that day, and variations in daily lifestyle can have a substantial impact on estimated diurnal variability.

c) Effect of drug regimens: Several asthma guidelines specify that in order to standardise recording conditions peak flow should be recorded before the inhalation of beta-agonist drugs. This is also standard practice in most clinical trials. However, the validity of diurnal variability as a measure of asthma severity was originally established when the recommended treatment regimen for beta-agonist drugs was routine inhalation

two to four times daily. Some have argued its validity cannot be assumed now that beta-agonists are usually taken only on demand (Reddel et al, 1999).

d) Diurnal variability and exacerbations: Calculating diurnal variability in peak expiratory flow during exacerbations of asthma is included in two current guidelines. The guidelines of the British Thoracic Society recommend that diurnal variability should be used to assess whether a patient admitted to hospital for an exacerbation of asthma can be discharged home safely. However, diurnal variability may not detect all important and sustained changes in lung function, and cannot be recommended for assessing the severity of asthma exacerbations. Also, in general practice, calculation of diurnal variability may not reliably identify short term reductions in peak expiratory flow because of the effect of averaging over one or two weeks (Siersted et al, 1996).

e) Other indices of variation in peak flow: Despite the problems with diurnal variability discussed above, visual inspection of peak flow charts can provide helpful information about the severity of asthma and the response to treatment, however this requires considerable experience, and is not appropriate for general practice. In the absence of a "gold standard," clinical practice guidelines for assessing asthma severity and monitoring asthma control recommend a variety of measures such as symptoms, lung function, and airway lability.

6.4.5 Measurement of Diurnal Variation in Peak Expiratory Flow (PEFDV)

As previously described in chapter one, diurnal variation in peak expiratory flow (PEFD) is considered the best variability index to use as it gives good distinction between asthmatic and non-asthmatic patients than other indices. Although cumbersome for use in the clinical setting and despite the associated problems with its measurement, at the time of performing this study it was the most widely used index (Higgins et al, 1989; Jamison and Mckinley 1993; Rees and Price, 1995).

Several definitions of PEFDV have been used. The *amplitude percent mean* was the method of choice for this study given its statistical performance and the simplicity of use. Serial PEF measurements taken in the morning and evening were entered into the formulae below to obtain the *amplitude percent mean* diurnal variation for individuals and practices (see over-leaf).

Individual diurnal variation = *(amplitude percent mean)*

$$\frac{\text{(pm PEF - am PEF)}}{\text{pm PEF}} \times 100 \text{ over 14 days}$$

From the individual PEFDV, the practice PEFDV can thus be calculated:

Practice diurnal variation = *mean* $\left\{ \frac{\text{(pm PEF - am PEF)}}{\text{pm PEF}} \times 100 \right\}$ over 14 days

Days with no readings or those with only one PEF reading were treated as missing data. The difference between the two readings was always expressed as a positive figure and was calculated using the **total** number of complete days. The range of possible values for diurnal variation was from 0 to 100 with higher scores implying poor control. A practice score was calculated from the *arithmetic mean* of individual patient diurnal variation scores.

6.4.6 Percentage Predicted FEV_1

In addition to PEFDV, spirometry was performed to capture measurements of FEV_1. The measurement of FEV_1 gives a highly accurate estimate of disease severity and is a more sensitive indicator of long-term airway damage than PEF readings (Vaughan et al, 1989; Bye et al, 1992; Enright et al, 1994). Therefore, in this study; each patient was also required to perform spirometry on one occasion. FEV_1 was measured against tables of predicted values for patients' age, sex and height and expressed as a percentage of the predicted value. A higher percentage implies better control. The practice score for percentage predicted FEV_1 was calculated as the mean of the individual measurements.

6.5 Summary

The ultimate aim of any intervention in the health care setting is to improve patient well-being. The focus of this study was to examine the relationship between adherence to the BTS guidelines and patient outcomes and the previous two chapters have described the methods used to measure these. However, occasionally an association between two variables can be explained by the influence of another and has little meaning in itself. It was not known what impact recent changes in practice organisation might have on patient outcomes and the following chapter describes how this has been explored in this study.

CHAPTER SEVEN

CHAPTER SEVEN:
ASSESSMENT OF PRACTICE ORGANISATION

7.1 Introduction

Aspects of practice structure and organisation may impact on clinical outcomes of patients with asthma and may alter or confound the effects of adherence to the BTS guidelines. Confounding effects can be managed by *restricting* the study to a homogeneous sample, or by *neutralising* with matching or randomisation. Neither approach was applicable to this study, instead I controlled for possible confounders in the statistical analysis.

In this chapter, potential for practice organisation to impact on the management of patients with asthma is described and the methods to measure are introduced.

7.2.1 Measuring Practice Organisation

I recognised from my review of the relevant literature that aspects of practice organisation may impact on patient outcomes and therefore wished to characterise practice organisation for inclusion in the analysis. Information about aspects of practice organisation was required to examine their existence as potential confounders to guideline adherence.

Thorough searching of the literature and contact with several experts in the field did not identify a questionnaire to capture information about practice organisation and therefore, a bespoke instrument was developed. Discussion groups with GPs, practice nurses and patients were organised in order to explore the practice characteristics and resources that were perceived as potential confounders to patient outcomes. The procedure I followed to develop the questionnaire is described below.

7.2.2 Development of the Questionnaire to Measure Practice Organisation

Discussion groups were organised and followed published guidance for conducting focus groups (Morgan 1992; Kitzinger 1995). The groups contained six to ten people, their members were 'homogenous strangers' and three groups were convened.

For ease of administration, questions about practice demography and practice organisation were included alongside questions about BTS guideline adherence. A

single questionnaire was developed that gathered information under logical headings. For example, the section regarding practice equipment asked not only about the equipment required to comply with the BTS guideline recommendations but also about other equipment not specified in the BTS, such as a spirometer. The resultant data collection instrument was referred to as The Asthma Management in Practice questionnaire (AMPQ) (see appendices five and six).

7.3.1 Organisational Structures in Place to Qualify for CDM Payments

In The Asthma Management in Practice questionnaire (AMPQ) the organisational aspects were divided into two groups:

1. Organisational structures in place to qualify for CDM payments
2. Innovative practice

Under the revised contract for the provision of health promotion services in general practices (NHS 1993) special 'chronic disease management' payments were introduced for diabetes and asthma. For the care of patients with asthma, to qualify for these payments practices were required to maintain a register of patients and demonstrate certain levels of care (including prescribing, review and audit). They also needed to have in place agreed practice protocols and demonstrate they were setting and maintaining standards for asthma care.

In the discussion groups the required elements for CDM payment in the 1993 contract were used as prompts to guide the discussions about aspects of practice organisation. These discussion groups informed the construction of questions in the AMPQ. The following data were captured regarding the organisational structures required to qualify for CDM payment:

- Participation in audit.
- The existence of an asthma register.
- The methods used to see patients (use of a specific asthma clinic).
- The 'recall and review' system.
- Prescription monitoring.

7.3.2 The Existence of Innovative Practice Organisation

As some innovative practices currently being implemented were not described in the literature, information about novel aspects of practice organisation was sought in the discussion groups with GPs, practice nurses and patients. In these meetings, features beyond the scope of the BTS guidelines or CDM scheme were considered as 'innovative practices' and explored. From the discussion groups the additional characteristics of practice organisation perceived to be important included:

- Computerisation of practice records.
- Practice nurse training in asthma management.
- Methods used to increase treatment compliance by patients.
- Availability of a spirometer.
- Skin prick testing with common allergens.

7.4.1 Administration of the AMPQ

In the original proposal for project funding it was planned the AMPQ would be completed as part of a semi-structured interview. However, it was decided to change the questionnaire for one that could be posted and *self-completed* for the following reasons:

- It would be less demanding on the researcher's time.
- Respondents could complete the questionnaire in their own time.
- It is relatively cheaper.
- It is less susceptible to interviewer bias.
- Questions are standardised.
- It can be administered by mail.
- It has greater anonymity (Altman 1992; Ross 1997).

Despite the advantages of mailed questionnaires a disadvantage is that they may be subject to high rejection and refusal rates. Non-completion/return of the AMPQ was considered unlikely as the practices had volunteered their participation and were likely to be interested in the care of patients with asthma.

Another potential disadvantage of mailed questionnaires is that they may be subject to mis-interpretation. Therefore, the questions were made as clear and concise as possible

and wherever possible, information was sought using closed response questions, with spaces for respondents to add comments. In areas where multiple-choice was used, respondents were informed that more than one answer may be selected. Care was taken when designing the questions to give adequate choice and ensure bias was not introduced by over-restricting the range of answers. To facilitate completion, the questionnaire was designed so that different members of the practices (practice manager, practice nurse and GP) were responsible for providing information. The questionnaire was arranged into the following three sections (see appendix 5):

1. The first section, completed by the Practice Manager was designed to gather *demographic information* about the practice, including the number of partners, number of patients registered and age composition of practice population, etc.
2. The second section, completed by the Practice Nurse, concentrated on *asthma-specific aspects of practice organisation,* including the use of a practice protocol for asthma management, organisation of review appointments and the presence of a nurse trained in asthma management.
3. The third section of the questionnaire was intended to gather information about *GPs' interest and training in the management of patients with asthma* and whether they followed the *BTS treatment guidelines*. This section of the questionnaire needed to be carefully phrased to elicit the required information.

7.5 The Validity and Reliability of the Asthma Management in Practice Questionnaire (AMPQ)

There are a variety of ways to test reliability. For a questionnaire to be considered a reliable tool, it should produce consistent responses if answered by the same subjects at a different time. Advice was sought regarding the feasibility of performing 'test-retest reliability' on the AMPQ by asking a sample of the respondents to repeat the AMPQ after a short interval of about a month. This was not done as it would have delayed production of the final questionnaire and would have confused the practices as some of the information sought was liable to change, such as the number of patients registered at the practice. However, on one occasion 'test-retest reliability' was performed unintentionally, as one of the practices lost a section of their original questionnaire. A

duplicate was completed prior to locating the original, and when the two were compared there were no significant differences.

Internal reliability can be checked to ensure a respondent is answering a questionnaire consistently throughout. This can be checked by asking the same question more than once, but phrasing the question slightly differently, or by asking the exact opposite of one question to ensure the exact opposite response is received. Validity is concerned with whether the indicator actually does measure the underlying attribute. Content validity of the AMP questionnaire was confirmed by firstly ensuring the questions to be included gathered pertinent information. The 1993 BTS guidelines were used as a frame of reference for all the questions pertaining to guideline adherence. Questions about practice organisation were developed from the discussions with experienced GPs, practice nurses and patients with recent experience of the management of asthma in general practice. To further consider the face validity of the questionnaire, expert opinion was sought from individuals with relevant experience on the design and phrasing of the questions.

The initial drafts of the questionnaire were shown to friends and colleagues to check for ambiguous and imprecise questions and then a pilot was conducted in general practice. This enabled me to check for unexpected non-conformity or unreasonable findings. It also provided a further opportunity to assess content validity, that is, whether all the components of each variable had been considered.

7.6 Piloting of the Asthma Management in Practice Questionnaire

It was originally intended to pilot the AMPQ at two practices to provide information regarding the time required to complete the questionnaire and to highlight any required modifications to layout, length and clarity of the instructions wording, order and format of the questions.

The pilot practices were in West Sussex, outside the area of the study. The first pilot practice was able to easily provide the information required for the questionnaire. In a meeting the Practice Manager, Practice Nurse and GPs fed back their comments about the length of the questionnaire, clarity of the questions and the time it took to complete. Their individual comments were also entered on a proforma (see appendix 7). They stated that the questionnaire could be completed in around four minutes and as a result of piloting, it was divided into discrete sections for completion by different members of the practice.

The wording of some questions was altered to improve clarity and the order of questions was re-arranged to enable the questionnaire to "flow" and follow a logical format. Additional questions were included, e.g. information about the size of the asthma register as a proportion of the total list size. Also, for some questions the number of response categories was increased, e.g. to allow for an unexpected response regarding 'out-of-hours' service provision. Additional boxes were also added to allow for respondents to select "don't know" and to exploit the amount of information received, respondents were encouraged to specify further details where-ever the category "other" was selected, by inserting "please specify" where appropriate.

Unfortunately feedback from the other pilot practice was less helpful. They gave verbal feedback and reassurance that the information required for the questionnaire could be easily identified.

7.7.1 Practice Organisation

The organisational initiatives required to qualify for CDM payments (including maintaining a register of asthma patients, an asthma clinic, monitoring prescriptions, audit and patient review) were evaluated for each practice. (These are summarised in Table 12).

The proportion of patients on the asthma register may reflect how proactive a practice is in identifying patients with the condition. A conservative figure of 5% of a practice list was used to calculate a potential asthmatic sample and ensure adequate numbers were recruited. However, a figure in the region of 7% was considered to demonstrate more accurate methods of patient identification at an individual practice. The proportion of patients on the asthma list was expressed as a percentage of the total patient register.

There has been a change in the way practices organise the care and review of their asthma patients. Many have 'asthma clinics', but these may not be at set-aside times as this may limit accessibility for patients. Instead, some practices have organised more 'ad hoc' systems, where a practice nurse sees patients as part of the general appointment system. Either version scored one point in the questionnaire. Therefore, if practices offered both, they scored more highly.

Practices who receive payments under the CDM scheme undertake annual 'process' audits and other practices qualify for additional payments for performing 'extended primary care audit'. Participation in audit has been associated with improved outcomes

in asthma, but the amount and type of audit performed in general practice varies greatly. Therefore, minimal participation in audit was given one point, moderate participation (i.e. process audit for CDM scheme) two points and maximum participation (i.e. extended primary care audit, or audit that measured patient outcomes) was given three points.

The frequency of asthma patient review may improve patient outcomes. The CDM scheme advises that patients with 'active' asthma should be reviewed annually. This was taken as the minimum frequency and given one point. If patients were called for review at six months, and the review interval was organised according to patients' needs an additional point was given for each.

7.7.2 Practice Organisation (equipment, structures, resources and the existence of innovative practice not required for CDM payments)

The existence of innovative practices not recommended in the BTS guidelines, nor a prerequisite for CDM payment were also explored. To help organise disease registers, patients' appointments and records, many practices are now computerised. Novel methods to monitor compliance, educate patients and deliver care were also examined. A score of one point was given to each additional facility or innovation.

From the discussion groups, it was evident that many different ways of checking patients' compliance with medication could be used by practices; such as monitoring prescriptions, checking diary cards for reduced PEF variability or symptoms. One practice nurse described a novel method; her practice informed patients that their repeat prescription for medication would not be issued until they had attended an appointment to have their medication and inhaler technique reviewed. This process enabled some patients to discontinue regular medication for symptom relief whilst also achieving a high attendance rate for review appointments. Other methods described were to send letters or to flag patients' prescriptions with requests to see the nurse or GP to have medication reviewed. Each of these was given one point.

In the discussion groups, patients and nurses felt it could potentially limit patient choice and reduce compliance if generic prescribing was used. This was included as a binary variable in the analysis.

Additional facilities used in the management of asthma were also sought, such as the use of a spirometer or skin prick testing. In the 1993 BTS guidelines, there is no mention of

the use of spirometry. However, spirometry is recommended in international guidelines for the management of asthma (NHLBI 1995) and its use appears to be increasing in general practice in the UK (personal observation). Therefore, to examine its impact as a potential confounder to guideline adherence in primary care it was included as a novel aspect of patient care.

In the 1993 BTS guidelines, skin prick testing to assess patients' reaction to common allergens is not mentioned at all for adult patients, and is not encouraged for children unless they are managed by a physician experienced in the interpretation of the results. Within the geographical area where this study was performed it was known that at least two practices performed skin prick testing for their patients. Therefore, it was included as a novel aspect of care that may act as a potential confounder to guideline adherence. A score of one point was given for the use of either a spirometer or skin prick testing at a practice. A summary of innovative aspects of practice organisation and care, not required for CDM is presented in Table 13 and a summary of all the aspects of practice organisation are presented in Table 14 at the end of this chapter.

7.8 Summary

In this study, it was not possible to use a pre-existing, well-validated questionnaire. Instead, The Asthma Management in Practice questionnaire (AMPQ) was derived from the 1993 BTS guidelines, current literature and the experiences of expert practitioners and their patients. Reliability, content and face validity and were confirmed in field-testing of the AMPQ. The use of discussion groups with enthusiastic and interested experts helped to ensure as far as possible that all aspects of practice organisation were considered.

Table 12. Questions Assessing Practice Organisation (structures in place to qualify for CDM payments)

Section 1	**Aspect of Practice Organisation**
Question 11 *(asthma register)* **a) Does the practice have an asthma register?** **b) How many patients are on this register?** (as a percentage of list)	practice structure
Question 12 *(asthma clinic)* **Is there an asthma clinic?** Set-aside time ad hoc	practice structure
Question 13 *(asthma audit)* **What aspects of asthma management have you audited in the past year?**	practice structure
Section 2	
Question 7b *(compliance - prescription monitoring)* **b) stop patients asthma prescriptions until reviewed by GP/PN?**	practice structure
Question 4 (asthma review) **a) Are patients routinely called for their asthma to be reviewed?** **b) How often is the minimum frequency?** **i) 6 monthly** **ii) 12 monthly** **iii) other?** **c) What is your averagely DNA rate for these appointments?** **d) Is a checklist/template used for follow up appointments?**	practice structure

Table 13. Questions Assessing Practice Organisation
(equipment, structures, resources and the existence of innovative practice not required for CDM payments)

Section 1	**Aspect of Practice Organisation**
Question 10 *(computerisation)* **a) Is the practice computerised?** **b) If yes, which functions are computerised?** Prescriptions Appointments Patient Case Records? **c) Which system do you use?**	practice structure
Section 2	
Question 7b *(compliance - prescription monitoring)* **b) Do you stop patients' asthma prescriptions until reviewed by GP/PN?**	practice structure
Question 7c*(use of generic prescribing)* **c) Does the practice prescribe generically?**	practice structure
Question 8 *(compliance - patient monitoring)* **a) Is treatment compliance monitored?** b) If yes, how i) ask patients about their use of medication ii) check peak expiratory flow diaries iii) check symptom diaries iv) monitor individual prescriptions v) other ?	practice structure
Question 9 b and j *(spirometer and skin prick testing)* **Which of these facilities does your surgery have for the care of patients with asthma?** b) spirometer j) skin testing kit	practice resources

Features of Practice Organisation	Measure	Range of Scores
demographic characteristic	Section 1 - question 1 *(number of patients registered)* Section 1 - question 3 *(number of partners)*	2000 to 20, 000 1 to 11
practice structure (CDM)	Section 1 - question 11 *(asthma register)* Section 1 - question 12 *(asthma clinic)* Section 1 - question 13 *(asthma audit)* Section 2 - question 4 *(asthma review)*	0 to 15% 0 to 2 0 to 2 0 to 3
practice structure (non CDM/innovative)	Section 1 - question 10 *(computerisation)* Section 2 - question 7b *(compliance - prescription monitoring)* Section 2 - question 7c *(use of generic prescribing)* Section 2 - question 8 *(compliance - patient monitoring)*	0 to 3 0 to 2 0 or 1 0 to 6
practice resources (non BTS or CDM)	Section 2 - question 9b *(presence of a spirometer)* Section 2 - question 9j *(presence of a skin prick testing kit)*	0 or 1 0 or 1

Table 14. Summary of Measured Features of Practice Organisation

CHAPTER EIGHT

CHAPTER EIGHT:
STATISTICAL METHODS

8.1 Introduction

In this chapter the methods used to calculate the required sample size of patients and practices are outlined. The procedures used to calculate the independent and outcome variables are presented. Finally the process of data analysis is described.

8.2 Plan of Analysis

Initially, Fiona Lampe, Medical Statistician University of Southampton, gave statistical advice. Whilst composing the protocol for funding applications, she advised on sample size requirements and methodology. After funding for the study was granted, Ms. Lampe left Southampton University and was replaced by Dr. J. Lorraine Low, Research Fellow in Medical Statistics and Mr. Jim Jeffs, Medical Statistician University of Southampton. They gave further advice regarding the most appropriate method of analysis for the study design.

Within the hypotheses there is the assumption that patients' quality of life and disease control may be *dependent* on members of the practice (i.e. the doctors and nurses) providing care that follow the BTS guidelines. Thus, quality of life and disease control are the dependent, or response variables and the independent or explanatory variables are guideline adherence (see Table 14a). Different aspects of BTS guideline adherence were measured and summarised at practice level as follows:

- GPs' reported use and knowledge of the guidelines
- GPs' behaviour
- GPs' prescribing habits
- Practice resources and structures necessary to comply with the recommendations in the BTS guidelines

Aspects of practice organisation outside the BTS guidelines were also summarised by practice. Patient outcome data were summarised for each practice with the *mean* of each response variable used in the analysis.

The statistical plan was to perform correlation analysis to look for any associations between the independent variables and outcomes and subsequently, develop a multivariate regression model using those variables that were of clinical interest or importance. Finally, it was intended to add variables measuring practice organisation to the model to assess their impact as potential confounders (see Table 14a below summarising the independent and dependent variables).

Independent / Explanatory Variables	Dependent / Response Variables
GUIDELINE ADHERENCE *(AMP)* **a) GP Knowledge and Behaviour** Vignettes **b) Practice/GP Resources for BTS** Equipment and Drugs **c) Practice Structures** Systems recommended in BTS **d) Practice Prescribing** *(PACT)* Ratio IHCS/β_2 Total inhaled steroid items	***Primary Outcome Variable*** **QUALITY OF LIFE** (mean patient score per practice) as measured by the SGRQ ***Secondary Outcome Variables*** **DISEASE CONTROL** *(Diary Card)* **a) PEFDV** (*mean* patient score per practice) **b) Symptom Score** (*mean* patient score per practice) **c) FEV_1** (*mean* patient score per practice)

Table 14a. Summary of Dependent and Independent Variables

8.3 Sample Size Estimation

a) Practical Considerations

In the original funding proposal, the size of the sample to be used was initially based on practical issues. This took into consideration the number of practices and patients that could be recruited within the geographical area of the study. Information was sought

from local community trusts regarding the number of GPs per practice and the number of patients registered per partner.

In the study area there were 79 practices to be approached and it was estimated half of these could be recruited to the study. Therefore, it was hoped that 40 practices would participate. The proportion of asthmatic patients in the general population is considered to be in the region of 5-10% and it has been estimated that a practice register of asthmatics should contain 7% of the practice list (Frank et al 1996; Levy and Hilton 1992). As the accuracy of the asthma registers for the practices in the study was unknown, a more conservative figure was set at 5%.

An average size practice in the study setting had 4 GPs and it was estimated from advice from the local Area Health Authorities that there were in the region of 2000 patients registered per partner giving an average number of 8000 patients per practice. Therefore it was estimated a practice list of 8000 would yield approximately 400 patients with asthma.

Advice was sought from local practice nurses regarding the proportion of different aged patients at their practices and it was estimated 50% of the registered asthmatics would be outside the entry criteria of 18 to 45 years old. Therefore, for the average size, four-partner practice the number of patients who fulfilled the entry criteria for the study was around 200.

At that stage, it was unknown what proportion of the patients on the asthma list would be smokers and therefore not eligible to take part in the study (the exclusion of smokers was discussed in Chapter Two.). However, it was considered reasonable to aim for a target of 60 to be recruited from an estimated average sample of 200 eligible patients per practice. Therefore, it was an objective to recruit a total sample of 2400 patients (60 from 40 practices). A 25% drop out would give 45 patients and 30 practices. A final sample in the region of 1350 patients (45 from 30 practices) was expected.

b) Statistical Considerations

In the original funding proposal, the sample size was based on practical issues and no power calculation was included in the sample size estimation. This omission had to be addressed before completion of the study to confirm there was sufficient power to examine the association between quality of life and measures of guideline adherence.

As the proposed method of statistical analysis was *correlation*, it was necessary to estimate the size of correlation coefficient that would represent the true correlation between the primary outcome variable - quality of life and the explanatory variable - guideline adherence. Cohen (1977) suggested r values for a correlation coefficient of 0.10 as small, 0.30 as medium and 0.50 as large. An estimate of the required sample size, sufficient to obtain a medium correlation coefficient value at the 2-tailed, 5% level of significance was calculated.

The unit of analysis was taken as the practice in order to calculate the required sample size and, although subjects were approached in a random fashion, it was assumed patients who attended the same practice would have a degree of commonality or *clustering*.

Clusters are non-overlapping groups of the population. Members are only represented once in each group and in this study, the *cluster* is the practice. Patients from the same practice lived in similar areas and the same personnel at the practice, following the same protocol, would deliver their care. Therefore, the effect of clustering was taken into account when calculating the required sample size as it was considered a likely occurrence.

To calculate the required sample size, an approach similar to that proposed by Donner (1984) was adopted that incorporates an inflation factor to take account of clustering at practice level. The target for the sample size of patients was retained at 2,400 (60 from 40 practices) with a 25% drop out rate for the practices and patients, the number of patients required to *complete* the study was set at 1350 (45 patients from each of 30 practices). To ensure the study had adequate power, once all the potential practices had been recruited these targets were looked at again.

Believing that patients recruited from the same practice would be more similar (less variable) than those from different practices, it was important to allow for this in the sample size calculation. It was estimated that if 37 practices were recruited the numbers of patients that were likely to be entered would be adequate to detect a correlation coefficient in the region of 0.3 with 80% power, at the 2-tailed, 5% level of significance.

8.4 Analyses

To address the hypotheses, the aims of the analyses were as follows:

1. a) To examine the relationship between BTS guideline adherence and quality of life using *correlation analysis.*

   b) To examine the relationship between BTS guideline adherence and disease control (peak expiratory flow diurnal variation, symptoms scores and FEV_1) using *correlation analysis.*

2. a) To examine the relationship between potential confounders (including practice organisation) and quality of life using *correlation analysis.*

   b) To examine the relationship between potential confounders (including practice organisation) and disease control (peak expiratory flow diurnal variation, symptoms scores and FEV_1) using *correlation analysis.*

3. a) To assess whether aspects of BTS guideline adherence are predictors of quality of life using *multivariate regression.*

   b) To assess whether aspects of BTS guideline adherence are predictors of disease control using *multivariate regression.*

4. To assess the impact of potential confounders on the relationship between BTS guideline adherence and quality of life, by adding them to the *model described* above (aim number 3a) and constructing a parsimonious model using *backwards elimination.*

5. To assess the impact of potential confounders on the relationship between BTS guideline adherence and disease control by adding them to the *model described* above (aim number 3b) and constructing a parsimonious model using *backwards elimination.*

The Statistical Package for Social Scientists (SPSS - PC) version 8.0 for windows was used to enter and check the data and version 9.0 for the analysis.

8.5.1 Correlation

This method of correlation analysis shows the closeness of the relationship between two variables. The *correlation coeffecient* denoted by the symbol *r* is based on the sum of the products about the *mean* of the two variables. A *positive correlation* is seen as one variable increases, so does the other. If one variable increases as the other decreases, this is a *negative correlation.*

If the two variables are not related when the data are plotted on a scatter diagram, there will be a similar number of points in each of the four sections of the diagram and there is *no correlation.* However, the *correlation coefficient* may be misleading and the data should also be plotted on scatter diagrams to visually examine the relationship.

8.5.2 Examination of the Relationship Between BTS Guideline Adherence and Outcomes

Correlation analysis was performed to see which features of guideline adherence were important in relation outcomes. The data were plotted on scatter diagrams to visually examine the relationship between the variables with the primary outcome variable - quality of life, followed by the secondary outcomes of peak expiratory flow diurnal variation and symptom scores.

Unfortunately the FEV_1 data could not be entered into the analysis, for two reasons. Firstly, a newly marketed spirometer was used to measure FEV_1. However, on occasions with intensive, repeated use this gave much higher than expected readings. The manufacturers were informed of this problem and they advised me to increase the time between readings. However, this still happened on occasions and when the data was checked and compared with the other secondary outcomes measured (PEF and symptoms etc.) many of the readings looked unreasonable. In the study, patients were not required to withhold their use of beta-agonist, as patients were seen at varying times of the day and it was considered an unreasonable request. Thus, prior to performing spirometry, some of the patients had used a beta-agonist inhaler within the previous 4 hours and this difference in data collection conditions introduced bias. (This is discussed in more detail in the final chapter).

The independent variables measuring guideline adherence were entered into correlation analysis matrices so the relationship with the outcomes could be examined univariately.

However, because of co-relationship between the independent variables, multivariate models that took this into account were required (see 8.6.2).

8.5.3 Examination of the Relationship Between Practice Organisation and Quality of Life

The same process was repeated and again correlation analysis was used to examine the relationship between potential confounders such as practice organisation and outcomes.

8.6.1 Regression

Regression is a method of estimating the numerical relationship between variables. It can be used to assess how well one variable can be used to predict another (Bland, 1997). The variable used to predict the outcome is often called the *predictor, or explanatory variable.*

In this study, the variables of quality of life and disease control are the outcome variables (denoted Y) and the predictor variable(s) are guideline adherence (denoted X). The slope of the line (denoted *Beta,*) of the prediction equation gives information about the direction of the association, that is, whether it is positive or negative, but it does not describe the *strength* of the association (Agresti and Finlay, 1997).

The univariate linear regression model uses a straight-line equation to describe the relationship between two quantitative variables. Linear regression analysis relates predictor variables to outcome variables using a linear additive model. The equation for this, known as the *regression line*, is as follows:

$$Y = a + bX + E$$

This denotes that a and b are constants and E is a random variable with mean 0, called the *error,* which represents that part of the variability of Y which is not explained by the relationship with X.

If multiple regression is used the formula is as follows:

$$Y = a + [b_1X_1 + b_2X_2 + b_3X_3]$$

The intercept denoted by *a,* is a constant term and is the fitted value of Y where the fitted regression line intersects the Y axis (i.e. X = 0).

8.6.2 Assessment of Aspects of BTS Guideline Adherence as Predictors of Outcomes

Univariate analysis helped select appropriate variables for multiple regression models. Selection is important, as the number of variables that can be entered into the model is limited. Degrees of freedom are defined by n - 1 and in this instance n is determined by the number of practices (37). The general rule is that the number of variables that can be entered into a model is the number of cases divided by ten. In this instance with 37 cases the number of variables would be limited to approximately four.

Results of the correlation analyses were used to produce subsets of variables. From the correlation matrices, variables with p values of 0.2 or less were identified and three multivariate regression models were constructed to assess the following:

1. Whether aspects of BTS guideline adherence are predictors of quality of life using *multivariate regression*
2. Whether aspects of BTS guideline adherence are predictors of peak expiratory flow diurnal variation using *multivariate regression*
3. Whether aspects of BTS guideline adherence are predictors of symptom scores using *multivariate regression* (see section 10.11)

8.6.3 Assessment of the Impact of Aspects of Practice Organisation on the Relationship between BTS Guideline Adherence and Outcomes

Certain aspects of practice organisation may be strongly associated with outcomes and in the analysis it was planned to review the impact of practice organisation as a potential *confounder* to guideline adherence. From the univariate analysis described above, five terms satisfied the criteria for selection. These are listed over-leaf (see section 10.12 for further details):

1. List size
2. Availability of a spirometer
3. Treatment compliance methods
4. Audit - level of activity
5. Use of information technology

When the regression models described in 8.6.2 had been constructed, these variables measuring practice organisation were added to examine their impact. Backwards elimination was then used to construct final models. Through this process, variables were removed one at a time, starting with the variable that appeared to be the least significant to the model at that stage, and repeating the multivariate regression until the remaining variables reached a statistically significant level ($p = <0.05$). This procedure enabled the construction of parsimonious models where variables were identified which explain the greatest amount of variation with the minimum number of terms.

Full results of the analysis are presented in Chapter 10.

CHAPTER NINE

CHAPTER NINE
STUDY SETTING AND METHODS

9.1 Introduction

The study was conducted in Basingstoke and the conurbation comprising of Bournemouth, Poole and Christchurch and this chapter describes the rationale for choosing these areas. The setting up of this large, community-based observational study required several protocol amendments and these are described as well as the final procedures used to recruit the practices and patients.

9.2 Study Setting

As I was based in Southampton, the immediate locality would have been preferable for convenience and ease of access. The decision not to use this area was made for the following methodological and pragmatic reasons:

- The area is demographically quite diverse and it may have been difficult to control for so much variation between practice populations.
- Many requests for help with research are targeted at practices around the university and 'research fatigue' may have jeopardised recruitment.
- Several of the practices in Southampton have close links with the largest asthma research group in the UK. This is likely to impact on the knowledge of GPs and their clinical practice, weakening the generalisability of the results.

Data from the Central Statistics Office (CSO, 1994) identified Basingstoke and Deane as a demographically homogenous area. Unfortunately, there are insufficient practices in Basingstoke so the conurbation comprising of Bournemouth, Poole and Christchurch was identified as a second demographically similar area. Basingstoke is in North Hampshire and has mostly light service industries. Bournemouth, Poole and Christchurch are seaside resorts with some light industry (see Table 14b).

A further difference is the higher proportion of elderly residents in Bournemouth compared with the Basingstoke area. However, as the intention was to recruit patients between the ages of 18 and 45, this difference was considered unimportant.

Table 14b. Characteristics of the Areas that were Included in the Study

Characteristics	Basingtoke and Deane	Bournemouth	Poole	C'church
Total population	146, 000	159, 200	65, 000	50, 000
Lone parents (as % of all households)	8.6%	8.4%	8.4%	7.8%
Ethnic minorities (other than white)	2.2%	1.6%	0.9%	0.6%
Unemployment*	32%	36.6%	34.5%	33%

Key
*Long-term unemployed, percentage of total unemployed more than 12 months

9.3 Seeking Ethical Approval

In April 1995, the Local Research Ethics Committees (LRECs) responsible for research projects in the two areas were approached. Approval was received swiftly from East Dorset's LREC (Bournemouth, Poole and Christchurch). Unfortunately, the submission to the LREC for North Hampshire (Basingstoke and Deane) was not approved in July 1995. The committee requested more information about the St. George's Respiratory Questionnaire (SGRQ) and the study data collection forms. These were duly presented, but the application was rejected again in October 1995. I met with the chair of the North Hampshire LREC to clarify their concerns about the method of analysis of the SGRQ and the wording of some questions. His suggestions were constructive and on receipt of the amended version the study was given approval. This process delayed the start of the study by some six months.

9.4.1 Practice Recruitment - Raising Awareness of the Study

To recruit more than 50% of the practices in the two localities was labour and resource intensive. As a high proportion of practices were required, I promoted the study by attending seminars and training days for GPs and practice. I also gave formal presentations to groups of asthma-interested GPs and practice nurses. This provided personal contact in the recruitment. Information about the study was also published in local bulletins and newsletters for primary health care teams. I met with the Primary Care Medical Advisors in each of the health authorities and they provided the practice and

partner lists and also the names of GPs and practice nurses who were particularly interested in asthma.

9.4.2 Practice Stratification

Practice size can affect service delivery and patient care (Campbell 1996, Griffiths et al 1997a). To ensure a variety of different sized practices in the sample a method of stratification was employed. The number of partners was used as a proxy measure to categorise the practices into four groups according to the number of partners as shown. Partners who worked part-time were included as "whole partners" (Table 14c).

Table 14c. Composition of Practice Sample

Practice Size	Number of Partners	Proportion of Sample
Single handed	One partner	13 (16%)
Small	2-3 partners	18 (23%)
Medium	4-5 partners	31 (39%)
Large	≥ 6 partners	17 (22%)
	Total	**79 (100%)**

The practices were approached randomly in batches that consisted of equal proportions of the various sizes. The response to each mailing was then examined to ensure no category of practice-size was over-represented, before sending out the next batch of letters. After the first two rounds of recruitment, the distribution was equal between all four groups and the remainder of the 79 practices was approached to achieve the final sample of 37 practices.

9.4.3 Practice Recruitment

Letters asking general practitioners to take part in the study were drafted and piloted on colleagues with no knowledge of the project to check that they provided the necessary information. Senior partners and practice managers were contacted to ask about their willingness to take part in the study. A copy of the patient's contact letter and study information sheets accompanied this letter. They were asked to indicate their willingness to participate and whether they required further information on a prepaid response card (see appendices 8, 9, 10 and 11). Practices that had not replied within two weeks were

sent a reminder letter. If a practice expressed interest in the study, I met with members of the practice to explain the study and its implications on practice workload. To cover administrative costs of participating, the practices were offered £100 reimbursement and were also promised feedback of the study results.

9.5.1 Inclusion Criteria and Proforma for Patient Selection

The inclusion criteria were:

- Aged 18-45 years
- Non-smokers
- Active asthma

These were confirmed from a short questionnaire that was completed by the patient (see appendix 12). Patients were asked if they had been given a diagnosis of asthma and to indicate how many years they had been asthmatic. They were also asked about current medication and smoking status (see Figure Three).

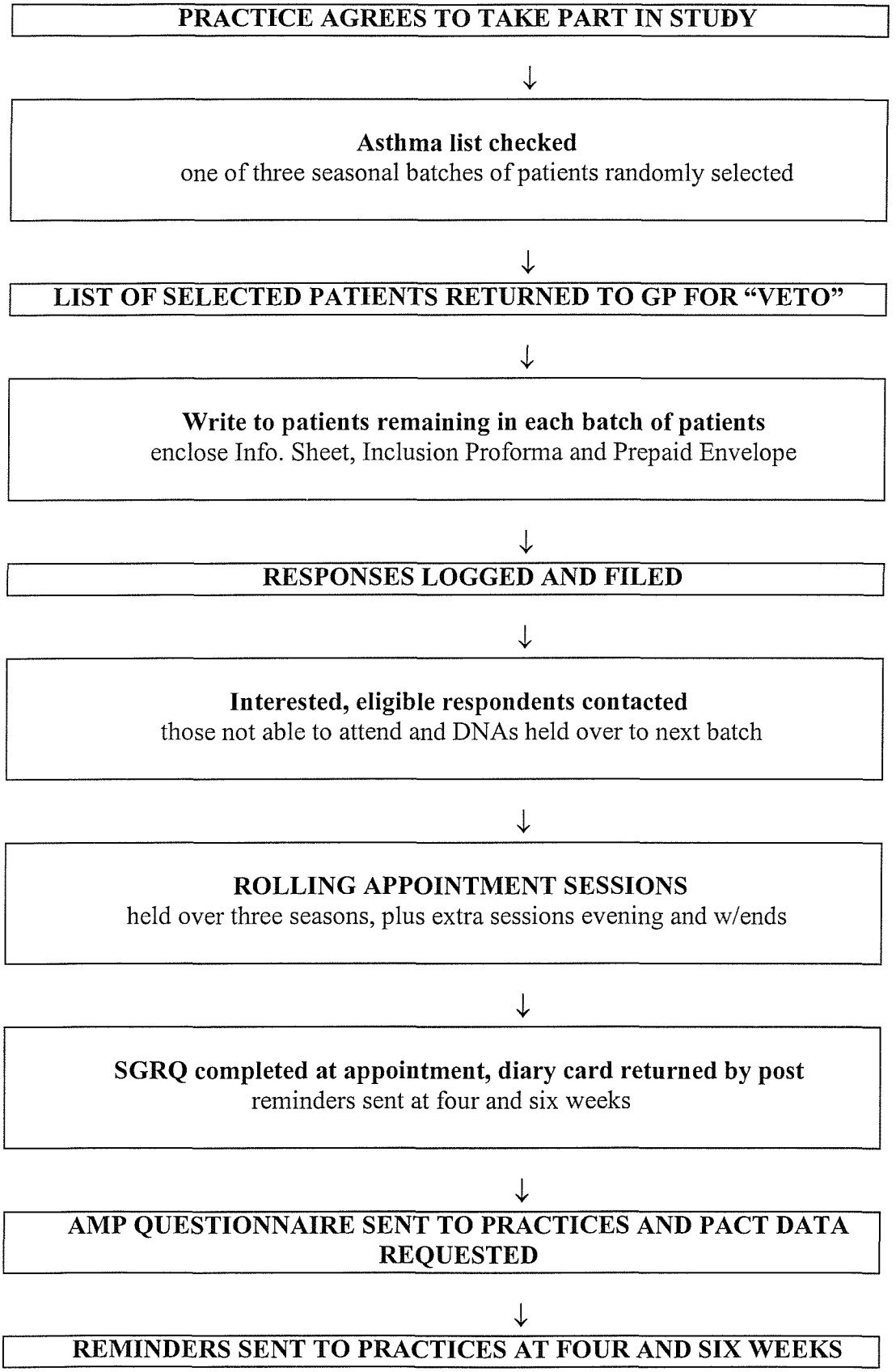


Figure 3. Flow Chart to show Recruitment Process and Data Collection

9.5.2 Rationale for Entry Criteria

a) Age Criteria

The minimum entry age was set at 18, primarily because of the differences in the management of asthma in children. The 1993 BTS guidelines for children recommended inhaled steroids to be added at Step 3 rather than at Step 2. At Step 2, it was recommended children were prescribed non-steroid anti-inflammatory – this has subsequently been changed (BTS, 1997). A secondary but practical consideration when setting the inclusion criteria was the practical and ethical issues of recruiting "minors" into a research study.

As the diagnosis of asthma is least secure at the extremes of age (Griffiths, et al, 1997b), an upper age limit of 45 was set to ensure as far as possible that the sampling frame included only patients with asthma and not other respiratory illnesses. Older patients often suffer with asthma-type symptoms, but are more likely than younger patients to have irreversible airways diseases, such as emphysema or chronic obstructive pulmonary disease (COPD) (Yoon et al, 1993; Van Shayck, 1996). Also, many general practices are not able to identify patients using a diagnostic label from computerised records. These practices are dependant on the use of data relating to the prescription of medication, such as salbutamol, to identify patients with asthma. These medications may also be prescribed for respiratory diseases other than asthma and are therefore less specific in older age groups.

b) Asthma and Smoking

The prescription of prophylactic medication, such as inhaled steroids, is one of the main recommendations contained within the BTS guidelines for asthma management, but smoking may attenuate the impact of inhaled steroids. In an observational study, Watson and colleagues compared the effect of inhaled steroids versus placebo in 14 middle-aged smokers with mild airways obstruction. There was no significant improvement in mean PEF or FEV_1 readings despite treatment with 12 weeks of 600μg budesonide twice daily (Watson et al, 1992). As smokers may not respond to medication and also because of the well-recognised association of smoking with irreversible airways diseases, such as Chronic Obstructive Pulmonary Disease (COPD) (ATS, 1995), smokers were excluded from this study.

The possibility of including smokers and analysing their outcomes separately was considered, but this was rejected because of the direct evidence that smoking affects the progression of asthma. Because of these factors, smokers have been excluded from other observational studies, for example when assessing the impact of patient education and self-

management on outcomes (Yoon et al 1993; Allen et al, 1995). I recognised in advance that a consequence of excluding smokers was that recruitment might be jeopardised in those practices with a high proportion of smokers.

c) Active Asthma

To ensure the patients included had active disease, patients were only entered into the study if they reported that they had required medication (bronchodilators, non-steroidal anti-inflammatory drugs or inhaled steroids) for their asthma at some time in the preceding twelve months.

9.6 Minimising Seasonal Variation

To minimise bias due to seasonal variation in asthma symptoms, it was planned to assess a similar proportion of patients from each practice during each season, the "seasons" were given arbitrary dates.

- SUMMER *'1st June - 31st August'*
- SHOULDER *'1st September - 14th November' and '1st April - 31st May'*
- WINTER *'15th November - 31st March'*

The seasons of 'summer', 'winter', and 'shoulder' were used as a guide to ensure that patients from one practice were not all seen in one particular season. Low response rates, the lack of appointment times and rooms at some practices meant this could not be strictly enforced. Therefore, some seasons had to be slightly extended to enable as many eligible patients as possible to be recruited. If a large proportion of patients from one particular surgery had been seen at a peak time for asthma exacerbations, this would have adversely affected the global assessment of symptom severity for patients from that practice.

Data regarding pollen counts were gathered from the Allergy Research Centre on the Isle of Wight to ensure that the pollen counts did not rise steeply before or after the season defined as 'summer'. If this had happened, the season defined as summer would have been extended to include the higher pollen count days and the timetable would have been adjusted accordingly.

9.7 Patient Sampling

Each practices provided a list of patients with asthma aged 18-45. These were computer generated for all but one practice, which still used a manual card system. The cards at this practice were checked for eligibility criteria and an electronic version was compiled on a computer for use in this study. All of the lists were generated without removing 'smokers' as this information was not consistently available from all the practices. Each list was carefully checked to ensure the dates of birth were within the entry criteria and that individuals were not identified twice if prescribed different medications from within the same category.

To be able to generalise the results from a limited number of individuals with a degree of confidence, it is necessary to ensure that the sample is representative of the population. Each patient on the asthma list in each practice was assigned an identification number. They were then selected at random using random number tables that were constructed using a bespoke computer program developed by the medical statistician. The random number table selected the order of the patient's identification numbers. The study subjects were selected from the total list each time and if a patient's number was generated twice, a replacement number was sought. This gave all patients chosen an equal chance of being selected in each season.

To prevent contacting any of the patients inappropriately, the GPs reviewed the names and were asked to remove anyone who had severe illnesses, or had recently experienced a serious life event. The initial contact and reminder letters were printed on the practices' headed notepaper and stressed that the project was a joint venture between their practice and my research department. With the initial letters of introduction, each patient received a copy of the information sheet and a questionnaire to confirm their eligibility to enter the study (see questionnaire, appendix 12).

To minimise seasonal variation, patients were approached in batches in each of the three seasons. To achieve a final sample of 60 patients from each practice, 20 patients needed to be recruited in each season. To achieve this level of recruitment up to 50 patients per practice were contacted each season.

A response rate of around 70% had been expected (Bland, 1997) but in reality, the initial mailings only yielded 50% and of those responding, a proportion of patients later declined to take part or was ineligible because they smoked. It soon became apparent that batches of 50 patients were unlikely to yield adequate positive responses and the protocol was

amended so that 100 or a third of the list supplied, whichever was the larger, were contacted.

9.8 Recruitment of Patients

Reliable information regarding smoking status was not available from all practices, so this was elicited directly from patients after they had expressed an interest in the study. Once it was established that the patient fulfilled the entry criteria, they were contacted by letter or telephone and invited to attend their practice for an appointment for 30 minutes. After contact had been established with the first batches of patients, it became apparent that some practices' asthma lists may include patients whose asthma was no longer active. To address this, the inclusion proforma was modified to ask if patients had required medication for their asthma in the last twelve months. Therefore, prior to making an appointment with them, I could confirm that their asthma was "active".

To increase the numbers of patients recruited, sessions were held at times convenient for patients to attend, which included evening and weekend appointments. Appointment sessions were held at the practices, but there were also regular sessions held elsewhere, including local hospitals and hotels.

9.9.1 Capturing Patient Details and Outcome Measures

The information required is summarised below:

- **Primary Outcome Measure**
  quality of life

- **Secondary Outcome Measures**
  peak expiratory flow measurements
  symptoms
  FEV_1

- **Patient details** asthma medication
  demographic information

9.9.2 Collection of Primary Outcome Data

The St. George's Respiratory Questionnaire (SGRQ) was used to measure quality of life. Professor Jones granted permission to use the SGRQ and provided an instruction booklet on administration of the questionnaire which stressed the need to provide consistent answers to queries and to avoid "supplying answers" if patients were unsure. To familiarise myself with the questionnaire and to estimate the length of time needed to administer it, I "piloted" it on colleagues. The average time taken to complete the questionnaire was seven minutes, but to allow a more detailed explanation and to answer patient's questions, ten minutes was allocated in the appointment schedule.

9.9.3 Collection of Secondary Outcome Data

A self-administered diary card designed for use in a community setting was used to collect the secondary outcome data. The diary card was originally developed by Johnston (1992) to monitor upper and lower respiratory symptoms in children with respiratory viruses; the section relating to upper respiratory symptoms was omitted for this study. The diary card captured information regarding serial peak expiratory flow measurements, lower respiratory symptoms over a two-week period, FEV_1 and medication use (see appendix 13).

a) Peak Expiratory Flow Measurements

On their diary cards, patients recorded serial peak expiratory flow measurements first thing in the morning and last thing at night. Although this practice is recommended in international guidelines, it has been proposed that recording PEF three or four times a day and specifying the time of recording the PEF in the afternoon or evening to coincide with the patient's *acrophase* will achieve more sensitive results (Enwright et al, 1994; D'alonzo et al, 1995; Lebowitz et al, 1997; Gannon et al, 1998; Reddel et al, 1999). The former method was preferred and it is accepted practice in a community setting to record values twice a day. Also, it is considered unreasonable to expect patients to perform more frequent readings and the more onerous the task the less likely they are to comply. Patients were asked to record the best of three readings and to avoid taking bronchodilating medication, such as salbutamol, in the four hours prior to their peak expiratory flow measurements. If this was unavoidable or if they forgot, they were asked to put an asterisk next to the reading to show that it may have been enhanced by recent dosing. These potentially enhanced readings were excluded from the calculation of their diurnal variation.

If they forgot to record their peak expiratory flow measurement they were instructed to leave the box blank, rather than feel compelled to make up a figure.

Although there are a variety of models of PEF meters, the Mini-Wright standard PEF meter by Clement Clarke International Ltd. is most familiar to patients as it is one of the devices available by prescription on the UK Drug Tariff. The Mini-Wright has been extensively evaluated in comparison to the original, less portable and more expensive Wright PEF meter (Perks et al, 1979; Brown and Sly, 1980). Both of these studies showed significant correlation (r = 0.970 and 0.982) when readings from the two devices were compared. However, in a study using a computer-driven, servo-controlled pump, it has been shown that peak expiratory flow measurements may be unreliable over time (Miller et al 1992). It has also been shown through studies in humans that the Mini-Wright may produce slightly low readings (Perks et al, 1979; Brown and Sly, 1980), and that its accuracy may deteriorate after extensive use. It may also be less sensitive at detecting clinically significant changes (Sly et al, 1984) and may over-read low values and under-read higher values (Shapiro et al, 1991). However, its availability, low cost and ease of use made the Mini-Wright the preferred option for this study.

b) Symptom Scores

Patients scored the following:

- symptoms on waking
- daytime symptoms
- problems with daily activities
- night time symptoms

This is laid out in detail in Section 6.4.2.

c) Measurement of FEV_1

FEV_1 was expressed as a percentage of the predicted value; this was automatically calculated by the spirometer (see below). The BTS guidelines recommend that patients whose FEV_1 readings are below 50% or less than 1.5 litres should be given a rescue course of steroid tablets. Therefore, any patients who had low readings, and who were not already taking oral steroids were encouraged to see their GP as soon as possible and a phone call was made or a note was left for the appropriate GP to inform them of the low readings.

d) Medication

Data were collected about medication use to allow some comparisons to be made with practices' PACT data. At the bottom of the diary card a section was added for patients to note down the amount of medication taken for their asthma each day. This enabled patients' individual drug consumption, especially the quantity and frequency of medication taken for the prevention and relief of symptoms to be examined.

9.10 Contact and Demographic Information

On the reverse of the diary card, patient identification data were captured including name, address and telephone number. This facilitated swift contact with patients after returning the diary card if it was necessary to clarify any entries. Demographic details including age, sex and social status, (employment, education, age at leaving full time education and housing tenure) were also collected in this section.

9.11 Appointment Procedure

At the appointment I introduced myself, thanked patients for their help and explained the purpose of the study and outlined their involvement. They were asked if anything was not clear in the information sheet and given time to read it prior to consenting to participation (see appendices 10 and 14).

To ensure all patients were rested for at least fifteen minutes before performing spirometry, their appointment began with self-completion of personal details on the reverse of the diary card and completion of the St. George's Respiratory Questionnaire (appendix 4). The questionnaire was checked for missed or unclear responses with the patient.

Height was measured using a metric Harpenden pocket stadiometer with spirit level (Harpendum, UK). Patient's age, sex and height were then keyed into the Vitalograph 2120* spirometer (loaned by Vitalograph, UK) and the patient were then shown how to perform spirometry. The Vitalograph 2120 spirometer calculates the percentage achieved for FEV_1 and FVC of an individuals' predicted value. This was preferred to checking each subject's results against tables of predicted readings to minimise calculation errors. Three readings were taken and the highest of the three was recorded.

*As the readings provided by these spirometers may fluctuate according to the atmospheric temperature, prior to seeing each group of patients the spirometer was calibrated using a 1 Litre Vitalograph calibration syringe.

At the appointments, patients were given a Mini-Wright PEF meter and shown how to measure their PEF readings. To minimise deterioration in accuracy in PEF readings, patients were given a new meter if their own PEF meter was a different type or it was more than 12 months old.

They were instructed how to enter their symptom scores and PEF readings onto the diary card for the following two weeks. The subjects were asked to return the diary card as soon as possible at the end of the two weeks and were given a prepaid, addressed envelope. All patients were asked again if they had any questions and were given a contact telephone number in case of any problems.

9.12 Administration of the Questionnaire to Practice Managers, Practice Nurses, and Partners

On completion of the data collection from patients, each practice was sent the Asthma Management in Practice (AMP) questionnaire. As described previously, the aim of the questionnaire was to capture information about BTS guideline adherence and potential confounding factors of practice organisation. As outlined in Chapter Eight, the questionnaire was arranged into sections to be completed by different members of the practice (practice manager, practice nurse and GP).

Prepaid envelopes were supplied for the return of the completed questionnaire and a follow-up telephone call was made to the practice manager (or practice nurse) within two weeks of the first mailing to provide clarification if required. This also acted as a prompt to remind them to complete (or encourage practice nurses and partners to complete) and return the questionnaire. Three reminders were sent at monthly intervals to non-respondents.

9.13 Collection of PACT Data

When all the outcome data were collected from patients, prescribing analysis and cost data (PACT) were requested from the Practice Prescribing Authority (PPA), about medication prescribed within Section 3 of the British National Formulary (BNF). This was requested in terms of the total cost and items of inhaled steroids and bronchodilators and drug volumes using the Defined Daily Dose calculation. So that these date were contiguous with the outcome data, the PACT data were requested for the same period.

9.14 Data Entry, Cleaning and Checking

The practices were identified by a unique code. The patients were also assigned unique numbers, prefixed by the practice code for cross-reference. Prior to the data being punched, data entry templates were drawn up for the diary card, St. George's Respiratory questionnaire (SGRQ) and Asthma Management in Practice (AMP) questionnaire. Data from the diary cards and the SGRQ were punched by a commercial punching agency into an 'ASCII file'.

All of the data were "double entered" and converted into SPSS-PC. Examining the frequency of variables helped to identify any errors. This method highlighted five duplicate identification codes. By referring to the original patient lists from the practices, the true identification codes were verified. Approximately 20 other minor errors were identified.

The distribution of each variable on the SGRQ, diary card, and AMP enabled further cleaning of the data. Each variable was examined to ensure the codes punched were correct according to the original templates and that the responses were within reasonable parameters. For example, the age range for entry into the study was 18 to 45, ages outside this range were checked and corrected or removed where appropriate. Logical skips and responses to related questions were also checked for consistency.

9.15 Summary

In this chapter I have presented the study setting and the methods used to recruit practices and patients. The appointment procedure for patients has been reviewed and the collection of primary and secondary outcome data has been described. Finally I have outlined the method used to collect information about practice and clinician guideline adherence and the potential confounders of practice organisation. The following chapter presents the results of the study.

NB. Patient level data were collected from May 1996 to July 1997. PACT data were collected from July 1996 to June 1997. The AMP questionnaires to gather information about BTS guideline adherence and potential confounding factors of practice organisation were first administered in August 1997 and the last one was returned in December 1997. As the revised BTS guidelines were published in February 1997, it is possible this may have impacted on outcomes and is discussed in Chapter 11.

CHAPTER TEN

CHAPTER TEN: RESULTS

10.1 Introduction

This chapter is divided into two distinct parts. Part A provides outline descriptive statistics about the participating patients and practices, together with summaries of the independent and dependant variables. Part B presents the results of the analysis set out in Section 8.4.

PART A: DESCRIPTIVE ANALYSIS

10.2.1 Participating General Practices

The two geographical areas used for recruitment were chosen to be representative of General Practice nationally; that is, the majority of practices are in urban or suburban areas and the majority are either medium or large in size (see Table 15). A total of 79 practices were approached, 63 in the Bournemouth area and 16 in and around Basingstoke.

10.2.2 Practice Participation Rate

Of the 79 practices approached, 64 replied and 43 agreed to take part in the study, but six practices later withdrew due to shortage of time. In the Bournemouth area 26 practices agreed to take part and in Basingstoke 11 consented. Therefore, 37 of the 79 practices invited took part in the study, giving a participation rate of 47% of the original practices approached.

10.2.3 Participating Practices - Characteristics

To ensure a reasonable spread of different sized practices, size was originally determined by number of partners in the practice (see Chapter 9). Information was also gathered regarding the number of patients registered. Demographic characteristics such as

geographical locality, practice size, and the size of asthma resister (expressed as a proportion of the total register) are presented in Appendix 17.

Table 15. Characteristics of Participating Practices

Practice Characteristic		Number	Percentage
Geographical Setting	Urban	13	35%
	Suburban	14	38%
	Semi-rural	10	27%
Practice Size	Single handed	4	11%
	Small (2-3 partners)	10	27%
	Medium (4-5)	11	30%
	Large (6 or more)	12	32%

10.3.1 Participating Patients - Response Rates

Of 6286 patients approached, 3065 (49%) responses were received. Of the responders, 1752 (57%) were eligible, 852 (28%) declined and 461 (15%) were not eligible to take part. A detailed breakdown of the overall number of patients contacted, declined and those not eligible to take part in the study is presented in Figure Four overleaf.

There was wide variation in initial response rates across the practices, ranging from 29% to 73% per practice. A comprehensive table regarding the response rates for each practice is presented in Appendix 15. Of the 1455 eligible patients, 397 could not be seen due to time constraints of the study reducing the eventual study population to 1054. The mean and median number of subjects seen per practice was 28, (range 2 to 69 patients).

10.3.2 Participating Patients - Characteristics

Nearly twice as many appointments were made to see female patients than men and the mean age of patients at the time of completing the SGRQ was 34.2 years (range 18.0 to 47.0). On the diary card, patients were asked at what age they left school in order to estimate the number of years they were in full time education; this ranged from 12 to 33 years. This lower age was checked and was found to be someone who had lived and attended school in Spain as a child. The majority of patients (n =551, 62%) had completed 11, 12 or 13 years of full time education, leaving school between the ages of 16 and 18.

Information on the diary cards showed a high proportion of patients was in paid employment. Of the 739 subjects (82%) who stated they were employed, 295 were men

(92%) and 444 (77%) were women. The 158 subjects who stated they were unemployed, constitute 18% of the total number of subjects who returned their diary cards. The most common reason stated for not working was looking after dependants, followed by studying. From Table 16 it can be seen the majority of those who participated in the study were 'owner occupiers'. To estimate social class the table of occupations from the Office of Population Censuses and Surveys was used. There was insufficient information to categorise everybody from their job description, but the majority of patients who could be classified belonged to social class II or III (n = 654, 72.8%).

Figure 4 Consort Diagram to Show Subject Response Rate and Eligibility

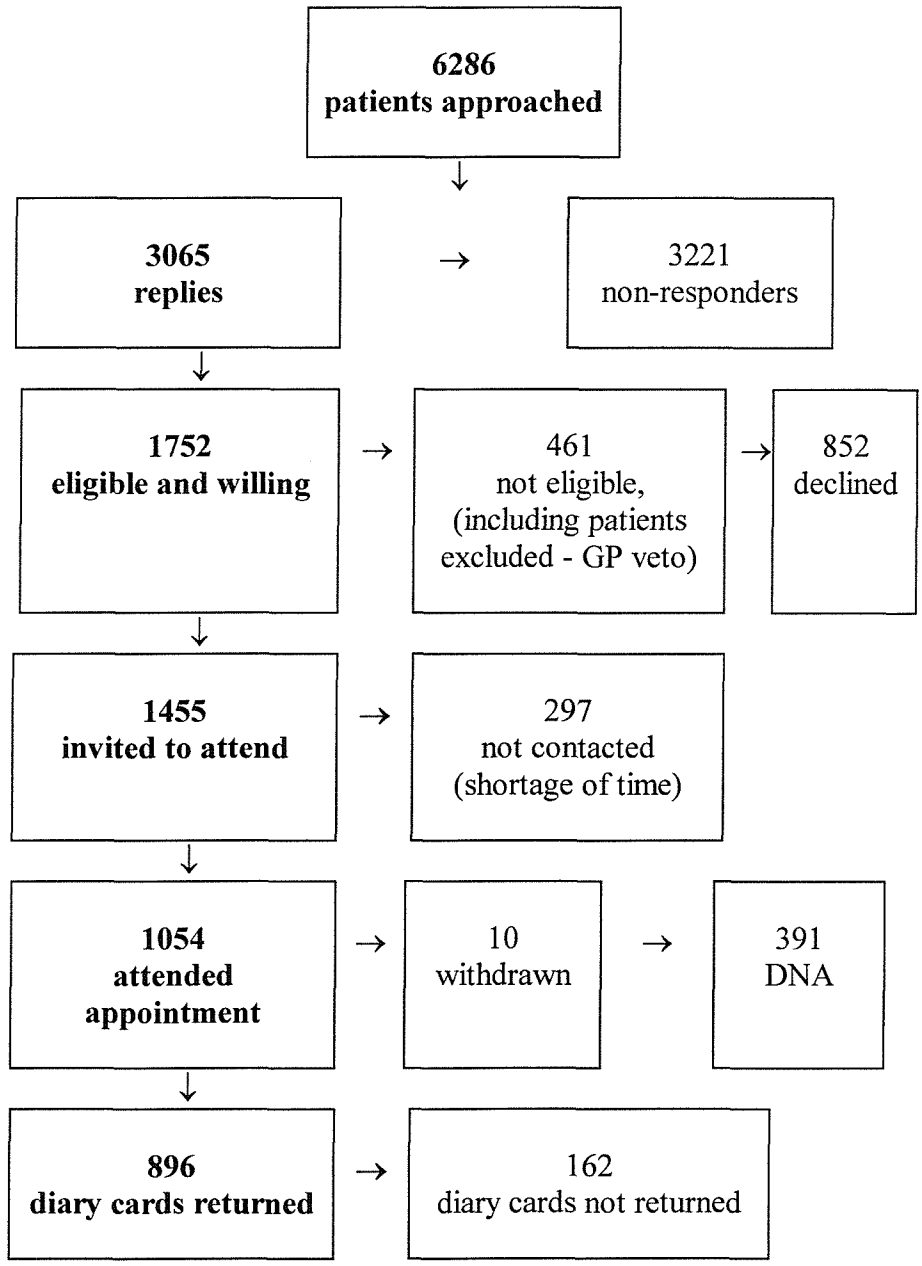


Table 16. Characteristics of Participating Patients

Patient Characteristic	Number	Percentage
Age in Years (*n*= 1054)		
Mean	34.22	
Median	35.00	
Mode	37	
Range	17 to 52	
Gender (*n*= 1054)		
Male	385	36.6%
Female	668	63.4%
Social Class (*n*= 893)		
I	16	1.8%
II	300	33.6%
III	354	39.6%
IV	59	6.6%
V	9	1.0%
Unclassified	155	17.4%
Education (*n*= 886)		
completed <11 yrs	73	8.2%
completed 11 yrs	314	35.5%
completed 12 yrs	85	9.6%
completed 13 yrs	152	17.2%
completed >13 yrs	228	25.7%
student	34	3.8%
House Tenure (*n*= 891)		
owner occupier	662	74.3%
rented privately	57	6.4%
rented from Local Authority/Housing Association	65	7.3%
living with parents	105	11.8%
other (lodgings provided by employer)	2	0.2%

NB. Total numbers vary according to source of information

From the figures presented above, it can be seen there was a degree of demographic bias in my sample. Participants were mostly female 'owner occupiers', from social class II or III and employed or looking after dependents. Although this is probably reflective of the local population, this has implications for the generalisability of my results; it is discussed in greater depth in the final chapter.

10.4.1 Quality of Life Measurement using the SGRQ

The quality of life score from the SGRQ has three components: symptoms, impacts and activities. These can be aggregated to provide a total score. The results of each individual question are presented in Appendix 18.

10.4.2 Summary of Quality of Life

The mean scores for the three components of the SGRQ are shown below in Table 17. The mean total score for all patients who completed the SGRQ was 24.60 (SD 14.02).

Table 17. Distribution of Individual Quality of Life Scores for the Three Components of the SGRQ

SGRQ	Mean	Median	Range of Scores	Standard Deviation
Symptoms	45.60	45.78	0.00 - 100	18.60
Impact	16.40	13.45	0.00 -100	13.63
Activity	27.40	23.72	0.00 - 91.39	19.25
Total	24.60	24.31	0.68 - 93.53	14.02

When plotted it can be seen the data from the SGRQ for the symptom scores were symmetrical with a bell-shaped curve and therefore normally distributed (see Figure Five); however, scores for the impact and activity components and consequently the aggregated total (Figures Six, Seven and Eight), are positively skew; that is, the tail on the right is longer and the majority of the data fall to the left of centre (Bland, 1995). This is probably due to the relative lack of severity in the majority of patients' asthma who are seen in primary care. However, most statistical methods (i.e. parametric methods) for analysing continuous data incorporate assumptions about the data in the population from which the sample was drawn. That is, it is assumed the data come from a population where the values are normally distributed.

Figure 5 Distribution of Scores

for Symptom Component of the SGRQ

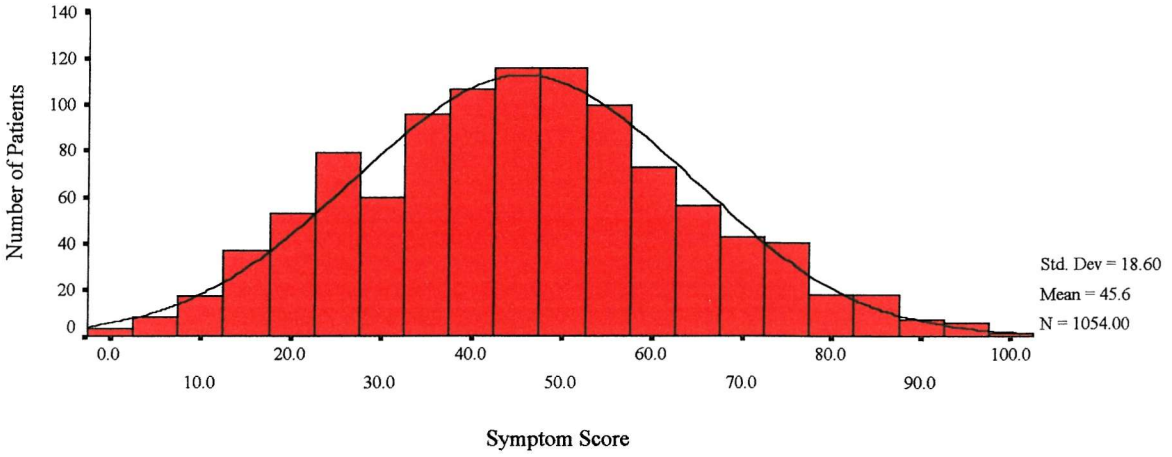


Figure 6 Distribution of Scores for

Impact Component of the SGRQ

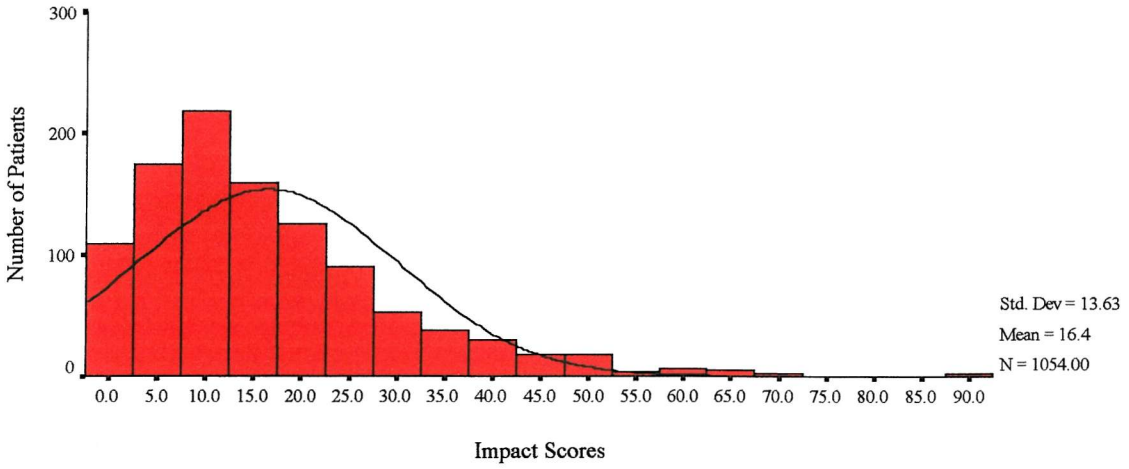


Figure 7 Distribution of Scores

for the Activity Component of the SGRQ

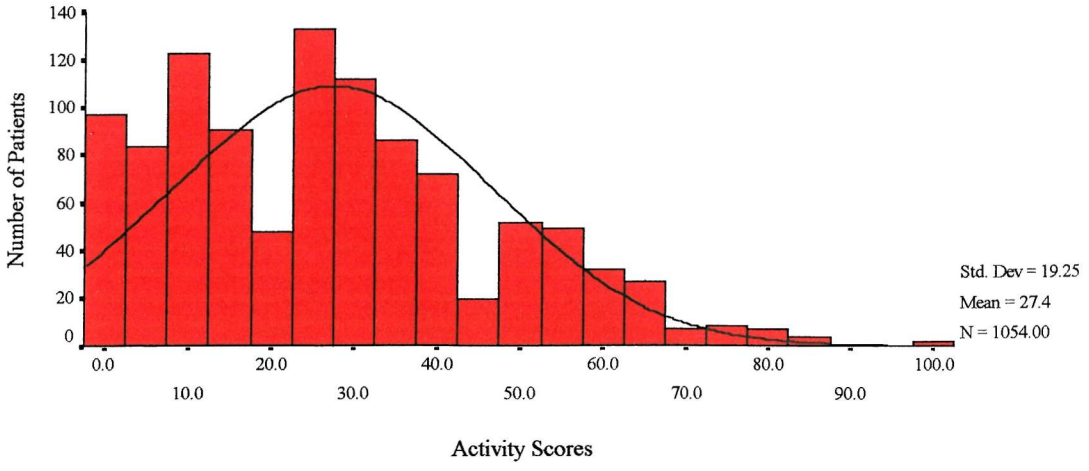
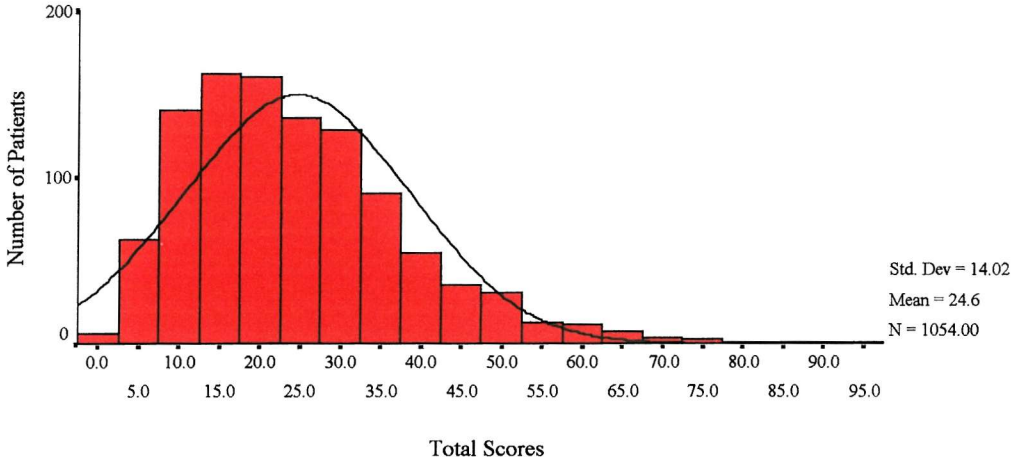


Figure 8 Distribution of Total Quality of Life Scores for the SGRQ



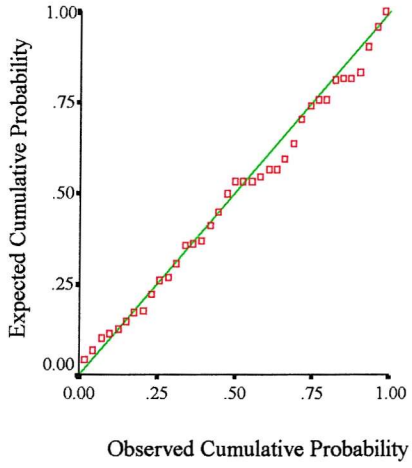
The mean of the total SGRQ scores was used as the primary outcome variable to explain guideline adherence at practice level. As these data were not normally distributed, one possibility was to 'normalise' the data using natural logarithmic transformation prior to analysis. However, according to Altman (1997) for some methods the distributional assumption is not too critical, especially if a sample larger than 50 is used, as in this study.

Another important assumption of many parametric methods is that different groups of observations have the same standard deviations. According to Altman (1997), variation in standard deviations often accompanies non-normal data; running a 'regression diagnostic test' can check this variation. Examining the residuals performs this test and in regression analysis, these are the differences between the observed values and the values that are predicted by the regression model. Specifically, if the assumption of normal distribution is satisfied on a scatter plot there should be no deviations and the residuals will follow the regression line (see Figure Nine). If the observations are normally distributed about the true regression equation, then the residuals should be approximately normally distributed.

Analysis of residuals is an important step in any analysis since the residuals are assumed to be normally and independently distributed with constant variance. It can be seen from the plots of residuals for the total SGRQ that the data did not violate the assumption of normal distribution. Therefore, normalisation of the data using logarithmic transformation was not required.

Figure 9 Plot of Regression Standardised Residuals

Dependent Variable: Mean Total SGRQ Score



10.5 Quality of Life Scores per Practice

The data for total and component quality of life scores for each practice are shown in Appendix 19.

10.6 Secondary Outcome Variables: Forced Expiratory Volume (FEV_1), Diurnal Variation in Peak Expiratory Flow and Symptom Scores

Data for the secondary outcomes of diurnal variation, symptoms scores and FEV_1 are summarised in Table 18. Summary statistics *per practice* are displayed in appendix 19.

Table 18. Summary Statistics for Secondary Outcome Variables

Lung Function of Study Population	Statistic	Result
FEV_1	range	13.5 - 177.9
(% predicted)	mean	95.67
(*n* = 874)	median	96.09
	SD	17.26
Diurnal Variation in Peak Expiratory Flow	range	0.09 - 56.16
(*mean* of 14 days)	mean	7.67
(*n* = 890)	median	5.65
	SD	6.77
Patients Symptom Scores	range	0.00 - 11.43
(*mean* of 14 days)	mean	1.58
(*n* = 891)	median	1.07
	SD	17.26

10.7 Guideline Adherence

Data regarding the independent or predictor variables of guideline adherence are presented in Appendix 20. As described in chapter eight, the aspects of guideline adherence assessed were:

- Clinician's use and knowledge of the BTS guidelines.
- Appropriateness of clinician's behaviour (use of vignettes to assess treatment).
- Clinician's behaviour (equipment available in their rooms).
- Clinician's behaviour (drugs and equipment taken on home visits).
- BTS guideline adherence at practice level (equipment, structures and resources).
- BTS guideline adherence assessed from respiratory PACT data.

10.8 Practice Prescribing Habits

BTS guideline adherence was assessed from respiratory PACT data of inhaled corticosteroid items and inhaled beta-agonist prescriptions (presented as Defined Daily Doses). Three of the 37 practices did not return their questionnaires therefore; prescribing data were only available for 34 practices. These data are presented in Appendix 21, and in Figures 10, and 11.

Figure 10 Practice Mean Prescription of Inhaled Steroid Items

(per patient expressed as DDDs)

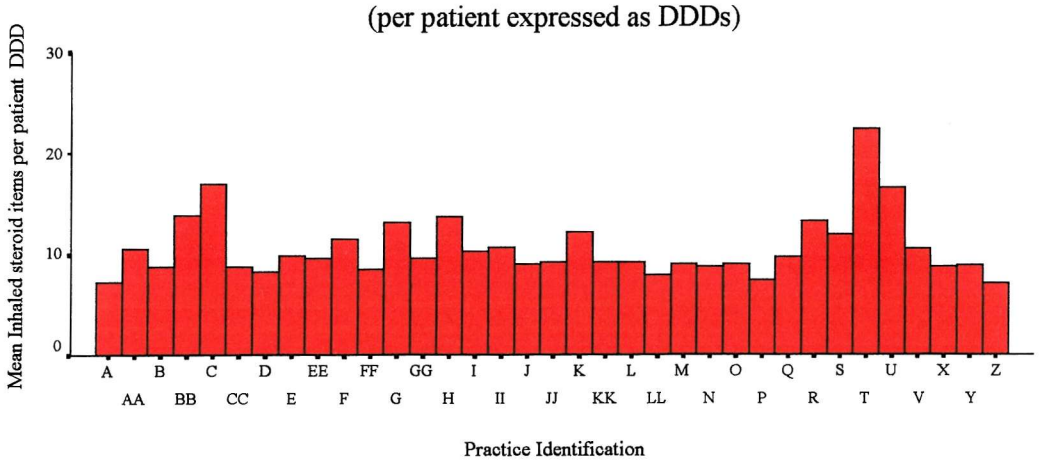
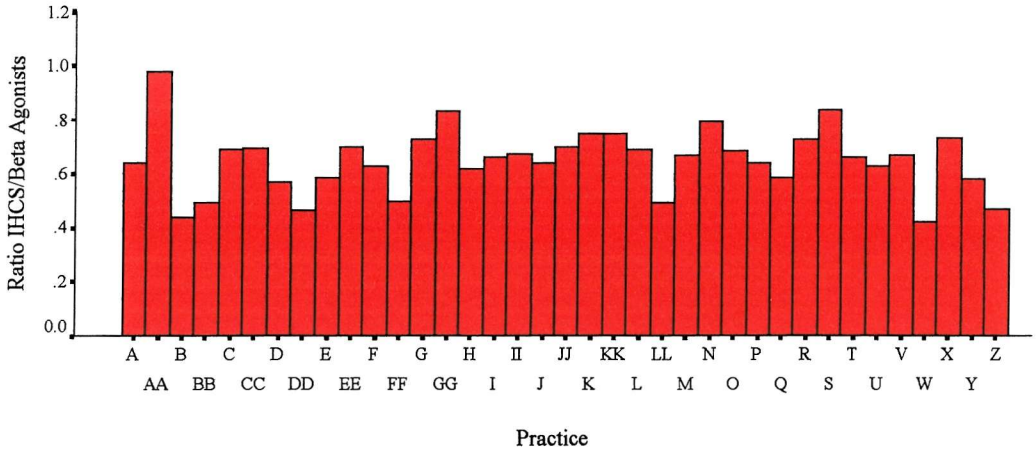


Figure 11 Ratio of IHCS/Beta Agonists

(by practice expressed as DDDs)



10.9 Practice Organisation

Data regarding aspects of practice organisation are presented in Appendix 22. The tables at Appendix 22 present structures in place to qualify for Chronic Disease Management payments and examples of innovative practice organisation not required for CDM payments.

PART B: ANALYTICAL STATISTICS

10.10.1 Introduction

In the following sections, the results of the analyses proposed in Section 8.4 are presented. The implications of these results are discussed in the final chapter.

10.10.2 Examination of the Association Between BTS Guideline Adherence and Outcomes Using Correlation Analysis

Correlation analysis was performed and the data were plotted on scatter diagrams to visually examine the relationship between the variables with the primary outcome variable - quality of life, followed by the secondary outcomes of diurnal variation in peak expiratory flow (PEFDV) and symptom scores. The independent variables measuring guideline adherence were entered into a correlation analysis matrix along with the primary outcome quality of life. This procedure was followed for the secondary outcomes of PEFDV and symptoms.

The relationships between the variables measuring guideline adherence and outcomes (primary and secondary) were examined univariately (Table 19). From these it can be seen there were four variables associated with quality of life (% of patients given self-management plans (SMPs), medication taken on home visits, management of an acute attack and prescribing). Two variables were associated with PEFDV (% of patients given SMPs, and use of rescue medication). It can be seen there were also two variables associated with symptom score (% of patients given SMPs and equipment in clinician's room). All these variables had sufficient association to be of interest, that is, they had correlation coefficients (denoted r) greater than or close to 0.2 and were therefore selected for entry into regression models. The percentage of patients given SMPs was the only variable that reached the required level of significance in all three outcomes.

10.10.3 Examination of the Association Between BTS Guideline Adherence and Outcomes Using Regression

Univariate analysis assisted the selection of appropriate variables for construction of multiple regression models. Selection is essential as the number of variables that can be entered into the model is limited (see section 8.6.2). Variables for inclusion in the model were identified as those with r values greater than or close to 0.2, in bold type in Table 19.

10.10.4 The Association Between Guideline Adherence and Quality of Life

From the correlation analysis, there were four variables that satisfied the criteria for inclusion in this model. These were:

1. Percentage of patients given Self-Management Plans (p= 0.166)
2. Medication taken on home visits (p= 0.013)
3. Treatment of an acute attack (p= 0.078)
4. Ratio IHCS/β_2 as Defined Daily Doses (p= 0.056)

The results of this regression analysis are presented in Table 20 and Table 21.

In this study, the level of statistical significance follows convention, namely that the probability of a relationship being found by chance is less than 5%; i.e. a level of significance would be of interest if it were 0.05 or less.

From Table 20 it can be seen that the model explains a significant amount of variability (p =< 0.001) and from Table 21 it can be seen that two variables predict statistically significant changes in outcome (quality of life). These were:

1. Medication taken on home visits (p= 0.011)
2. Ratio IHCS/β_2 as Defined Daily Doses (p = 0.037)

For each unit change in the variable, the SGRQ would change according to the value and sign of Beta, which is the definition of the parameters for the dependent variable, in this case quality of life. A negative Beta for the SGRQ denotes a lower score and better quality of life.

The model (described in Tables 20 and 21) predicts, that if the mean number of medications taken on home visits by GPs is increased by one, the mean SGRQ score for patients from that practice will be reduced (improved), by 2.376 points. Therefore, to achieve a clinically significant improvement (a reduction in SGRQ score of 5), the mean number of medications taken on home visits would need to be increased by two. A mean improvement in SGRQ score of 12.981 is predicted if the ratio of IHCS/β_2 items prescribed is 1:1.

Table 19. Variables Associated with BTS Guideline Adherence and Outcomes (using correlation)

Guideline Adherence Variable	Quality of Life		Diurnal Variation		Symptom Scores	
	corr. coeff. (*r*)	signif. (*p*)	corr. coeff. (*r*)	signif. (*p*)	corr. coeff. (*r*)	signif. (*p*)
PRACTICE RESOURCES						
Experience of Nurse Trained in Asthma	-0.101	0.610	0.061	0.759	-0.086	0.664
PRACTICE STRUCTURE						
Practice Protocol Score	-0.198	0.261	0.016	0.928	-0.067	0.706
Percentage of patients given SMPs	**0.251**	**0.166**	**0.245**	**0.176**	**0.282**	**0.117**
PRACTICE EQUIPMENT						
Presence of Nebuliser, PEF meters etc.	0.129	0.461	-.024	0.890	0.115	0.511
CLINICIAN'S BEHAVIOUR - EQUIPMENT						
Equipment in clinician's room	-0.004	0.982	0.187	0.289	**0.431**	**0.011**
Equipment taken on home visits	-0.026	0.884	0.055	0.757	-0.058	0.745
Medication taken on home visits	**-0.423**	**0.013**	0.076	0.669	-0.013	0.941
CLINICIAN'S BEHAVIOUR -MANAGEMENT						
Treatment at Step 2 of BTS (vignette)	0.055	0.756	-0.010	0.957	-0.059	0.742
Use of rescue medication (vignette)	0.186	0.293	**0.284**	**0.103**	0.211	0.231
Management of an acute attack	**-0.171**	**0.078**	0.071	0.688	-0.140	0.429
CLINICIAN'S BEHAVIOUR -PRESCRIBING						
Ratio IHCS/β_2 as DDDs	**-0.317**	**0.056**	-0.167	0.323	-0.059	0.731

KEY **Data in emboldened text = correlation coefficients (r) greater than or close to 0.2 and selection criteria for regression model**

SMPs = self management plans IHCS/β_2 = Inhaled corticosteroid/Beta agonists DDD = Defined Daily Dose

Table 20. Analysis of Variance Table for Linear Regression Model (Guideline Adherence and Quality of Life)

	Sum of Squares	df	Mean Square	F stat.	Sig.
Regression	5167.911	3	1722.637	9.008	<0.001
Residual	4972.050	26	191.233		
Total T	10139.962	29			

Table 21. Regression Coefficients for Guideline Adherence Variables Associated With Quality of Life

Aspect of Guideline Adherence	Unstandardized Coefficients			
	B (95% C.I.)	S.E	t	p
(constant)	40.917 (30.75 to 51.09)	4.947	8.272	<0.001
% patients with self-management plans	0.004 (-0.031 to 0.039)	0.017	0.250	0.805
drugs taken on home visits	-2.376 (-4.158 to -0.593)	0.867	-2.740	0.011
treatment of acute attack	0.178 (-1.553 to 1.910)	0.842	0.212	0.834
ratio of IHCS/β_2	-12.981 (-25.101 to -0.861)	5.896	-2.202	0.037

Key =C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

10.11.1 The Association Between BTS Guideline Adherence and Peak Expiratory Flow Diurnal Variation

The same procedures outlined in sections 10.10.2 and 10.10.3 were used to examine the relationship between guideline adherence and PEFDV. From Table 19 it can be seen correlation analysis identified the following variables that satisfied the criteria for entry into a multiple regression model:

1. Percentage of patients given Self Management Plans ($p = 0.176$)
2. Use of Rescue medication ($p = 0.103$)

It can be seen from Table 22 the model did not predict a significant amount of variability. The results of the multivariate regression for diurnal variation are presented in Table 23.

Table 22. Analysis of Variance Table for Linear Regression Model (Guideline Adherence and Peak Expiratory Flow Diurnal Variation)

	Sum of Squares	Df	Mean Square	F	Sig.
Regression	125.214	2	62.607	1.096	0.348
Residual	1599.514	28	57.125		
Total	1724.728	30			

Table 23. Regression Coefficients for Guideline Adherence Variables Associated With Peak Expiratory Flow Diurnal Variation

Aspect of Guideline Adherence	Unstandardized Coefficients			
	B (95% C.I.)	S.E.	t	p
(constant)	5.134 (1.662 – 8.605)	1.771	2.898	0.007
% patients with self management plans	0.004 (0.012 – 0.020)	0.008	0.492	0.626
use of rescue medication	1.165 (0.419 – 2.749)	0.808	0.442	0.160

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

A clinically significant improvement in PEFDV would need to be a reduction of at least 5%. From Table 22 it can be seen the regression analysis does not predict a significant change in outcome for either of the variables. From Table 23 it can be seen from the value and the positive sign of Beta that the model predicts for each mean increase of 1 point in response to the question about prescription of rescue medication would *increase* (worsen) diurnal variation by 1.165% (range 0.419 to 2.749 out of a potential score of 8 points). Also, a mean 1% increase in the number of patients given self-management plans would *increase* (worsen) PEFDV by 0.004%, which means adhering to these two aspects of the BTS guidelines has no meaningful impact on PEFDV.

10.11.2 The Association Between BTS Guideline Adherence and Symptom Scores

The same procedures outlined in sections 10.10.2 and 10.10.3 were used to examine the relationship between guideline adherence and symptom scores.

From Table 19 it can be seen correlation analysis identified the following variables that satisfied the criteria for entry into a multiple regression model:

1. Percentage of patients given Self Management Plans (p =0.117)
2. Equipment in clinician's room (p =0.011)

The results of the multivariate regression for symptom scores are presented below in Table 24 and 25. It can be seen from Table 24 the model does predict a significant amount of variability (p = 0.008). From Table 25, it can be seen the regression analysis predicted no significant improvement in symptom scores with increased use of self-management plans and an additional item of equipment in a clinician's room increases (worsens) patients' symptoms by 0.231 points (out of a total score of 15) or 1.5%, which is too small to be of interest.

Table 24. Analysis of Variance Table for Linear Regression Model (Guideline Adherence and Symptom Scores)

	Sum of Squares	df	Mean Square	F	Sig.
Regression	35.704	4	8.926	4.378	0.008
Residual	53.005	26	2.039		
Total	88.709	30			

Table 25. Regression Coefficients for Guideline Adherence Variables Associated With Symptom Scores

Aspect of Guideline Adherence	Unstand Ardized Coeff Icients			
	B (95% C.I.)	S.E.	t	p
(constant)	0.731 (-.275 to 1.736	0.491	1.489	0.148
% patients with self-management plans	0.0004 (-.004 to .005)	0.002	0.223	0.825
equipment in clinician's room	0.231 (-.035 to .497)	0.130	1.777	0.086

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

10.12.1 Examination of the Relationship between Practice Organisation and Outcomes

The relationship between the variables measuring practice organisation and outcomes was examined univariately using correlation analysis (see Table 26). The independent variables measuring practice organisation were entered into a correlation analysis matrix along with the primary outcome, quality of life. This procedure was followed for the secondary outcomes of PEFDV and symptom scores. From Table 26 it can be seen three variables had a level of association with quality of life of interest (list size, monitoring compliance and availability of a spirometer), three with PEFDV (list size, audit activity and availability of a spirometer) and three with symptom score (list size, use of information technology and availability of a spirometer). Practice list size and availability of a spirometer were associated with all three outcomes.

10.12.2 Assessment of the Impact of Practice Organisation on the Relationship between BTS Guideline Adherence and Quality of Life

Variables for entry into a multivariate regression model were selected using the same criteria (r >/= 0.2) outlined in section 10.10.3. These are in bold type in Table 26 and were as follows:

1. List size (p= 0.096)
2. Availability of a spirometer (p= 0.026)
3. Treatment compliance methods (p= 0.055)

To examine the impact of practice organisation on the relationship between guideline adherence and quality of life, the selected variables were added to the multivariate regression model constructed and backwards elimination was used to construct a final parsimonious model.

Table 26. Variables Associated with Practice Organisation and Outcomes (using correlation)

Practice Organisation Variable	Quality of Life		Diurnal Variation		Symptom Scores	
	corr. coeff (*r*)	**signif. (*p*)**	**corr. coeff (*r*)**	**signif. (*p*)**	**corr. coeff (*r*)**	**signif. (*p*)**
DEMOGRAPHIC CHARACTERISTICS						
Practice list size	**-0.286**	**0.096**	**-0.245**	**0.155**	**-0.244**	**0.158**
Patients per partner	-0.089	0.612	-0.80	0.648	-0.145	0.406
PRACTICE STRUCTURE (CDM)						
Percentage of list on asthma register	0.198	0.255	0.056	0.750	0.150	0.390
Nature of asthma clinic	-0.208	0.237	-0.152	0.392	-0.144	0.418
Asthma Audit	-0.172	0.325	**-0.351**	**0.038**	-0.166	0.342
PRACTICE STRUCTURE (non CDM)						
Use of computer	0.181	0.297	0.148	0.397	**0.233**	**0.197**
Methods to monitor patient compliance	**0.332**	**0.055**	0.047	0.792	0.173	0.329
PRACTICE RESOURCES (non BTS or CDM)						
Availability of a spirometer	**-0.377**	**0.026**	**-0.326**	**0.056**	**-0.243**	**0.160**
Availability of skin prick testing	0.052	0.771	-0.019	0.917	-0.032	0.856

KEY CDM = Chronic Disease Management

It can be seen from Table 27 the model predicts a statistically significant amount of change in outcome (quality of life). From Tables 28 and 29 it can be seen through the regression analysis four variables (% SMPs, management of an acute attack, availability of a spirometer and treatment compliance) were removed and the following three remained:

Guideline Adherence

1.Drugs taken on home visits ($p = 0.002$)

2.The ratio of IHCS/β_2 prescriptions ($p = 0.037$)

Practice Organisation

3.List Size ($p = 0.009$)

The final model shown in Table 29, predicts a mean improvement in SGRQ score of 2.576 for each extra appropriate medication recommended in the BTS guidelines taken on home visits. A mean improvement in SGRQ score of 10.503 is predicted if the ratio of IHCS/β_2 items prescribed is 1:1. As the number of IHCS items increases, the SGRQ score improves (reduces).

Practice list size was the only aspect of practice organisation related to quality of life that stayed in the model through the process of backwards elimination. However, its addition to the multivariate regression model did not significantly impact on the relationship between guideline adherence and quality of life.

The final model predicts an improvement in SGRQ score of 0.232 for an increase in list size of 1000 patients, which is not of interest as the list size would need to increase by 20,000 patients to significantly increase the practice mean SGRQ score.

Table 27. Analysis of Variance Table for Linear Regression Model (Guideline Adherence, Practice Organisation and Quality of Life)

	Sum of Squares	df	Mean Square	F	Sig.
Regression	5125.001	3	1708.334	9.568	<0.001
Residual	5356.311	30	178.544		
Total	10481.312	33			

Table 28. Regression Coefficients for Guideline Adherence and Practice Organisation Variables Associated with Quality of Life

Aspect of Guideline Adherence or Practice Organisation	Unstandardized Coefficients			
	B (95% Confidence Interval)	**Standard Error**	**t**	**p**
(constant)	37.363 (25.270 to 49.455)	5.831	6.408	<0.001
GUIDELINE ADHERENCE				
% patients with self management plans	0.013 (-.024 to 0.050)	0.018	0.739	0.468
drugs taken on home visits	-2.294 (-4.212 to -0.376)	0.925	-2.481	0.021
treatment of an acute attack	0.252 (-1.344 to 1.847)	0.769	0.327	0.747
ratio of IHCS/β_2 prescriptions	-7.875 (-19.447 to 3.697)	5.580	-1.411	0.172
PRACTICE ORGANISATION				
list size	-0.207 (-.382 to -0.331)	0.084	-2.468	0.022
availability of a spirometer	-1.700 (-4.119 to 0.719)	1.166	-1.458	0.159
treatment compliance methods	0.656 (-.205 to 1.517)	0.415	1.581	0.128

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

Table 29. Regression Coefficients for Final Model to Examine the Impact of Practice Organisation on the Relationship Between Guideline Adherence and Quality of Life

Aspect of Guideline Adherence or Practice Organisation	Unstandardised Coefficients			
	B (95% Confidence Interval)	**Standard Error**	**t**	**p**
(constant)	43.995 (35.094 to 52.896)	4.330	10.160	<0.001
GUIDELINE ADHERENCE				
drugs taken on home visits	-2.576 (-4.140 to -1.012)	0.761	-3.386	0.002
ratio of IHCS/β_2 prescriptions	-10.503 (-20.344 to -0.662)	4.787	-2.194	0.037
PRACTICE ORGANISATION				
list size	-0.232 (-.400 to -0.638)	0.082	-2.834	0.009

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

10.12.3 Assessment of the Impact of Practice Organisation on the Relationship between BTS Guideline Adherence and Diurnal Variation in Peak Expiratory Flow

Three variables measuring practice organisation to be added to the model were selected using the criteria previously described. These are in bold type in Table 26 and were as follows:

1. Practice list size ($p = 0.155$)
2. Audit - level of activity ($p = 0.038$)
3. Availability of a spirometer ($p = 0.056$)

These variables were added to the multivariate regression model examining the relationship between guideline adherence and PEFDV (described in section 10.11.1). The regression coefficients for the five variables entered into the model are presented in Table 31.

It can be seen from Table 30 below the model did not predict a statistically significant amount of variability and through the process of backwards elimination all of the variables were eventually removed from the multivariate regression model. In the original regression model (see Tables 22 and 23) a statistically significant relationship between guideline adherence and PEFDV was not found. The addition of practice organisation variables to the regression model did not have any impact on this relationship.

Table 30. Analysis of Variance Table for Linear Regression Model (Guideline Adherence, Practice Organisation and Diurnal Variation in Peak Expiratory Flow)

	Sum of Squares	df	Mean Square	F	Sig.
Regression	108.278	1	108.278	2.099	0.157
Residual	1702.561	33	51.593		
Total	1810.839	34			

Table 31. Regression Coefficients for Guideline Adherence and Practice Organisation Variables Associated Diurnal Variation in Peak Expiratory Flow

Aspect of Guideline Adherence or Practice Organisation	Unstandardised Coefficients		t	p
	B (95% Confidence Interval)	**Standard Error**		
(constant)	6.149 (2.413 to 9.884)	1.814	3.390	0.002
GUIDELINE ADHERENCE				
% patients with self-management plans	0.005 (-.012 to 0.023)	0.008	0.644	0.525
use of rescue medication	1.160 (-.514 to 2.834)	0.813	1.427	0.166
PRACTICE ORGANISATION				
list size	-0.0656 (-.157 to 0.026)	0.044	-1.472	0.154
Audit - level of activity	0.0968 (-.454 to 0.648)	0.268	0.362	0.721
availability of spirometer	-0.724 (-1.829 to 0.380)	0.536	-1.351	0.189

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

10.12.4 Assessment of the Impact of Practice Organisation on the Relationship between BTS Guideline Adherence and Symptom Scores

Three variables measuring practice organisation added to the multivariate model were selected using the criteria previously described. These are in bold type in Table 26 and were as follows:

1. Practice list size ($p = 0.158$)
2. Use of Information technology ($p = 0.197$)
3. Availability of a spirometer ($p = 0.160$)

These variables were added to the multivariate regression model examining the relationship between guideline adherence and symptom scores (described in section 10.11.2). The regression coefficients for the variables entered into the model are presented in Table 33.

Table 32. Analysis of Variance Table for Linear Regression Model (Guideline Adherence, Practice Organisation and Symptom Scores)

	Sum of Squares	df	Mean Square	F	Sig.
Regression	9.081	2	4.541	1.597	.220
Residual	79.628	28	2.844		
Total	88.709	30			

Table 32 shows the model does not predict a significant amount of variability and adding the variables of practice organisation did not significantly impact on the relationship between guideline adherence and symptom scores. It can be seen from Tables 33 and 34 one of the five variables fell out of the model - the percentage of patients given self-management plans.

The final model predicts an additional item of equipment in a clinician's room *increases* (worsens) patients' symptoms by 0.312 points (out of a total score of 15) or 2%. This is not clinically significant but the trend may reflect the fact that patients with unstable asthma need increased monitoring and treatment more frequently so in response the practice invests in more equipment. Interestingly, in contrast to the equipment, the availability of a spirometer *reduces* (improves) symptoms by 0.204 (out of a total score of 15) or 1.4%. This is not a clinically

significant finding; however, it is of interest as it may reflect other factors associated with improved outcomes, such as having staff who are more knowledgeable and motivated about respiratory care and who provide a service that includes respiratory assessment and spirometry.

As the score for computer use (information technology) increases, patients' symptom scores *increase* (worsen) by 0.176 or 1.17%. In contrast, the model predicts an increase in practice list size of 1000 patients would *improve* (reduce) symptoms by 0.023 or 0.1%. These two results only predict small changes in outcome that are not clinically significant and this demonstrates that practice organisation does not impact on the positive association between guideline adherence and symptoms.

Summaries of all of the results of the regression analysis are presented in Table 35 at the end of this chapter. The findings are discussed in greater detail in the final chapter.

Table 33. Regression Coefficients for Guideline Adherence and Practice Organisation Variables Associated with Symptom Scores

Aspect of Guideline Adherence or Practice Organisation	Unstandardised Coefficients			
	B (95% Confidence Interval)	**Standard Error**	**t**	**p**
(constant)	0.310 (-0.679 to 1.299)	0.480	0.645	0.525
GUIDELINE ADHERENCE				
% patients with self management plans	0.001 (-0.003 to 0.005)	0.002	0.652	0.520
equipment in clinician's room	0.338 (0.090 to 0.585)	0.120	2.811	0.009
PRACTICE ORGANISATION				
practice list size	-0.023 (-0.043 to -0.005)	0.009	-2.495	0.020
use of information technology	0.167 (-0.011 to 0.346)	0.087	1.932	0.065
availability of a spirometer	-0.231 (-0.469 to 0.006)	0.115	-2.004	0.056

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

Table 34. Regression Coefficients for Final Model to Examine the Impact of Practice Organisation on the Relationship Between Guideline Adherence and Symptom Scores

Aspect of Guideline Adherence or Practice Organisation	Unstandardised Coefficients			
	B (95% Confidence Interval)	**Standard Error**	**t**	**p**
(constant)	0.414 (-0.506 to 1.344)	0.448	0.925	0.364
GUIDELINE ADHERENCE				
equipment in clinician's room	0.312 (0.081 to 0.542)	0.112	2.781	0.010
PRACTICE ORGANISATION				
practice list size	-0.023 (-0.042 to -0.005)	0.009	-2.557	0.017
use of information technology	0.176 (.001 to 0.350)	0.085	2.072	0.048
availability of a spirometer	-0.204 (-0.423 to 0.015)	0.106	-1.918	0.066

Key = C.I. Confidence Interval S.E. Standard Error B Beta (value of parameter in model)
t = t statistic p = p value, 5% significance

Table 35. Summary of Variables in Multivariate Regression Models examining the Impact of Practice Organisation on the Relationship between Guideline Adherence and Outcomes

Variables Entered into Models	Quality of Life			Diurnal Variation			Symptom Scores		
	entered?	**remained?**	**Value of *p***	**Entered?**	**remained?**	**Value of *p***	**entered?**	**remained?**	**Value of *p***
Guideline Adherence									
Percentage with SMPs	**Yes**	**No**		**Yes**	**No**		**Yes**	**No**	
Medication taken on home visits	Yes	Yes	(-) 0.011	**No**					
Management of an acute attack	**Yes**	**No**		**No**					
Ratio IHCS/ β_2 as DDDs	Yes	Yes	(-) 0.037	**No**					
Equipment in clinician's room	**No**			**No**			Yes	Yes	0.010
Use of Rescue medication	**No**			**Yes**	**No**				
Practice Organisation									
List Size	Yes	Yes	(-) 0.009	**Yes**	**No**		Yes	Yes	(-) 0.017
Availability of Spirometer	**Yes**	**No**		**Yes**	**No**		Yes	Yes	0.048
Treatment Compliance Methods	**Yes**	**No**		**No**					
Audit – level of activity	**No**			**Yes**	**No**				
Use of Information Technology	**No**			**No**			Yes	Yes	(-) 0.066

Key = minus sign denotes positive direction of relationship and better outcomes
(decreased quality of life score, diurnal variation, and symptoms)

CHAPTER ELEVEN

CHAPTER ELEVEN: DISCUSSION

11.1 Introduction

In this chapter, I will rehearse the results of the study and discuss my findings. I will review the study design and the methodology I chose to answer my research question, discussing possible alternatives. Finally, I will draw conclusions from the study findings and discuss the implications for practice and future research.

11.2.1 Guideline Adherence

On the whole, self-reported adherence to the 1993 BTS guidelines for asthma management was good. Most of the GPs reported they used the guidelines to inform their management of patients with asthma; their decisions about treatment were also consistent with the recommendations in the guidelines. Whilst overall adherence was good and most of the practices had appropriate equipment, structure, and resources to follow the recommendations in the 1993 BTS guidelines, there were also some exceptions and evidence of wide variation.

11.2.2 The Measurement of Guideline Adherence with Respect to Organisation of Care and Facilities

An example of the variation across the practices was the percentage of patients who were given self-management plans. This varied from 0 to 100% (*mean* 45.8%). This variation may reflect differences in style of practice, differences in interpretation of the term 'self-management plan,' or differences in the types of self-management used. The BTS guidelines do not recommend any particular self-management plans and this lack of direction has previously been criticised (Neville, 1996).

Thirty-four of the 37 practices (92%) had a written asthma protocol and the majority of these (70%) had protocols containing six or more items included in the BTS guidelines. All of the practices had nurses who were interested in the care of patients with asthma and 70% of these nurses had received formal training in asthma management.

On the whole, practices were well-equipped to manage asthma according to the BTS guidelines, and out of the total of 13 items recommended, most had at least 11 available within the practice. Recent re-organisation within one practice appears to have jeopardised the resources available. One single-handed GP had only six of the expected 13 items of equipment available for the management of asthma at his practice. This GP had recently split away from four other partners to work alone and was in the process of equipping his new practice.

Also, not only were there differences between practices, but also there were differences within practices. In some, partners reported varying amounts of equipment available in their rooms and for home visits. Although some individual partners reported they had all of the recommended items of equipment with them on home visits and in their rooms, no practice attained the maximum. This implies that choice of equipment remains an individuals' decision rather than a practice policy.

11.2.3 Guideline Adherence Assessed from Vignettes of Clinical Practice

Adherence with respect to the use of medications was particularly high (use of rescue medication - 94%, management of an acute attack - 88% and treatment at step two of the guidelines - 70%). My results are similar to Jones and Gruffydd-Jones (1996), but the levels of adherence are higher than those found in a survey conducted by Davies and colleagues (1997). This may reflect a shift in practice over time, although one has to be cautious as different methods of measuring adherence were used.

There were some clinical areas where BTS guideline adherence was less good. Only 60% of GPs stated they routinely enquired about nocturnal symptoms, and for the treatment of an exacerbation requiring rescue medication (oral steroids), 20% would consider prescribing antibiotics. Jones and Gruffydd-Jones (1996) reported higher use of antibiotics (58% for children and 66% for adults); however, the focus of their study was the prescription of antibiotics and oral steroid use in the treatment of asthma attacks, associated with respiratory infection. In contrast, in this study I composed the vignette so that it deliberately

excluded any suggestion of clinical signs of infection, and therefore antibiotics were inappropriate.

In summary, no individual GP totally adhered to all aspects of the guidelines. Overall, 60% of the practices adhered to 60% of the guidelines, a finding that is comparable with work performed in Holland by Grol and colleagues (1998).

11.3.1 Study Findings - Main Conclusions

In this study the hypotheses were:

- *Patients who attend a practice, where the Primary Health Care Team follow the 1993 BTS guidelines, have improved quality of life.*

- *Patients who attend a practice, where the Primary Health Care Team follow the 1993 BTS guidelines, have improved asthma control.*

The main intention of this study was to look at the relationship between practice guideline adherence and quality of life. The chronic impairment in health caused by asthma is sometimes not discernible from conventional clinical outcomes such as peak expiratory flow rates. Although these are useful, patients' own perception of their well-being may be a more valuable indicator. An unhappy patient with perfect physiological measurements is a rarely desirable outcome. Therefore, quality of life was used as the primary outcome measure with which to assess BTS guideline adherence.

From the analyses, only two features of guideline adherence were statistically significant predictors of quality of life. These were:

1. The ratio of IHCS/β_2 as Defined Daily Doses ($p = 0.037$)
2. Medication taken on home visits ($p = 0.011$)

11.3.2 The Ratio of IHCS/β_2 as Defined Daily Doses

This study demonstrates prescribing based on the recommendations in the BTS guidelines can improve patient quality of life and supports the proposal that the ratio of IHCS/β_2 is a marker of quality asthma care (Majeed et al, 1995 and 1997; Shelley at, 2000).

In the SGRQ, a higher score represents worse quality of life. In the table presenting the regression coefficients for guideline adherence and quality of life (Table 21) it can be seen from the value of *Beta*, the model predicts that as the number of IHCS items prescribed increases, the SGRQ score improves. The minus sign denotes that the relationship with quality of life is negative, that is, the SGRQ score reduces as guideline adherence increases. A mean improvement in SGRQ score of 13 points (β= -12.981) was predicted if the ratio of IHCS/β_2 items prescribed increased to 1:1. If the number of IHCS items prescribed is double that of beta-agonist items, the model predicts that the mean SGRQ score would be improved by 26 points (13 x 2).

A clinically significant change in SGRQ score in an *individual* is about 4 points, (Paul Jones personal communication). In this study, data are presented as *mean scores per practice* and therefore, my results predict that for the "average" patient their quality of life will be improved. In practice, it is unlikely all patients will notice the same level of improvement.

This relationship between steroid prescribing and favourable patient outcomes has been observed previously. Griffiths and colleagues (1996) demonstrated an association between prescribing and 'process measures', such as hospital admissions; in addition, Patterson (1997) demonstrated a positive relationship between the prescription of IHCS and improved patient outcomes in 18 general practices over a 6 month period.

In this study, the quality of prescribing by GPs in the practices was a little below average in comparison to national figures for the ratio of IHCS/β_2. It was found the mean ratio of IHCS/β_2 prescriptions for the 37 practices was 0.65 compared to a national figure of 0.73, for the same period of time (PPA, 1998). There were also differences within the study: in the Basingstoke area the ratio of IHCS/β_2 prescribed was higher (0.70) than that in the Bournemouth and Poole area (0.63).

The lower ratio for Bournemouth and Poole may not be due entirely to inappropriate prescribing, but rather reflect the higher proportion of elderly patients in these localities. Older patients are more likely to have obstructive airways disease than asthma, and as beta-agonists are more effective than IHCS for the former, this would contribute to the lower ratio.

11.3.3 Medication taken on home visits

The second aspect of guideline adherence that was a significant predictor of quality of life was 'medication taken on home visits'. The BTS guidelines give clear directions for doctors attending patients with exacerbations at home and list the following treatment:

- Oxygen (highest concentration available)
- High doses inhaled β_2 (via nebuliser or large volume spacer)
- High dose oral and systemic steroids
- Ipratropium bromide (via nebuliser or large volume spacer)
- Intravenous aminophylline

For the purposes of this study, the minimum requirements were considered to be two types of beta-agonist (inhaler and nebule) and two types of steroid (oral and intravenous); additional points were given for ipratropium bromide, aminophylline, and oxygen. Although in the BTS guidelines it is recommended that oxygen be taken when attending patients with exacerbations at home, when constructing the scoring system, it was excluded from the list of minimum requirements because of its limited availability in the community.

In the table presenting the regression coefficients for guideline adherence and quality of life (Table 21) it can be seen from the value of *Beta*, the model predicted if the mean number of medications taken on home visits by GPs increased by one, the mean SGRQ score for patients from that practice will be reduced by 2.4 points (β= -2.376). Practices scored 2.3 to 5.0 out of a total of 8.0, demonstrating all practices that took part had the potential to make improvements and take at least three more medications with them on home visits. An increase of

just two medications would theoretically achieve an improvement in score of 4.8, which is a clinically significant improvement in quality of life.

Although this finding is significant at a theoretical level, it may only have limited impact in the clinical setting as this measure is of the *practice mean SGRQ score* as discussed above. Also, it is naive to assume that just having the appropriate drugs recommended in the BTS guidelines in a GP's bag is sufficient to improve outcomes - adequate knowledge of their correct use is also required. The relationship observed in my study probably arises because GPs with increased knowledge of asthma carry more drugs, but it is their enthusiasm and interest in the care of patients with asthma that impacts positively on patients' quality of life. The contents of an on-call bag are unlikely to have a great impact on outcomes as so few adult patients receive emergency treatment at home.

11.4.1 Guideline Adherence and Patient Outcomes Routinely Measured in Primary Care

Quality of life is not routinely used to monitor patients' asthma control. In clinical practice, monitoring patient progress is achieved by checking the frequency and severity of symptoms and the variability of peak expiratory flow measurements. In this study, a standardised symptom checklist together with diurnal variation in peak expiratory flow (PEFDV) calculated from diary card information was used. However, from the regression analysis (Table 23) it can be seen no aspects of guideline adherence predicted significant amounts of variation in PEFDV.

There were just two interesting findings related to symptom scores. From the original regression model (Table 25) it can be seen that in statistical terms, the equipment kept in a clinician's room was a significant predictor of symptom score (p= 0.086) and this variable remained in the model and actually increased in relative significance in the presence of other co-variates measuring demographic characteristics and practice organisation (p= 0.009). Although surprisingly, more equipment predicted increased symptoms! Out of a possible six items of equipment, one additional item predicted a worsening in symptom score of 0.338 points (Table 33). After backwards elimination was performed, the final model

shows the equipment kept in a clinician's room was the most significant predictor of symptom score (p= 0.010), (Table 34).

It may be the amount of equipment a practice holds for the treatment and monitoring of asthma is not a sensitive predictor of improved outcomes, or that the acquisition of more equipment may be related to the prevalence and severity of asthma in the practice population. Practices who have patients with more challenging respiratory problems on their list may invest more in equipment for diagnosis and monitoring. However, it is likely that buying equipment per se is not related to the quality of care.

Interestingly, from the correlation analysis it can be seen one piece of equipment is related to all outcomes including symptom scores (Table 26). In the final regression model, the availability of a spirometer predicted improved symptoms, although this was not statistically significant in the presence of other variables (p = 0.066). The model predicted a reduction of 0.204 points out of a potential maximum score of 15; this equates to a 1.36% improvement in symptoms if a spirometer was available at the practice, which is too small to be of clinical interest (Table 34).

The use of spirometry in primary care is not a recommendation in the BTS guidelines. My results are not sufficient to challenge this omission and only add to the uncertainty and differing opinions that exist regarding the value of using spirometry for the diagnosis or monitoring of asthma in primary care (Jones, 1995; Fried et al, 1995; and Picken et al, 1998). The role of spirometers in the management of asthma in general practice needs further consideration and clarification before their widespread use in primary care can be justified.

11.4.2 The Role of Practice Organisation on Quality of Life and Disease Control

Inadequate control of chronic diseases such as asthma often has a multifactoral origin, with a combination of patient, doctor and practice factors determining how well the individual is managed (Pringle et al, 1993). The lack of a close relationship between guideline adherence and patient outcomes might, in part, be explained by the contribution of practice organisation. This study captured

extensive data on various features of practice organisation and these are discussed below.

At the time of designing this study, it was not known which aspects of practice organisation might impact on patient outcomes. The literature was searched extensively and discussions with GPs and practice nurses regularly involved in the management of patients with asthma provided many examples of 'accepted good practice,' and innovative systems. These were captured in the bespoke Asthma Management in Practice Questionnaire (AMPQ).

From Table 26, it can be seen correlation analysis showed that some aspects of practice organisation were significantly associated with outcomes. However, when these variables measuring practice organisation were added to the regression models previously constructed to examine the relationship between guideline adherence and outcomes, their importance to the models was overshadowed by the strength of the relationship between guideline adherence and outcomes. That is, adding practice organisation variables did not significantly impact on the relationship between guideline adherence and outcomes. For example, the final model in Table 29 predicted an increase in practice list size of 1000 patients would improve the mean SGRQ score by 0.232 (p = 0.009). Although statistically significant, this is much too small to be clinically relevant as a practice would need to increase by 20, 000 patients to achieve a clinically relevant improvement in quality of life!

Interestingly, the use of information technology predicted worsening symptoms and was statistically significant (p = 0.048), but only predicted a very small change of 0.176 points, which out of a total score of 15 is 1.2% and would hardly be noticed in an individual, and as a *mean per practice improvement* is not sufficient to base any recommendation (Table 34). None of the variables relating to practice organisation was a significant predictor of PEFDV.

So in summary, although the variables measuring practice organisation appear to have a significant impact on patient outcomes from the results of the analysis; when the *Beta* values are examined in the final regression models, it can be seen these results are not sufficient to recommend changes in practice in the clinical setting. Practice organisation does not appear to confound the relationship between guideline adherence and outcomes in either a positive or negative way.

Does this mean that practice organisation is unimportant, or does this suggest that the aspects of practice organisation that are simple to measure are not the ones that influence outcomes? Other studies have also observed minimal impact of measurable features of organisation on patient outcomes (*vide infra*).

The Chronic Disease Management (CDM) programme introduced in 1993 encouraged increased collection of information and more systematic care for patients with enduring illness. Annual process audits for the CDM scheme provide practices with information about the 'size of the problem', but there is no evidence that these changes in 'process' have contributed to improved outcomes. Dunn and Pickering (1998) showed that there was almost no relationship between a practice's efficiency in measurements of process criteria and any outcome criteria for patients with diabetes mellitus, suggesting that other components are required to deliver optimum diabetes care in general practice. In the management of patients with asthma, Neville and colleagues (1996) also found no association between accreditation for CDM and patient outcomes.

There are several other aspects of practice organisation that may improve outcomes. They include:

a) Practice asthma protocols
b) The role and impact of the practice nurse
c) Accessibility of service for the patient

a) Practice asthma protocols

The presence of a practice asthma protocol is required for financial reimbursement for the practice under the CDM scheme, but there is no clear guidance on required scope and content of these documents. Ideally, a practice protocol should provide a framework for all aspects of asthma management and it should set the standard for treatment (using national or local guidelines). Furthermore, the organisational structures and systems within the practice need to be effective in facilitating patient care according to the protocol and finite resources; and some method of targeting those most in need is essential (Jones et al, 1992b).

In this study, I assessed the practice protocol for adherence to the BTS guidelines using a ten point scoring system. I found there was a wide variation in the format and presentation of protocols. Of the ten key points (see Chapter Five, section 5.3) the most frequently missed features were 'the emphasis on prophylactic medication', 'introducing anti-inflammatory medication if $beta_2$-agonist required more than once a day' and 'teaching patients how to recognise signs of asthma worsening'. Out of a total score of 10.0, the mean number of guideline-based features in the practice protocols was 6.4, with a range of scores from 4.0 to 9.0. The level of association between practice protocol and outcomes was not sufficient for entry into any of the regression models (highest $p = 0.261$).

The assessment of the practice protocol was focused on the written word rather than translation of the contents into clinical practice; similarly, I made no assessment of the feasibility within the practice to comply with the practice protocol. Theoretically, a practice could score highly with a well-prepared protocol whilst lacking in the equipment, staff, motivation, and organisational infrastructure to effectively manage patients with asthma. This could have been explored further with interviews of practice staff and more recently others have used this method. For example, in a study examining the roles and attitudes of GPs towards asthma self-management, 20 Dutch and 25 British GPs were interviewed. In the interviews with the British GPs, the need for efficient organisation, an explicit protocol and a clear division of tasks between GPs and Nurses were expressed (Thoonen et al, 1998).

b) The role and impact of the practice nurse

Undoubtedly, nurses play a major role in the management of patients with asthma in general practice. Practice nurse characteristics were explored in a pragmatic, but rather superficial manner (presence or absence of a practice nurse, receipt of formal training and time interval since training). Thirty-six of the 37 practices that took part in the study employed nurses interested in asthma and the length of time since practice nurses had completed their asthma training ranged from 1 to 10 years (mean 4 years), but 6 (16.2%) of them had not received formal training. My assessment of practice nurse training was rather simplistic, ignoring the issues of quality and nature of training, frequency of updates, practical

experience etc. As nurses play a particular role in proactive, rather than reactive asthma care, I would have liked to have explored to what extent nurses were encouraged in some practices, or 'stifled' in others. By simply measuring the length of time since completing asthma training, insufficient insight into their level of activity was obtained. This could have easily been assessed using definitions of 'minimum, medium and maximum', originally proposed by the National Asthma and Respiratory Training Centre in Warwick. It may be that maximum involvement is facilitated in practices with particular attributes and that less well-organised practices may not have the facilities to enable a well-trained practice nurse to have a more independent 'maximum' role.

c) Accessibility of service for the patient

One aspect of practice organisation that has an impact on the delivery of good care is accessibility for patients. In the process of conducting my research I became very aware of the difficulties patients experience accessing primary care services. In the study, twice as many appointments were made to see female patients and despite concerted efforts to make appointments for male patients to participate in the study, the closing times of practices made this very difficult. Many men travelled out of the area to work and did not return until late in the evening and, although I made separate arrangements to see them on Saturday mornings, they commented on the difficulties obtaining routine prescriptions and appointments at their practices.

Practice nurses often work part-time hours, so some asthma clinics may have been set up with specially allocated appointment sessions according to the nurse's availability. Larger practices benefit from 'economies of scale' and may have greater flexibility, time and resources for their patients of working age. This was observed in this study, where larger practices ran both dedicated asthma clinics and ad hoc arrangements incorporating patients into the general appointment system. In all the practices it was found that the most commonly favoured style was to see patients within the general appointments, recognising this option to be a more efficient use of the practice nurse's time. However, this may limit patient choice. From the results of a survey of patients, a preferable

structure would be to offer a range of options that are responsive to patients' requirements but include a system of regular review (Paterson and Britten, 2000). Within the confines of this study it was not possible to explore in greater depth such factors as accessibility, the role of the practice nurse and the impact of practice protocols on the management of asthma in primary care. These areas warrant further research and are discussed in more detail in the following sections.

11.5.1 Study Findings - Discussion

So why was a closer relationship between guideline adherence and patient outcomes not observed? There are several possible explanations, discussed in turn below:

1. The BTS guidelines are not evidence-based, so their recommendations are not of proven benefit.
2. GPs report adherence to the BTS guidelines, but their actual practice differs from the recommendations.
3. Patients may not adhere with the treatment regimes prescribed.
4. Patients' quality of life and disease control may be dependent on factors of practice organisation rather than guideline adherence.
5. Issues of study design and methodology have masked any true relationship between guideline adherence and patient outcomes.

11.5.2 The BTS guidelines are consensus rather than evidence-based

The 1993 BTS guidelines are a consensus statement; rather than being based on high-grade evidence from randomised controlled trials, so many recommendations are not of proven benefit, with some recommendations reflecting what is considered 'best practice' and others based on evidence not derived from primary care.

The management of patients with asthma in the community is complex and the effectiveness of treatments may be less than that achieved in well-controlled studies conducted in secondary care settings. Practice, patient, and health professionals may detract from the effectiveness of these recommended treatments when they are translated to real life situations.

Almost all of the recommendations about organisation and delivery of asthma services to patients in general practice are not evidence-based, but rather have been made in the belief that these interventions are beneficial. For instance, in the early 1990s, self-management became accepted practice for patients with chronic diseases, and many practice nurses started giving patients with asthma guided self-management plans. Although the concept of self-management was included in the 1993 guidelines, no specific guidance regarding how to organise this, or which plans should be used was given. By the mid 1990s, despite a significant fashion for the use of self-management plans, emerging evidence suggested self-management might not have the beneficial impact that had first been anticipated. Some benefits were observed in outpatient or accident and emergency departments, but these results were not necessarily transferable to primary care. In primary care, it became apparent that rigid adherence to self-management plans requiring daily peak flow measurements was unreasonable and unnecessary (Jones et al, 1995).

A recent Cochrane review has helped clarify some of the uncertainties regarding self-care (Gibson et al, 2000). The review concluded that training in asthma self-management which involves self-monitoring by either peak expiratory flow or symptoms, coupled with regular medical review and a written action plan appears to improve health outcomes for adults with asthma. Programmes that enable people to adjust their medication using a written action plan appear to be more effective than other forms of asthma self-management. Although self-management continues to be considered an indispensable aspect of domiciliary asthma care, doubts still exist regarding its widespread use (Pill et al, 2000). In primary care, further work is required to examine the effectiveness of targeting these plans to patients with adequate understanding and motivation to monitor their asthma, and vary the dosage of their medications according to instructions in the plan.

11.5.3 GPs report adherence to the BTS guidelines, but in practice depart from their recommendations

Picken and colleagues proposed three reasons why a primary care physician may not comply with national guidelines (see over-leaf):

- They may not be aware of the guideline.
- They may have a negative attitude toward the guidelines.
- They may agree with the guidelines in general, but disagree with a specific part (Picken et al, 1998).

We know from earlier work that GPs in the UK in the main have a positive attitude towards the BTS guidelines, are knowledgeable about their content and my results concur with this. However, during the consultation, when faced with an individual patient whose asthma and treatment plan do not fit exactly within the guidelines, a GP may have a less positive attitude towards a certain aspect of the guidelines.

My results show variation in the choice of medications taken on home visits. Some GPs reported they would take all the appropriate medications on home visits whilst their partners reported using a more limited list, which implies they were unaware of or chose not to concur with that part of the BTS guidelines. A survey of over 400 primary care physicians conducted in the USA also found patchy implementation. Whilst several aspects of national guidelines had been incorporated into clinical practice, other recommendations had not been so readily adopted. The authors concluded that attitudes of physicians are key to adherence and, as in other studies, found that primary care physicians often disagree with several aspects of national guidelines (Picken et al, 1998; Grant et al, 1999).

To capture true adherence requires different methods. One could observe GPs consultations with individual patients or perform note searches. The latter method of gathering information about treatment decisions will become easier with more increased computerisation within practices and more efficient coding. Unfortunately these two alternative observational approaches are methodologically challenging, resource intensive and were well beyond the budget of the study.

As an alternative for observation of practice, I developed vignettes to access reported behaviour. Vignette development is not easy; the treatment pathways for patients with asthma are complex and, in real life, patients do not present with clear-cut histories. To make the vignettes more realistic, I included inaccurate

answers to act as 'red herrings'. For example, the prescription of antibiotics when the appropriate rescue medication recommended in the guidelines is oral steroids. The disadvantages associated with using vignettes have been observed in other work (Jones and Gruffydd-Jones, 1996). Respondents may give the answer that is expected of them, which merely demonstrates knowledge of the content of the guidelines, rather than what they actually do in the consultation. Also, providing a choice of responses is almost like censorship and may be prejudicial. Actual practice may differ substantially from reported adherence. Therefore, an observed level of guideline adherence may be artefact and therefore any relationship with outcomes may be coincidental.

One of the most straightforward ways to measure guideline adherence is to examine prescribing habits. Prescribing is a behaviour that can be easily measured and assessed for concordance with the BTS guidelines and is less subjective than self-reported adherence. These data are readily available and represent the most straightforward way to collect information about GPs' prescribing habits. However, PACT data are not without their limitations. It is impossible to identify if respiratory medication has been prescribed for conditions other than asthma, and lower ratios of IHCS/β_2 in a particular practice may be related to a higher proportion of patients with COPD. Also, a high number of corticosteroid prescriptions may be an example of appropriate action taken by GPs, or may simply be associated with severity of the asthma population (Aveyard, 1997).

There have been requests for the current prescribing surveillance system to be developed further, increasing the validity of PACT data for assessing prescribing habits in general practice. The changes suggested include a unique patient identification number and information about diagnosis. The first would provide patient-based PACT data that could be linked to other information such as health service utilisation, or hospital admission data. The inclusion of diagnostic data would remove the uncertainty about the intended use of certain medications that can be prescribed for a variety of conditions (Majeed et al, 1997). However, these changes would be expensive to instigate, requiring national consensus, protection of patient confidentiality and significant restructuring of the PPA database.

Whilst the limitations of PACT data are recognised, there are no immediate plans for such improvements to be implemented.

In this study, examining routinely collected prescribing data provided an opportunity to gather objective information regarding GPs adherence to the BTS guidelines. An alternative would have been to examine prescribing habits at the patient level, using ad hoc data collection within the practices. However, when this study started, not all the practices had a computerised prescription system and it would have been impractical to collect such data in those practices.

Until PACT data include diagnostic identifiers, using this information to judge the quality of prescribing is not completely reliable. In the interim, it is the only marker by which to assess the quality of asthma prescribing and despite its recognised limitations, the results of this study support the use of PACT data and the ratio of IHCS/β_2 as a proxy marker of good asthma care.

11.5.4 GPs adhere to the BTS guidelines, but patients do not follow treatment regimes prescribed

It is known that few patients follow instructions on their prescriptions exactly and they may not take their medication for the correct duration, or at the correct dose (Jones and Gruffydd-Jones, 1996, Newton et al, 1996 and Aveyard, 1997). Therefore, non-compliance in patients may have distorted the relationship between BTS guideline adherence and patient outcomes.

"Primary non-compliance" describes the deliberate act of not redeeming prescriptions. It is estimated that between 5 and 7% of all prescriptions are not redeemed (Britten, 1994). A common reason given for non-redemption is the cost of the prescription (Wilcock, 1998). For asthma, the precise rate of primary non-compliance is unknown, as many patients are supplied with prescriptions for multiple items, but it can be assumed to probably be higher than average.

"Secondary non-compliance" occurs when the medication is not taken according to the prescriber's instructions. In a questionnaire survey to patients with asthma, 39% of patients admitted to not complying with their medication regimes and 76% stated that they frequently omitted their preventive medication. The most common reason given for non-compliance was that the patient did not believe it was necessary (Tettersall, 1993).

In this study, self-reported medication use was recorded on patient diary cards. However, due to time constraints these data have not yet been analysed. There is therefore the opportunity in the future to assess whether compliance with medication has confounded the relationship between guideline adherence and outcomes.

11.5.5 Patients' quality of life and disease control may be dependent on factors of practice organisation rather than guideline adherence

The organisation of a practice is multidimensional and complex. In order to assess the extent that a health system is adequately providing care, it has been suggested two characteristics should be measured: one addressing the effectiveness of structural features to provide the service and another that examines the actual process of delivering that service (Starfield 1994). These were both considered in this study using a pragmatic approach for selecting aspects of practice organisation to be considered. To ascertain which organisational methods appeared to work in practice, comments from GPs were sought and discussion groups were held with Practice Nurses involved in the management of asthma.

The measurement of these characteristics is challenging and trying to reduce complex issues to a few simple questions is ambitious. Guidelines for good questionnaire design were followed and in piloting the questionnaire face validity was confirmed. Ideally greater assessment of validity and reliability could have been made with more extensive field-testing of the questionnaire.

It was apparent from the site visits, that practices differed a great deal in their ethos and culture from each other and that not all of them seem to have a clear management structure. It seemed that whilst some procrastinate and make few changes, others thrive on innovation. It was also apparent that in some practices the nurses were very much part of the 'decision making' process, whilst others appeared to have a more passive role. If redesigning the questionnaire, I would wish to capture more detail about the role of the nurse.

With the almost incessant modifications in the way primary care has been organised and funded over the last decade, it would have been valuable to include some estimation of how a practice manages 'change'. However, measuring the process of change is not easily done. General practices, are as different and varied as the nations and societies of the world, with differing cultures, sets of values, norms and beliefs; these are all reflected in differing structures and systems and it is tempting to cast judgement over a style of management that does not fit with ones own, just because it is different.

Spiegal and colleagues describe a model for managing change in general practice. Although they do not specify *how* change can be measured, they do set out the steps required for developing a strategy and a team approach to change (Spiegal et al, 1992). In future assessments of practice organisation it may be appropriate to access the following:

- Is the practice ready for change, does it have adequate resources to support its services (staff, equipment, room)?
- How are decisions reached (individual, consensus across GPs, inclusive of other members of the PHCT)?
- How are meetings conducted (involves only key members, all personnel, open or formal)?

The strategies Spiegal proposes are from a well-validated model for managing change and underlying all of them is the recognition of a team approach to managing change (Spiegal et al, 1992). From visiting the practices in this study it was apparent that partners and practice managers had a variety of management styles. Some practice teams were obviously more cohesive and able to cope with changes in organisation and service delivery than others.

11.5.6 Issues of study design and methodology have masked any true relationship between guideline adherence and patient outcomes

The study has several methodological limitations, which can be categorised under the following headings (over-leaf):

- Practice Factors
- Case Definition
- Patient Factors
- Study Design
- Analysis
- Outcomes

a) Practice factors

A high level of socio-economic deprivation in a practice population increases the prevalence of asthma, increases the workload of the PHCT, and thus threatens the quality of the service delivered to patients (Carney, 1989; Yuen and Balarajan, 1989; Balarajan et al, 1992; Littlejohns and MacDonald, 1993). Therefore, when designing this study, it was decided to minimise those differences attributable to socio-economic characteristics of the patient population by sampling practices from two demographically homogeneous areas. This was to increase the certainty that any differences found in the outcomes measured (quality of life and disease control) were due to differences in guideline adherence. In fact, what this may have done is reduce the 'natural' variation that was observed, by recruiting practices that were too homogenous to represent the very broad range of clinical practice that exists.

There was a further loss of variation as practice participation in this study was voluntary. Even though some practices were still developing their asthma service and participated in the study as a way of gaining insight into their asthma population, the majority of practices that were attracted to the study were highly interested and actively involved in asthma management and therefore more likely to adhere to the BTS guidelines. So, once again some of the expected variation in responses regarding guideline adherence may have been minimised.

b) Case definition

Establishing a diagnosis of asthma is often difficult as there is no single, or *gold standard* test that easily distinguishes asthma from other respiratory diseases. Patients were eligible for entry to the study if they had been prescribed

medication for their asthma in the last 12 months. The diagnosis was not verified with a questionnaire or pulmonary function tests (such as reversibility to bronchodilator or bronchial challenge), as this was not considered practical, and would have increased the cost of the study. In retrospect, reversibility to bronchodilator via a spacer may have been a reasonable addition to ensure all patients entered into the study truly met a robust "case definition" of asthma.

It is known that the diagnostic threshold for asthma may differ across GPs and practices, so without an independent assessment of the diagnosis of asthma, inappropriate patients may have been included in the study. Across the 169 GPs, the decisions about the diagnosis of asthma may have varied considerably. In larger practices with more GPs, there is greater potential for the number of clinicians who 'under-diagnose' or 'over-diagnose' to balance out. However, in smaller practices, if a partner significantly deviates from the norm, this may influence the diagnostic threshold to a greater extent.

The diagnosis of asthma is least secure at the extremes of age. So, entry to the study was restricted to subjects under the age of 45 to minimise the recruitment of patients with fixed airway disease. Another precaution was to exclude patients who were smokers. The rationale for excluding patients who may have fixed airways disease, such as COPD, is that bronchodilator medication may be given more frequently and in higher doses, thus distorting the ratio of bronchodilators to inhaled steroids used by patients.

Unfortunately, by excluding smokers, a large proportion of the patients cared for by GPs, were not included in the study. It is difficult to estimate how many patients with asthma smoke. It is probably about 25%, slightly less than the general population where the figure is between 27 and 31% (DOH 1998c). Therefore, my sample was probably obtained from approximately 75% of the target population and was only representative of 'non-smoking asthmatic patients', who were prepared to volunteer their participation in this research.

The care of asthmatic smokers in general practice warrants further investigation that was not possible in this study. We know smoking is a major risk factor in asthma morbidity and mortality (Abramson et al, 2001). Encouraging patients with asthma to stop smoking is one of the most important aspects of helping them manage their asthma. Perhaps the quality of asthma management in a practice

could have been judged by their success at reducing the incidence of asthmatic patients who smoke.

The majority of patients seen in primary care have relatively mild disease and the very nature of the disease features long periods of remission with minimal or no symptoms. This study only monitored symptoms during a 'two week window', thus providing only a snapshot of patients' asthma and their management. Therefore, during the window of observation, very few patients had particularly large amounts of PEFDV and this method of assessing disease severity may not have been the best choice for a large community-based population.

The case definition and severity could have been endorsed with spirometry, but unfortunately the FEV_1 data I collected could not be used. I used a newly marketed spirometer to measure FEV_1 that with intensive, repeated use gave much higher than expected readings. When these data were checked and compared with the other secondary outcomes measured (PEF and symptoms etc.), many of the readings looked unreasonable. When these discrepancies were reported to the manufacturer, their opinion was that repeated use in a busy, warm clinic room had created condensation within the machine and distorted the readings.

A second problem relating to spirometry was that with a large sample of patients to see at varying times of the day, it was considered unreasonable to ask them to withhold their use of beta-agonist. Therefore, some of the patients had used a beta-agonist inhaler within the four hours prior to performing spirometry. The variability in the conditions under which data were collected rendered the results of the spirometry tests unreliable and unusable.

These two examples illustrate the conflict between getting precise, reliable measurements and the pragmatic considerations of conducting a large community-based study.

At the start of the study, I employed a research nurse to help with assessing patients and data collection. However, when she left prematurely it was decided to replace her with an administrative assistant to help with the large volume of correspondence and filing that had accumulated. This meant that I performed all the fieldwork and in retrospect, it may have been preferable to request extra finance from my funding body for additional staff. With this extra support more

patients could have been seen at convenient times and asked to withhold their use of beta-agonist for four hours prior to their appointment for spirometry.

c) Patient factors

It is important to look at the characteristics of my sample to assess how representative it is of the wider population. Demographic information regarding employment, social class, education, and house tenure was available for patients who returned a diary card (n = 897, 85%).

Twice as many women than men were seen. No positive steps were made to ensure equal numbers of men and women were recruited to the study, as such unequal proportions were not anticipated. The proportions were calculated at the end of the study and the SGRQ scores per practice were adjusted for age and sex, prior to performing the analysis. The excess of women in my sample probably arises from the national tendency for more women than men to attend consultations (see Table 36) and was exaggerated by the particular difficulties men had in attending my assessment clinics.

As the majority of participants in my study were women and their associated symptoms become worse as they progress from adolescence, a higher than the observed level of symptoms might be expected. However, as none of my sample was a smoker, this has impacted to decrease the overall amount of symptoms and has counteracted the expected effect of gender.

	Men	**Women**
NHS GP Consultation Rates	34%	66%
Patients Attended (SGRQ)	37%	63%

Table 36. Attendance Rates and Estimated Numbers of NHS GP Consultations by Gender

Comparison with other study populations is difficult given the variation of descriptors used. However, in comparison to another general practice-based study that used the same method of calculating the mean diurnal variation in peak flow, the mean diurnal variation was smaller in my sample indicating less

morbidity, probably because smokers were excluded from my sample (Jones et al, 1992a).

Jones	mean diurnal variation 10.1 (n=284)
Dorward	mean diurnal variation 7.67 (n=890)

In this study, the subjects were patients who were willing and eligible to participate. At first, I assumed that patients who consented to take part in this study would be in the main enthusiastic individuals who already knew about the management of their asthma. At the appointments, it became apparent that some had responded to the invitation out of curiosity to know more; many had in fact never monitored their peak flow, or had their inhaler technique checked, or their treatment reviewed.

As a nurse trained in the management of asthma, this presented me with a dilemma. As far as possible, I needed to make sure that I was not giving additional information or providing an intervention. To protect the integrity of the data, during the appointments I explained to patients that as I was only a visitor, I could not provide information regarding their asthma or its treatment, but advised them to speak with their GP or practice nurse if they had any concerns.

One or two patients complained that they could hardly ever get to see anyone at their practice; therefore, I suggested they contacted the National Asthma Campaign telephone help-line. On a couple of occasions I referred patients to a doctor straight away as their symptoms and spirometry readings indicated their asthma was worsening, and needed urgent medical attention. At the commencement of the study, practices were notified that I would refer any patient to a GP who caused me concern and that also, as a result of my visits the asthma patients at their practice may request more appointments. This increased focus on asthma may in addition have encouraged some practices to change their procedures and adherence to the BTS guidelines; this is known as the *Hawthorne Effect*. It is named after a study of Western Electric Corporation workers, from the Hawthorne plant in the USA. Researchers wished to study the effect of different interventions, such as soft music and different lighting on productivity.

It was observed productivity increased regardless of the intervention and the researchers concluded this was due to the workers' response at being studied, rather than the interventions.

Although there may have been some change in practice due to increased attention, it was not felt any effect would be maintained for the duration of the study.

d) Study design

At the planning stage, to calculate the number of practices required, information regarding the number of patients registered per partner was sought from local health authority offices. I was given an estimation of 2000 patients registered per partner, but in fact, in Bournemouth, the average list-size is less than 1800. As the majority of the practices that participated in the study were in the Bournemouth area (60%), the lower than anticipated number of patients registered reduced the expected target population, from 8000 to 7200 patients, and eligible asthmatic patients from 200 to 180 per average four-partner practice.

Non-response is a problem frequently reported in observational studies, especially in young adults (Altman, 1997, Hilton et al, 1986). To minimise under recruitment an intensive recruitment schedule was used. This achieved a mean response rate for the practices of 45.1%, (range 29.4 to 73.3) which exceeded our target of a 30% response rate. Nonetheless, in the early stages of the study there were some alarmingly low patient response rates from certain practices.

Patients who did not respond to the original letter and questionnaire were sent one reminder letter. Patients who did not respond to either of these letters were classified as "non-responders". To assess the differences between non-responders and responders, a sample of records of the non-responders were examined in the practices. Notes of patients from a small three-partner and a large six-partner practice were reviewed. Information was sought about their attendance history for appointments, the length of time they had had asthma and whether they smoked. The only difference detected was that in the non-responders from the large practice the proportion of smokers was lower (10%) than in the responding sample (17%), (see Table 37).

	Small Practice		Large Practice	
	Non-responders	Responders	Non-responders	Responders
Sample	28	73	43	144
Mean Age	30	32.12	31	34.5
Asthma (yrs)	11.4	11.7	11.5	12.1
Smokers	7 of 28	18 of 73	10 of 73	10 of 43
(% total)	(25%)	(25%)	(23%)	(17%)

Table 37. Characteristics of Non-responders

At the time I performed these note searches, it was customary to allow researchers access to patient records. With changes in the legislation surrounding data protection, this is no longer acceptable. To achieve access, one would now require permission from local research ethics committees and from individual patients.

There was wide variation in response rates across the practices ranging from 29 to 73% per practice. The number of patients required to *complete* the study, after drop-outs from practices and patients was 1350 (an average of 45 patients from each of 30 practices). The resultant sample size was 1065, which is 11% less than the expected sample of 1350 patients. Despite this, 37 practices were recruited which exceeded the target number and compensated for the lower than expected number of patients. The mean number of patients recruited per practice was 30, but there were some very low numbers of patients recruited from single partner and small practices. Small samples may have impacted on the variation in asthma severity and symptoms observed within a practice and therefore skewed the means of outcomes measured.

When it was observed that the number of patients recruited was well below target in some of the practices, I discussed the necessity of removing these from the analysis with the statistician. However, I wanted to retain the natural variation in practice size, so to compensate for these small numbers, prior to performing the analysis the outcome variables were weighted according to the number of patients recruited per practice. Overall the reduction in sample size to 1065 reduced the expected power of the study from 80% to 69%.

e) Analysis

Because of the *hierarchical* and *clustered* nature of the data in this study - patients within practices, registered with different GPs - the technique of Multi-Level Modelling (MLM) was considered. This is a method often used in social sciences where the existence of data *levels* or *units* may help explain social activity, as behaviour may be a result of the situation (data level or unit) rather than the individual (Goldstein, 1995). A commonly used example is where different teaching techniques have been used and children's performance examined. In a study originally conducted by Bennet (1976), the child was used as the unit of analysis and traditional multiple regression techniques were employed to compare traditional and modern teaching techniques. However, the importance of group effects was not taken into account and no consideration was made of grouping children into classes with varying teachers. Therefore, when the data were re-analysed using multilevel analysis, it showed that the teacher and clustering effect of children from the same class were the most important predictors of performance and not children's individual characteristics (Aitken et al, 1981).

Elaborate procedures have been developed to take hierarchical structures into account when carrying out statistical analysis of multilevel data and software is commercially available. However, MLM is a complex methodology and the computer software was not readily available at the stage the study was designed. Local experience of using MLM was also limited and there was insufficient time available to fully explore the use of this methodology. With improved local facilities and expertise, it is now intended to explore the use of advanced statistical techniques such as MLM for a paper to be submitted at a later date.

f) Outcomes

The difficulty examining the impact of interventions on asthma control due to a lack of universally accepted outcome measures is well-documented. Also, comparison across studies is often difficult as variations occur in the methods used to calculate apparently similar outcomes such as diurnal variation in peak expiratory flow (PEFDV).

Despite current national and international guidelines recommending the use of PEFDV to aid the diagnosis and monitoring of asthma, there are some well-recognised associated problems. Since the commencement of this study, it has been criticised due to its insensitivity at assessing the severity of exacerbations, because of the cumbersome calculations involved and the variation in the frequency and times that PEF readings can be taken (Bucknall, 1996; Reddel et al, 1999).

In this study, patients were requested to measure their PEF twice a day, in the morning and evening prior to medication, which is the recommendation in the BTS guidelines. However, studies have shown just taking two readings may grossly underestimate diurnal variability and by doing this, the severity of asthma in my sample may have been misrepresented (D'Alonzo et al, 1995; Gannon et al, 1998). However, I am reassured that this did not happen as the PEFDV values were correlated with the total SGRQ score (r = 0.261, p = <0.001) and with symptoms (r = 0.627, p = <0.001).

There is still a need for a sensitive marker of asthma control that is also practical for use in primary care. Quality of life measures are relatively quick and easy to administer, but most of them still have fairly cumbersome calculations for everyday use in primary care.

Prior to the 1990s, health-related quality of life was rarely included in the assessment of asthma due to the absence of suitable instruments to measure this aspect of health or well being (Juniper et al, 1993). Disease-specific questionnaires are still a fairly new concept in asthma and most questionnaires have been developed since 1990. At the time of selecting which quality of life measure to use, there were few researchers with practical experience to draw on.

The SGRQ was developed for patients with chronic airflow limitation, whether caused by chronic bronchitis, emphysema, COPD or asthma. A priority when considering which quality of life tool to use for this study was ease of administration and the SGRQ is particularly suited for a large community-based study. The second reason for its selection was that it provided the opportunity to validate its use in assessing quality of life in a large sample of patients with asthma.

With over 1000 patients to see, the SGRQ proved easy to administer and was ideal for this large study. In primary care, it has been shown to be a valid measure of quality of life in patients with asthma. However, occasionally patients needed clarification of how to respond to some of the questions, therefore reducing its suitability for postal surveys. I am confident that the outcomes I measured, produced a fairly accurate picture of the level of impairment experienced by those who participated in this study. That is, the majority had mild to moderate asthma, demonstrated by their fairly modest PEFDV, low symptom and SGRQ scores.

11.6 Implications for Clinical Practice

This study has demonstrated that the ratio of IHCS/β_2 can be used as a proxy measure to predict improved quality of life and this will be of particular interest to primary care organisations charged with achieving good clinical practice. Previous studies have only shown a relationship between prescribing and "process measures", such as hospital admissions (Griffiths et al, 1996). This is the first study to report a positive relationship between prescribing habits and patient outcomes.

Despite the practical difficulties encountered, this study remains the only one to evaluate BTS guideline adherence and outcomes in primary care. Whilst the results may not reflect what I anticipated, there is sufficient rigour in my method and analysis to challenge the widely held belief that the BTS guidelines have made a positive impact on patient's quality of life. Despite the involvement of GPs in their development, the 1990 BTS Guidelines for Asthma Management attracted some criticism about their relevance to primary care. GP involvement increased in the 1993 revision and so their appropriateness for primary care was increased. Subsequently, they have been widely adopted and there is a general belief that they are beneficial. The minimal impact of the BTS guidelines on patient outcomes demonstrated in this study will be disappointing for those who advocate their use.

In a recent review of the development of interventions for trials, we are reminded of the need to ensure that multifaceted interventions have a sound theoretical

approach. This is particularly pertinent in asthma. Perhaps the development of more effective interventions, including guidelines for the management of asthma in primary care, will arise from closer collaboration between professionals across a variety of disciplines. As well as GPs and nurses, future work should include social scientists and educationalists (Bradley et al, 1999).

Guidelines are one method of encouraging the delivery of evidence-based health care and there is support for the distillation of clinical evidence. In a survey of GPs perceptions regarding evidence-based health care, it was found most would like to base their clinical decisions on evidence believing that this would improve patient care (McColl et al, 1998). However, the very nature of primary care, with doctors and nurses being generic practitioners, makes it difficult for those who work in this field to synthesise and keep abreast of all the latest information. Indeed, 90% of British GPs believe that learning evidence-handling skills is not a priority; instead they prefer summaries of evidence produced by experts (McColl et al, 1998).

Guidelines can be a compendium of evidence-based summaries that have been distilled into recommendations for clinical practice. Unfortunately, it appears that in the process of distillation over-simplification and disregard for the complexities of patient care occur. In surveys of primary care physicians in the UK and USA, lack of compliance with national asthma guidelines was attributed to negative attitudes towards guidelines. Although the physicians agreed with the content of the guidelines, they felt there were problems applying recommendations in everyday practice. Many patients in primary care have multiple problems of which asthma is only a small part and with limited time to see patients, prioritisation occurs (Picken et al, 1998; Watkins et al, 1999).

One reason for the lack of impact of asthma guidelines on patient well-being may be the 'evidence' upon which the guidelines are grounded. Much of the existing 'evidence' is derived from subjective assessment of good practice or from secondary care. There is an urgent need for more studies to identify how best to improve patient outcomes and asthma control in primary care. Members of the primary health care team, using outcome measures that can be easily incorporated into routine consultations, should conduct this research in primary care.

The National Institute for Clinical Excellence (NICE) has been charged with providing NHS staff with clear and robust advice that will help them meet their own, and their patients', aspirations. The Institute's guidance will cover individual technologies as well as the management of a wide range of conditions, including asthma. NICE will also advise on appropriate methods of clinical audit and appraise existing guidelines according to the strength of evidence of their clinical effectiveness. It will be interesting to see how the new asthma guidelines differ from those produced by the BTS and also other international guidelines such as those produced by groups such as the Global Initiative for Asthma (Bousquet, 2000).

11.7 Future Research

The NHS recognised the need for more information about asthma management in general practice and in 1998 identified the following as priorities for further research and development:

- The evaluation of the impact of guidelines on managing asthma
- The impact of asthma nurses on primary health care teams
- Evaluation of the models of delivery of care for asthma management in different settings (DOH, 1998b)

In reviewing the literature, performing this study and visiting many practices in the South of England, I have become increasingly aware of the limitations of the BTS guidelines and the challenges of delivering high quality asthma care. Within the three areas highlighted above, my personal interests in further research are focused on the following questions (cont'd over-leaf):

a) What are the aspects of practice organisation that particularly enhance good asthma care and which aspects act as barriers?
b) What performance indicators are both pragmatic and meaningful in primary care?
c) Does a brief smoking cessation intervention for patients with asthma in primary care lead to improved outcomes?

d) Is a national programme for nurse prescribing in asthma required?
e) How can guideline adherence be best measured in primary care?
f) How can quality of life be easily measured in primary care?

a) Practice organisation

Since the commencement of this study, there have been further changes in the organisation of primary care that favour innovation. With the advent of Primary Care Trusts there has been a shift in the management and funding of primary care; the style is much more collaborative and there is the potential for resources to be targeted and for services to be tailored to local need.

Visiting the practices in the study, I became aware that there are many different management styles; some practices have a clear management structure, whilst others muddle through (Pringle et al, 1993). For patients with chronic diseases, there are probably more efficient ways for practices to manage and monitor patients. However, in times of rapid change, evaluation can easily be overlooked. Primary Care organisations need to be encouraged, supported and funded to critically examine changes in practice and service delivery.

It has been suggested that for changes in practice to be successful and for barriers to effective treatment to be overcome, clinicians need knowledge, skills, motivation, and the practical and organisational conditions for new behaviour to happen (Wensing et al, 1998). Results from this study reiterate the suggestion that good asthma management in general practice is complex and requires a 'total package' of care for patients with asthma that considers issues of accessibility and service delivery as well as good clinical practice (Tattersfield and Holmes, 1995; Eastwood and Sheldon, 1996). Further investigation of the potential barriers and appropriate management styles for effective asthma management is required so that expensive and ineffective interventions are not continued.

b) Performance indicators

It has been suggested Primary Care Trusts have to ensure that by 2002 they are delivering measurable improvements against all locally agreed targets. The contract for general practice introduced in 1990 demanded GPs look more critically at the services they provide by producing annual reports, conducting

medical audit and setting standards of care; and now another significant change is upon us - the introduction of clinical governance.

Members of the PHCT are responsible for providing high quality care and also for developing ways of monitoring and improving its quality. GPs have voiced concerns that the available measures of quality do not reflect what GPs believe they are really trying to do, and that extra time and resources are required to document the outcomes of their care (Roland, 1999).

Pragmatic indicators of good management are urgently required in primary care. These need to be a balance of indicators that reflect patient's perspectives and are also acceptable to professionals (Wensing et al, 1996). Qualitative interviews of adults with asthma in general practice showed that patients may not view asthma as central to their lives and that patients often have goals that conflict with those set by professionals (Steven et al, 1998).

Hospital admission rates have limited relevance for assessing performance in primary care as the proportion of patients admitted to hospital is very small (Griffiths et al, 1997a) and whilst data about prescribing habits are easily measured, the limitations associated with PACT data are well known. The development of valid performance measures to assess the quality of asthma management in primary care presents a formidable challenge. It is imperative that further development work is conducted in this area and that all members of the PHCT have an opportunity to play a role in deciding how quality is determined (Roland, 1999).

c) Smoking cessation for patients with asthma in primary care

Smoking is the single greatest cause of preventable illness and premature death in the UK. Smoking kills over 120,000 people in the UK a year - more than 13 people an hour. Morbidity due to smoking costs the NHS approximately £1.7 billion each year (DOH, 1998a). The government white paper details the cost of smoking and their strategy to tackle the problem. One element of this is to provide smoking cessation programmes for the adult population.

Also, there is considerable support for the use of antidepressants as an adjunct to smoking cessation programmes (Hughes et al, 2000). Two drugs in particular have been shown to enhance long-term quit rates, nortriptyline and bupropion.

Current evidence relates to these drugs being prescribed as an adjunct to a health education programme and such programmes are now being set up across the UK as part of the government anti-smoking strategy. Members of the PHCT are also encouraged to offer brief advice as this is recognised to improve smoking cessation rates above those achieved by trying to quit without support. However, the combination of antidepressants with brief GP intervention is untested but if successful would be of widespread value.

In collaboration with Dr. Michael Moore, a GP from Wiltshire and Dr. Susan Latter, a Reader from the School of Nursing, Southampton University the following research question has been developed: (over-leaf

"Does the addition of drug therapy (nortriptyline or bupropion) increase the short and long term smoking cessation rates with brief advice in primary care?"

We have applied for a small grant to set up and run focus groups with smokers to ensure that this would be a service valued by consumers. We are also hoping to collaborate with Professor Theresa Marteau, a health psychologist from the Medical Research Council, who is developing an intervention for smoking cessation in primary care.

d) Is a national programme for nurse prescribing in asthma required?

The recent Department of Health review sets out recommendations for the prescribing and administration of medicines (DOH, 1999). These recommendations propose desired frameworks for adequate legislation, training of health professionals and strategies to safeguard patient care.

One of the traditional roles of the nurse, to administer (or supply for self-administration) medicines prescribed by doctors, no longer fully reflects the needs of modern clinical practice. This is especially evident in areas of nurse specialism where the boundaries of practice have pushed towards proactive, autonomous delivery of expert care. In the management of patients with respiratory conditions, especially asthma, considerable effort has been expended

to train nurses in various ways from basic understanding of the disease area to diploma and degree level.

From discussions with nurses working in respiratory medicine both in primary and secondary care, it is clear that there is wide variation both in the responsibilities that nurses are given or take within their working practices and in their perceptions of the role of a specialist nurse. There is also wide variation in the training and qualifications of nurses who may be carrying out theoretically similar functions, including "prescribing" in their departments or practices (Pearce et al, 1997).

The recommendations in the United Kingdom Central Councils' 'Fitness for Practice' review of nurse training and education will give nurses the opportunity to operate at different levels (UKCC, 1999). Prescribing will be one of the aspects of higher-practice. The increase in nurse-led asthma clinics and specialised nursing positions has led to nurses independently managing patients with chronic respiratory diseases and a natural progression would be nurse prescribing.

Two types of nurse prescribing have been proposed – *independent* and *dependent* prescribing (DOH, 1999). Structured protocols will provide safeguards for the professional and the patient alike, but before these can be developed, some idea of the size of the problem is required.

In March 2000, I joined a group of respiratory nurses to consider at length the need for prescribing protocols for nurses working in asthma care, and to develop a study to provide the background information required to formulate such protocols. In collaboration, we are conducting a postal survey of 1200 nurses to highlight the many variations in practice and levels of responsibility in asthma management with respect to prescribing and the administration of medications. It is hoped that this work will provide a clear understanding of the current position so recommendations for best practice can be developed. These recommendations would cover training to agreed standards, working practices and evaluation of nurses in the area of asthma management who are undertaking the role of prescribing.

e) Measuring guideline adherence in primary care

Over the last few years, research evaluating the effectiveness of guideline implementation in primary care strategies has increased exponentially. Since the commencement of this study, according to the DOH National Research Register there have been approximately 30 studies set up or completed. This is more than double the number of studies (there were 14) evaluating the effectiveness of guideline implementation strategies on the register in 1996.

To develop a shared understanding of methodological problems, a workshop on guideline implementation research in primary care was held in London in 1999. This brought together many experts in the field of 'guidelines research' and the papers from each of the six sessions were published as a supplement in Family Practice in February 2000. These papers serve as a timely overview of the state of the art in guidelines research at that time. Littlejohns and Cluzeau formalised the process for checking the strength of evidence into a checklist to assess potential guidelines for widespread use (Littlejohns and Cluzeau, 2000). However, even if guidelines are well-designed, evidence-based, and implemented in a manner that has previously proven to be effective, they may still fail to change clinical practice. Practitioners' behaviour may not comply with recommended practice within clinical guidelines and the following explanations have been suggested:

- Despite the guideline and its implementation, practitioners may still lack knowledge of the evidence it was based upon.
- Practitioners know the evidence but may not believe it.
- They know of and believe the evidence, but may consider it is not relevant to their own practice (Littlejohns and Cluzeau, 2000).

To date, there has been minimal work evaluating the most appropriate variables to use when measuring guideline adherence. There is continuing debate surrounding the methodology, the choice of variables to be used, and whether each variable or guideline component should be formally assessed before its implementation (Morgan, 2000).

Different indicators of clinical management have been proposed, such as those listed below:

- Prescribing
- Referral rates
- Specific tests

These indicators only consider medical factors in the decision making process. Increasingly in primary care, a more patient-centred approach is encouraged and treatment decisions are made not only in relation to a patient's condition, but also taking into consideration their beliefs about their illness. Therefore, rigid adherence to a specific clinical guideline may not be congruent with more holistic approaches and this poses the patient-centred family practitioner with a dilemma.

Morgan states that patients' views and opinions may be of less significance when guidelines are concerned with a specific aspect of practice, such as referral for a specific test; but states they are particularly crucial if guidelines are concerned with changes in the management of common diseases and therefore in patterns of care (Morgan, 2000). In evaluating guideline adherence in chronic diseases such as asthma, it is therefore imperative to make some assessment of patient well-being.

f) Measurement of quality of life in asthma patients in primary care

Most of the quality of life measures (with the exception of The Airways Questionnaire) are prohibitively long for everyday use in primary care. A much simpler, pragmatic measure is required. The revised Jones' morbidity index is a tool that has good predictive validity and due to its simplicity (it asks just three questions) could easily be incorporated into every-day clinical practice (Jones et al, 1999).

Quality of life measures have not received large scale testing in primary care populations, and for all of the questionnaires in current use, no comparison with physiological measurements has been performed. Such a comparison would be useful and would confirm whether these questionnaires are appropriate for a

general practice population; this would also be an ideal opportunity to further validate the revised Jones' morbidity index.

In the study that forms the work for this thesis 500 of the 1065 patients who completed The St. George's Respiratory (SGRQ) also completed The Airways Questionnaire (AQ20). I will be performing a comparison of the (SGRQ) questionnaire and the Airways Questionnaire '20' (AQ20) in measuring quality of life for patients with asthma in primary care and I am liasing with Professor Paul Jones at St. George's Hospital regarding the analysis and interpretation of the data and publication of the results.

11.8 Summary

At the time of writing, the British government has committed itself to a programme of enhancing the quality of care given to NHS patients. Dissemination of guidelines based on relevant, cost effective clinical evidence is seen as the principal mechanism for setting quality standards in the NHS (Dowie et al, 2000). The National Institute for Clinical Excellence (NICE) is charged with the responsibility for taking this forward. It is envisaged that monitoring will take place shortly after the publication of each NICE guideline appraisal and then six months later to track progress on implementation. The Commission for Health Improvement will then incorporate successive NICE appraisals into its clinical governance monitoring. However, some practical problems are envisaged, as it will be difficult to assess the quality of practitioners' prescribing as no current information system can differentiate between the different illnesses for which a drug may be prescribed. Before guidelines are implemented, the obstacles to change need to be identified and Grol has produced a classification of change strategies, and proposes that for the successful dissemination and implementation of guidelines, several steps are needed, these are:

- Orientation (getting to know the guidelines and their content)
- Insight (becoming aware of ones' own gaps in performance)
- Acceptance (adopting a positive attitude towards guidelines)
- Change (actual implementation in practice), (Grol, 1992).

Barriers need to be overcome to progress along these steps. In the UK there are many examples of unacceptable inequalities and inefficiencies in health care. Health care managers need to find ways to ensure that professionals are able to provide patients with the highest possible, affordable standards of clinical care.

The development of clinical guidelines as a means of implementing evidence-based practice is currently a topical issue and there is an expectation that practitioners will modify national guidelines for local needs and adapt them to individual patients' requirements for treatment. This has created considerable debate in the medical press between the critics and advocates of evidence-based medicine surrounding the relative usefulness of clinical guidelines.

The introduction of clinical guidelines as a simple and cheap way of improving patient care is attractive. In primary care, where a generic knowledge of diseases and treatments is required, clinical guidelines are the most straightforward way to introduce evidence-based medicine. However, the findings from this study highlight the difficulties that exist in securing evidence to support the belief that guideline adherence translates into better patient outcomes.

Successfully incorporating new guidelines into routine clinical practice in all the sectors of the health service presents a significant challenge for managers and health care professionals, and suitable implementation and evaluation strategies are crucial to achieving this end. At the same time further investigation is required regarding the best way to deliver a 'total package' for patients with asthma in primary care and the changes in practice organisation that may be required. From now on, any modifications to the way asthma care is delivered in the community should only be put in place if there is robust, supporting evidence that they contribute to the aim of all clinicians - improved patient outcomes.

Appendices

Chart 1

Management of chronic asthma in adults

- Avoidance of provoking factors where possible
- Patient's involvement and education
- Selection of best inhaler device
- Treatment stepped up as necessary to achieve good control
- Treatment stepped down if control of asthma good

Note
Patients should start treatment at the step most appropriate to the initial severity. A rescue course of prednisolone may be needed at any time and at any step

Prescribe a peak flow meter and monitor response to treatment

Step 1:

Occasional use of relief bronchodilators

Inhaled short acting β agonists "as required" for symptom relief is acceptable. If they are needed more than once daily move to step 2.
Before altering a treatment step ensure that the patient is having the treatment and has a good inhaler technique. Address any fears.

Step 2:

Regular inhaled anti-inflammatory agents

Inhaled short acting β agonists as required
plus:
beclomethasone or budesonide 100-400 µg twice daily. Alternatively use cromoglycate or nedocromil sodium, but if control is not achieved start inhaled steroids.

Step 3:

High dose inhaled steroids

Inhaled short acting β agonists as required
plus:
beclomethasone or budesonide increased to 800-2000 µg daily via a large volume spacer.
Alternatives
In a few patients who experience problems with high dose inhaled steroids (see notes) inhaled long acting β agonists or sustained release theophylline may be added to step 2 medication. Cromoglycate or nedocromil may also be tried.

Step 4:

High dose inhaled steroids and regular bronchodilators

Inhaled short acting β agonists as required with inhaled beclomethasone or budesonide (800-2000 µg daily via a large volume spacer)
plus:
a sequential therapeutic trial of one or more of:
- inhaled long acting β agonists
- sustained release theophylline
- inhaled ipratropium or oxitropium
- long acting β agonist tablets
- high dose inhaled bronchodilators
- cromoglycate or nedocromil

Step 5:

Addition of regular steroid tablets

Inhaled short acting β agonists as required with inhaled beclomethasone or budesonide (800-2000 µg daily via a large volume spacer) and one or more of the long acting bronchodilators
plus:
regular prednisolone tablets in a single daily dose

Stepping down

Review treatment every three to six months. If control is achieved a stepwise reduction in treatment may be possible.
In patients whose treatment was recently started at step 4 or 5 or included steroid tablets for gaining control of asthma this reduction may take place after a short interval. In other patients with chronic asthma a three to six month period of stability should be shown before slow, stepwise reduction is undertaken (see notes).

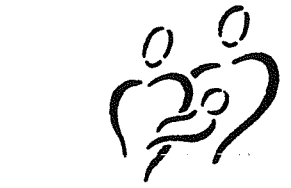
Outcome of steps 1-3: control of asthma

- Minimal (ideally no) chronic symptoms, including nocturnal symptoms
- Minimal (infrequent) exacerbations
- Minimal need for relieving bronchodilators
- No limitations on activities including exercise
- Circadian variation in peak expiratory flow (PEF) <20%
- PEF ≥80% of predicted or best
- Minimal (or no) adverse effects from medicine

Outcome of steps 4 and 5: best results possible

- Least possible symptoms
- Least possible need for relieving bronchodilators
- Least possible limitation of activity
- Least possible variation in PEF
- Best PEF
- Least adverse effects from medicine

Adapted from poster designed by Business Design Group



POOLE HOSPITAL
NHS TRUST

Our Ref: GPC/RCH/LREC/MAY95 Ext:

22 May 1995

Ms Martina Dorward
Postgraduate Student
University Medicine
D Level, Centre Block
Southampton General Hospital
Tremona Road
SOUTHAMPTON

Dear Ms Dorward

Community Asthma Study

The Local Research Ethics Committee met on 18 May 1995 to consider the above application.

I am pleased to inform you that the Committee have granted approval for your project to proceed.

Members present at the meeting were :-

Dr G P Clein	Dr M Lesna	Dr C Moran	Dr C Ellis
Dr S Kirkham	Mrs E Crockford	Dr C J H Williams	

Could you please forward the results of your trial to myself upon completion.

Yours sincerely,

R Hanson

MRS R C HANSON
SECRETARY
LOCAL RESEARCH ETHICS COMMITTEE

The North Hampshire Hospital

Basingstoke Ethics Committee of the North &
Mid Hampshire Health Commission

7 February 1996

Direct Dialling Line 01256 314901

Ms Martina Dorward RGN
University Medicine
D Level
Southampton General Hospital
Tremona Road
Southampton
Hants

Dear Ms Dorward

Protocol No 236A
Study to assess the uptake and impact of consensus guidelines for asthma management on disease control and quality of life.

The Ethics Committee reviewed your submission at its meeting on the 31st January. I am pleased to advise you that the Local Research Ethics Committee have now given their approval to the above study. Approval is subject to the Committee being advised of progress on the research after six months and a report on completion.

The Committee wish you well with this work.

Yours sincerely

J. Campbell

Rev Dr P Goold
Chairman
Basingstoke Ethics Committee

Code _____

The St. George's Hospital Respiratory Questionnaire

Introduction

This questionnaire is designed to help us learn much more about how your breathing troubles you and how it affects your life. We are using it to find out which aspects of your illness cause you most problem, rather than what the doctors and nurses think your problems are.

Please read the instructions for each question carefully and ask if you do not understand any thing. Do not spend too long deciding about your answers.

Name_____

Age_____ **Male** ☐ **Female** ☐ (please tick)

PART A

Questions about how much chest trouble you have had over the last year. Please tick one box for each question.

	most days a week	several days a week	a few days a a month	only with chest infections	not at all
1) Over the last year, I have coughed :	☐	☐	☐	☐	☐
2) Over the last year, I have brought up phlegm (sputum) :	☐	☐	☐	☐	☐
3) Over the last year, I have had shortness of breath :	☐	☐	☐	☐	☐
4) Over the last year, I have had attacks of wheezing :	☐	☐	☐	☐	☐

5) During the last year how many severe, or very unpleasant attacks of chest trouble have you had?

more than 3 attacks..... ☐
3 attacks..... ☐
2 attacks..... ☐
1 attack..... ☐

6) How long did the worst attack of chest trouble last?
(Go to **Question 7** if you had no severe attacks)

- a week or more..... ☐
- 3 or more days..... ☐
- 1 or 2 days..... ☐
- less than a day..... ☐

7) Over the last year, in an average week, how many good days (with little chest trouble) have you had?

- no good days ..... ☐
- 1 or 2 good days ..... ☐
- 3 or 4 good days ..... ☐
- nearly every day is good..... ☐
- every day is good..... ☐

8) If you have a wheeze, is it worse in the morning?

- no..... ☐
- yes..... ☐

PART B

SECTION 1

How would you describe your chest condition? (please tick one box)

- The most important problem I have..... ☐
- It causes me quite a lot of problems..... ☐
- It causes me a few problems..... ☐
- It causes no problem..... ☐

If you have ever had paid employment, please tick one box:

- My chest trouble made me stop work althogether..... ☐
- My chest trouble interferes with my work or made me change my work..... ☐
- My chest trouble does not affect my work..... ☐

SECTION 2

This is about what activities <u>usually make you feel breathless these days</u>. For each item, please tick in the box as it applies to you:

Sitting or lying still.....	☐ True	☐ False
Getting washed or dressed.....	☐ True	☐ False
Walking around the home.....	☐ True	☐ False
Walking outside on the level.....	☐ True	☐ False
Walking up a flight of stairs.....	☐ True	☐ False
Walking up hills.....	☐ True	☐ False
Playing sports or games.....	☐ True	☐ False

SECTION 3

This is about your cough and breathlessness <u>these days</u>. For each item, please tick the box that applies to you:

My cough hurts	☐ True	☐ False
My cough makes me tired	☐ True	☐ False
I am breathless when I talk	☐ True	☐ False
I am breathless when I bend over	☐ True	☐ False
My cough or breathing disturbs my sleep	☐ True	☐ False
I get exhausted easily	☐ True	☐ False

SECTION 4

This is about other effects that your chest trouble may have on you <u>these days</u>. For each item, please tick in the box that applies to you:

My cough or breathing is embarrassing in public	☐ True	☐ False
My chest trouble is a nuisance to my family, friends or neighbours	☐ True	☐ False
I get afraid or panic when I cannot get my breath	☐ True	☐ False
I feel that I am not in control of my chest problem	☐ True	☐ False
I do not expect my chest to get any better	☐ True	☐ False
I have become frail or an invalid because of my chest	☐ True	☐ False
Exercise is not safe for me	☐ True	☐ False
Everything seems too much of an effort	☐ True	☐ False

SECTION 5

This is about medication. If you are receiving no medication go straight to SECTION 6. To complete this section please tick the box that applies to you:

My medication does not help me very much	☐ True	☐ False
I get embarrassed using my medication in public	☐ True	☐ False
I have unpleasant side effects from my medication	☐ True	☐ False
My medication interferes with my life a lot	☐ True	☐ False

SECTION 6

These are questions about how your activities might be affected by your breathing. For each question, please tick true if <u>one or more</u> parts of the question applies to you <u>because of your breathing</u>. Otherwise tick <u>false</u>.

I take a long time to get washed or dressed	☐ True	☐ False
I cannot take a bath or shower, or I take a long time	☐ True	☐ False
I walk slower than other people, or I stop for rests	☐ True	☐ False
Jobs such as housework take a long time, or I have to stop for rests	☐ True	☐ False
If I walk up one flight of stairs, I have to go slowly or stop	☐ True	☐ False
If I hurry or walk fast, I have to stop or slow down	☐ True	☐ False
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, do light gardening such as weeding, dance, play bowls or play golf	☐ True	☐ False
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim	☐ True	☐ False
My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports	☐ True	☐ False

SECTION 7

This is to find out how your chest trouble usually affects your daily life. Please tick the box that applies to you: (Only tick true if you cannot do something because of your breathing).

I cannot play sports or games.....	☐ True	☐ False
I cannot go out for entertainment or recreation.....	☐ True	☐ False
I cannot go out of the house to do the shopping.....	☐ True	☐ False
I cannnot do housework.....	☐ True	☐ False
I cannot move far from my bed or chair.....	☐ True	☐ False

This is a list of other activities that your chest trouble may prevent you doing. (You do not have to tick these, they are just to remind you the ways in which your breathlessness may affect you) :

- **Going for walks or walking the dog**
- **Doing things at home or in the garden**
- **Sexual intercourse**
- **Going to church, or places of entertainment**
- **Going out in bad weather or into smoky rooms**
- **Visiting family or friends or playing with children**

Please write in any other important activities that your chest trouble may stop you doing:

_____

_____

_____

_____

Now, tick the box (one only) which you think best describes how your chest affects you:

It does not stop me doing anything I would like to do.....	☐
It stops me doing one or two things I would like to do.....	☐
It stops me doing most of the things I would like to do.....	☐
It stops me doing everything I would like to do.....	☐

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Asthma Management in Practice (AMP) Questionnaire

This questionnaire is designed to gather data about asthma management in the community and to look for any relationship between certain characteristics in practices and patients disease control - measured with diary cards of peak expiratory flow readings and symptom scores, plus quality of life, measured by the St. George's' Respiratory Questionnaire.

The AMP questionnaire is comprised of four sections.

SECTION ONE

This will be administered by the investigator and will provide information about the size of the practice and other 'general' details. The information for this section will be sought from the Practice Manager (and possibly a Practice Nurse). Some details may also be sought from the FHSA if not readily available at the practice. This section also asks for general information about aspects of the organisation of the practice, that may impact on the care of patients with asthma.

SECTION TWO

This section will also be administered by the investigator and will gather information about how patients with asthma are managed at the practice. It also establishes the practices' facilities to perform this service. This information will probably be gleaned from a Practice Nurse or GP.

SECTION THREE

This section will be completed by each partner and will collect more specific information about the clinical management of patients with asthma, with 'vignettes' that have been devised using the framework of the British Thoracic Society guidelines (1993 and 1997).

SECTION FOUR

This section will be completed by the investigator mostly in the form of semi-structured FIELD NOTES. Most of the information for this section will be gathered from personal observation.

"AMP" QUESTIONNAIRE

practice code_____(1-2)

SECTION ONE (To be completed by Investigator/Practice Manager)

				office use
1. Total list size			_____	3-8
2. Age profile of patients	(as a percentage of total list)	0-17	_____	9-11
		18-45	_____	12-14
		46-65	_____	15-17
		66 and over	_____	18-20
3. Number of partners (WTE)?			_____	20-22
			Yes ☐ No ☐	
4.a) Is the practice in receipt of deprivation payment?			☐ ☐	23
b) If the answer to above was yes, is this payment		low	☐ ☐	24
		medium	☐ ☐	25
		high	☐ ☐	26
5. What was your average DNA rate for over the last 12 months?			_____%	27-28
6. Number of practice nurses (WTE)?			_____	29
7. Is the practice fund holding? (Add dates)			Yes ☐ No ☐	30
	_____	Total	☐ ☐	31
	_____	Standard	☐ ☐	32
	_____	Community	☐ ☐	33
8.a) Is it a training practice? (GP registrars)			☐ ☐	34
b) Is it a teaching practice? (medical students)			☐ ☐	35
9. How is out of hours care provided?		Own On Call	☐ ☐	36
		Deputising Service	☐ ☐	37
		Co-operative	☐ ☐	38
		Consortium	☐ ☐	39
		Other?	☐ ☐	40

(If "other" please specify)_____

_____

10.a) Is the practice computerised? Yes ☐ No ☐ office use 41

b) Which functions?

	Yes	No	office use
Prescriptions	☐	☐	42
Appointments	☐	☐	43
Patient Records?	☐	☐	44

c) Which system?

(please specify)_____

_____

d) Any problems with system re: asthma?_____

_____

_____

11. a) Does the practice have an asthma register? Yes ☐ No ☐ 45

b) How many patients are on this register? _____

(As a percentage/proportion of total list size) _____% 46-47

12. Is there an asthma clinic? Yes ☐ No ☐ 48

	Yes	No	office use
Set Aside Time	☐	☐	49
Ad Hoc	☐	☐	50

(comments)_____

_____

13. What aspects of asthma management have you audited in the past year?

SECTION TWO
(To be completed by the Investigator/Practice Nurse or GP)

			office use
1.a) Do any practice nurses take a special interest in asthma?	Yes ☐	No ☐	51
b) How many?	_____		52
c) Have any of the nurses completed asthma training?	Yes ☐	No ☐	53
d) How many?	_____		54
e) Dates (Expressed in years since training)	_____		55
	_____		56
	_____		57

(comments, which courses, professional membership etc.)

_____

_____

_____

2.a) Does the practice have an asthma protocol?	Yes ☐	No ☐	58
b) Is the protocol based on any asthma guidelines?	Yes ☐	No ☐	59

(please specify)_____

_____

3.a) Are self management plans used?	Yes ☐	No ☐	60

b) Which ones?

(please specify)_____

_____

c) What percentage of patients are given them? (estimate) _____% 61

4. a) Are patients routinely called for their asthma to be reviewed?	Yes ☐	No ☐	62
b) How often is the minimum frequency? **i) 6 monthly**	☐	☐	63
ii) 12 monthly	☐	☐	64
iii) other?	☐	☐	65

(If "other" please specify)_____

c) What is your average DNA rate for these appointments? _____% 66-67

d) Is a checklist/template used for follow up appointments?	Yes ☐	No ☐	68

Please specify)_____

	Yes	No	office use
5.a) Is inhaler technique assessed for patients with asthma?	☐	☐	69
b) Who usually assesses inhaler technique? GP	☐	☐	70
Practice Nurse	☐	☐	71
..... .Both	☐	☐	72
c) How is inhaler technique checked?			
i)Using a written checklist	☐	☐	73
(Please specify)_____			
ii) Using a "mental " checklist	☐	☐	74
iii) Other, e.g. Ames	☐	☐	75
(Please specify)_____			
6. How often is inhaler technique assessed? a) monthly	☐	☐	76
b) six monthly	☐	☐	77
c) annually	☐	☐	78
d) p.r.n. re: patient	☐	☐	79
e) other	☐	☐	80
(If "other" please specify)_____			
7. Does the practice :	Yes	No	
a) monitor patients asthma prescriptions	☐	☐	81
b) stop patients asthma prescriptions until reviewed by GP/PN?	☐	☐	82
c) prescribe generically?	☐	☐	83
(comments)_____			
_____			
_____			
8.a) Is treatment compliance monitored?	Yes	No	
	☐	☐	84
b) If yes, how?			
i) ask patients about their use of medication	☐	☐	85
ii) check peak flow diaries	☐	☐	86
iii) check symptom diaries	☐	☐	87
iv) monitor individual prescriptions	☐	☐	88
v) other ?	☐	☐	89
If "other" please specify)_____			
_____			
_____			
_____			

9. Which of these facilities does your surgery have for the care of patients with asthma?

	Yes	No	office use
a) nebuliser	☐	☐	90
(please specify availability of nebuliser)			
i) treatment room	☐	☐	91
ii) for loan by patients	☐	☐	92
iii) for home visits	☐	☐	93
(comments)_____			
b)spirometer	☐	☐	94
(comments)_____			
_____			

	Yes	No	
c) peak flow meters (number_____)	☐	☐	95
d) peak flow meter, for low readings (_____)	☐	☐	96
e) selection of inhaler devices for teaching	☐	☐	97
f) spacer devices for teaching	☐	☐	98
g) height measure	☐	☐	99
h) means of estimating patients predicted values	☐	☐	100
(comments)_____			
_____			

	Yes	No	
i) diary cards	☐	☐	101
Symptoms	☐	☐	102
PEF	☐	☐	103
j) skin testing kit	☐	☐	104

10. Are there any limitations to service provision for asthma patients at your practice?

Yes	No	
☐	☐	105

practice code_____(1-4)

Asthma Management in Practice (AMP) Questionnaire

SECTION THREE

As you will be aware your practice is taking part in the Community Asthma Study. To give an accurate picture of asthma management at your practice **each partner** is being asked to fill out this questionnaire. It should only take about 10 minutes to complete and no individual GPs or practices will be identified in the final analysis of the results. **For each question you may tick more than one box if appropriate.**

office use

1. Are you

male ☐ 5
female ☐ 6

2. How old are you? _____**years** 7-8

3. How many years since you finished your basic medical training? _____**years** 9-10

4. Do you take a special interest in asthma? Yes ☐ No ☐ 11

5. Are you a member of any professional bodies or local groups relevant to asthma management? Yes ☐ No ☐ 12

(If "yes" please specify)_____

_____

6. Do you use any of the following when deciding the management of asthmatic patients ?

	Yes	No	
a) British Thoracic Society Guidelines	☐	☐	13
b) Local Guidelines	☐	☐	14
c) Practice protocol	☐	☐	15
d) other?	☐	☐	16

(If "other" please specify)_____

_____

7. How familiar are you with the British Thoracic Society Guidelines for asthma management?

a) Not at all, you have not heard of them ☐ 17
b) You have heard of them but are unsure of their content ☐
c) You know what the guidelines recommend for **most** aspects of asthma management ☐
d) You know what the guidelines recommend for **all** aspects of asthma management ☐

office use

8. Which of the following do you have <u>in your room</u> for the assessment of patients with asthma?

a) peak flow meter	☐	18
b) peak flow meter for low readings	☐	19
c) predicted values (for PEF)	☐	20
d) height measure	☐	21
e) other?	☐	22

(If "other" please specify)_____

_____

9. Which of the following items of equipment do you <u>routinely</u> take with you on home visits ?

a) peak flow meter	☐	23
b) peak flow meter for low readings	☐	24
c) predicted values (for PEF)	☐	25
d) spacer device	☐	26
e) portable oxygen	☐	27
f) nebuliser (inc. mask and tubing)	☐	28
g) other	☐	29

(If "other" please specify)_____

_____

10. Which of the following drugs do you <u>routinely</u> take with you on home visits?

a) beta agonist metered dose inhaler	☐	30
b) oral steroids	☐	31
c) steroids for injection	☐	32
d) adrenaline for injection	☐	33
e) ventolin for nebulisation	☐	34
f) other?	☐	35

(If "other" please specify)_____

_____

office use

11. If you were asked to visit a patient at home with uncontrolled, or acute severe asthma, would you take any equipment or drugs with you in addition to those listed in questions 9 and 10?

Yes ☐ No ☐ 36

(If "yes", please list additional equipment/drugs)_____

_____

_____

12. What would be your preferred management for a 36 year old male patient recently diagnosed with asthma, taking 200mcg beclomethasone twice daily who is getting nocturnal symptoms?

a)prescribe oral theophylline ☐ 37
b)prescribe inhaled long-acting beta- agonists ☐ 38
c)increase his dose of beclomethasone ☐ 39
d)prescribe ipratropium bromide ☐ 40
e)none of the above ☐ 41
f)other? ☐ 42

(If "other" please specify)_____

_____

_____

13. Do you enquire about nocturnal symptoms due to asthma?

a) always ☐ 43
b) sometimes ☐ 44
c) never ☐ 45

14. A 27 year old female patient whose usual treatment is high dose inhaled steroids, via a large volume spacer has developed a cold and over the last two days has required short acting beta-agonists several times a day. Her inhaler technique is satisfactory but her peak flow readings are below 50% of her best.
What would be your preferred management for this patient?

a)prescribe oral theophylline ☐ 46
b)prescribe inhaled long-acting beta-agonists ☐ 47
c)prescribe a rescue course of oral steroids ☐ 48
d)prescribe a broad spectrum antibiotic ☐ 49
e)other ☐ 50

If "other" please specify)_____

_____

_____

15. You have made arrangements for an asthmatic adult to be taken to hospital. The patient is cyanosed and has a respiratory rate of 30 per minute; What management would you consider for this patient who is particularly distressed, whilst waiting for the ambulance to arrive?

office use

a) intravenous sedation	☐	51
b) intravenous aminophylline	☐	52
c) intravenous steroids	☐	53
d) nebulised beta agonist	☐	54
e) nebulised ipratropium bromide	☐	55
f) nebulised steroids	☐	56
g) 40 puffs of a beta agonist via a large volume spacer	☐	57
h) peak flow measurements	☐	58
i) other?	☐	59

(If "other" please specify)_____

_____

_____

16. Do you think there are any limitations to the service your practice provides for patients with asthma at your practice? Yes ☐ No ☐ 60

If you have answered "yes", to 16 please could you provide more information in the space below.

Thank you for completing this questionnaire

Please return it in the envelope provided

Focus Groups

Preamble and Question Route

Good evening everyone and thank-you for coming tonight. My name is Martina Dorward, I am conducting some research into the treatment and management of patients with asthma. My research project is sponsored by a grant from the Regional Health Authority to look at the services provided to patients with asthma in general practice. I decided the best way to find out more about this was to talk to people who use this facility (patients) and the primary service providers (GPs and Practice Nurses).

Over the next few weeks I will be talking to groups, including patients,GPs and Practice Nurses, to find out more about the services that are provided in general practice for patients with asthma. I am particularly interested in your experiences and what you think could be described as an optimum service. I am also interested in your experiences of managing other chronic diseases, such as diabetes, as some aspects of the care of these patients may be relevant to asthma management.

From your ideas it is hoped to devise a scale of standards. These may then be used in general practice as assessment criteria to measure the performance of primary health care teams in managing patients with asthma.

The discussion will be taped so that I do not miss anything that is said; However, I would like to assure you that everything you say is confidential and your name will not be linked to anything when the final report is published.

"Rules of the Discussion"

-To protect individuals' identity where-ever possible do not refer to people by name, use "my GP", "one of my patients", "the nurse at my practice", etc.

-I will try to ensure every body has a fair chance to share their experiences and opinions. So that the person transcribing the tape can understand what is being said, if everybody is talking at once I will raise my hand to indicate this and then hopefully we will remember to take turns to speak.

Question prompts

PART ONE (general structure)

1.Tell me about the organisation at your practice;

For example is there set aside asthma clinic/ad-hoc; Which is best?
(EXPLORE ease of appointments speaking to GP?PN over the phone.)
Tell me more about the clinic/appointments.
(EXPLORE system for GP or PN seeing patients, holidays, self referral etc.)
What system do you think is the most helpful?
(EXPLORE PN involvement, patient choice/protocol?)

2.Are patients given long term appointments or is there a system of re-call? How are patients records organised; Are they computerised? (EXPLORE hospital referrals.)

3.How are prescriptions for patients with asthma filled?
(EXPLORE repeat prescriptions, especially B2s.)

4.Is there a register for patients with asthma?
(EXPLORE how this is updated, used etc.)

5.Does the practice have a protocol for the management of patients with asthma? Does your practice have a copy of the BTS or local guidelines? How do you encourage the use of these guidelines?
(EXPLORE how they are used.)

PART TWO (information/communication/education)

1.Tell me about the process of diagnosing asthma. What would make this process easier? (EXPLORE definitive diagnosis)
What can you remember about how you were told you had asthma? Could that have been improved?

2.Are any leaflets, books or videos used for patient education? How is their use encouraged? (EXPLORE asthma helplines, local groups etc.)

3. What do you think is important information to gather at appointments? (EXPLORE history, baseline obs., symptoms, trigger factors.)

4.Are patients introduced to others with asthma? Is there an asthma club? All education 1:1 or groups? Do you think these are a good idea?

PART THREE (Resources)

1.Which personnel are involved in care of patients with asthma at your practice, what about shared care? Which personnel do you think make a significant contribution to the care of patients with asthma? (EXPLORE Physio, HV, dietician, school nurse.)

2.How long do you think appointments should be for patients with asthma?
(EXPLORE initial appointments and follow-up.)

3.What equipment does your practice have? Which do you think are particularly important for good standards of asthma care? (EXPLORE basic requirements, ask re: emergency nebuliser/oxygen, loan service, vitalograph, skin testing, PEF meter, predicted values table/wheel, self management diaries, supply of variety of inhaler devices and spacers.)

4.How well do you think the personnel are trained to look after patients with asthma?
(EXPLORE level of training, qualifications, GP trainer, PN teaching qualifications. etc.)

5.How is knowledge/skills updated?
(EXPLORE attendance on update days, relationship with drug companies, attendance of study days, conferences, use of journals, membership of asthma interest groups, GPIAG, local forums, ask re: news letters)

PART FOUR (treatment/compliance)

1.Now I would like to spend a little time talking about **compliance**:. Patients often do not take their medications as prescribed, what do you do at your practice to improve compliance? What else do you think would help?
(EXPLORE methods used, give examples:- video, scoring system, Ames machine)

2.What indicators can be used to ensure a patient is ready to self manage?
(EXPLORE *clinical*, such as minimal diurnal variation, *psychological* "I know when to increase medication/seek medical assistance", *social* "I can carry on with my life as normal".)

3.Some Doctors/Nurses think patients should have their lung function checked/inhaler technique/self-management plans checked at each visit to the practice; do you think this is reasonable? What do patients expect?

PART FIVE (monitoring effectiveness/audit)

1.GPs/PNs Does your practice have a protocol for asthma management? To assess the effectiveness of your asthma care what information do you think it is useful to collect?
(EXPLORE audit process).

2.How useful is the data from practice audit collected for the FHSA?
(EXPLORE asthma specific patient satisfaction/expectation surveys GPs/PNs system of review of asthma services, team meetings etc.)

3.Some Doctors prescribe generic medications(EXPLAIN). What do you think about this?

4.The ratio of inhaled steroids vs B2 agonists is used by some purchasers as an indicator of good asthma management, tell me what you think.

5.Hospital referrals/admissions. How is this decided, is there a system in place for sending copies of peak flow diaries etc, who makes the decisions?
(EXPLORE patients attending A&E for asthma, hospital clinic; inappropriate referrals, possibly avoidable deaths.)

6.Use of new drugs/devices. How is it decided/monitored?

7.Discuss level of out of hours/emergency visits for patients with exacerbation of asthma.

8.Discuss what methods would improve asthma care;
(EXPLORE relationship with Physicians, Pharmacists, FHSA, fundholding, management systems, TEAMWORK).

Quality of Asthma Management (AMP) Questionnaire
Pilot Study Evaluation Form

Please complete this short evaluation form so the questionnaire can be modified before the final draft. You may prefer to add comments in the "office use" column that apply to specific questions.

1.How long did it take you to complete the AMP questionnaire?

2.What did you think about the length of the questionnaire?

3.Was the introduction adequate?

4.Were the instructions for the questions clear?

5.What did you think about the questions? Were any questions ambiguous or difficult to answer?

6.Please add any other comments you feel would be useful.

Thank you

Please return this form and the questionnaire in the envelope provided.

University of Southampton

University Medicine
Level D, Centre Block
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

(01703) 777222 ext. 3904

(01703) 794834 (answer phone)

S T Holgate MD DSc FRCP
MRC Clinical Professor of Immunopharmacology

M A Dorward RGN DPSN BNSc
Postgraduate student

Fax (01703) 701771

Re:Community Asthma Study

Dear Dr.

The Asthma Research Department at Southampton have secured a grant from the Regional Health Authority to undertake a project looking at asthma management in primary care. The aim of the project is to determine whether the uptake of the British Thoracic Society guidelines for the treatment of asthma impacts on disease outcome, patients' symptom control and quality of life.

The study will examine two variables, namely prescribing habits and the methods used to manage asthma in primary care. Prescribing habits (if you give us permission) will be examined using PACT data. We will examine the nature of your practice set up and service provision by a questionnaire, completed by the senior partner (or another doctor if appropriate). It is hoped this questionnaire will be completed during a semi-structured interview that should only take about thirty minutes to complete.

This study will not interfere with the daily activities of your practice; we will need access to patient records and repeat prescription lists to "flag up" potential recruits. We will then randomly select sixty subjects who have been prescribed some sort of asthma medication in the last twelve months and invite them to take part in the study. They will be asked to complete a diary card of symptoms and peak flow measurements for a period of two weeks and complete a questionnaire about how their asthma affects their quality of life.

All the data will be collected by staff from this department and although we will do all the work for the study ourselves, we are able to make a contribution of up to £100 towards your practice funds. All data received from you and your patients will be handled in the strictest of confidence and only accessed by the members of this department. No individual practices will be named and no information about specific practices will be divulged to the Regional Health Authority

I have enclosed a response card for your convenience (Freepost) and look forward to meeting with you to discuss the study further.

Yours sincerely

Prof Stephen Holgate
MRC Professor Immunopharmacology

Martina Dorward
PhD student

Dr. Jonathan Corne
MRC Training Fellow

Dear

In conjunction with the research team at Southampton University we are conducting a project about the treatment of patients with asthma in the community. This is an important study that has received funding from the Regional Health Authority to find out more about the provision of health services in the community.

According to your records you may have been prescribed medication at some time for asthma symptoms, so we are writing to ask whether you would be interested in helping us with our research. The investigators would like to meet you at the surgery for about an hour and will ask you to measure your lung function for two weeks and answer some questions about your asthma. You will **not** be asked to take any new medications or have any extra investigations such as blood tests.

If you do feel you can help, could you please complete the enclosed questionnaire and return it to the investigators in the pre-paid envelope. They will then contact you by telephone (or letter) with more details of the study and only then would you need to decide whether you wish to take part. Any information you give will be treated in the strictest confidence and your medical care will not be adversely affected regardless of what you decide.

Yours sincerely,

NB If you have any questions about the study please contact members of the research team at Southampton, as listed below, not your GP.

Martina Dorward and Jonathan Corne
University Medicine, D Level, Centre Block,
Southampton General Hospital,Tremona Road,
SO16 6YD **Telephone 01703-794834**

Information Sheet

Thank you for your interest so far. The purpose of this information sheet is to explain the study in more detail. If you have any questions please do not hesitate to ask.

The majority of patients with asthma are cared for by their General Practitioner (GP). A variety of drugs are used to treat asthma and some GPs have established asthma clinics, with specially trained Practice Nurses to help look after asthmatic patients. National and international guidelines have been developed to help practitioners decide patients' treatment. This study aims to look at the value of these guidelines and see how they affect patients with asthma.

According to your records you may have been prescribed medication at some time that is used to treat asthma. Today you will be asked to perform a simple breathing test in order to establish the severity of your asthma and then you will be asked to fill out a questionnaire that should only take about ten minutes to complete. You will be shown how to measure your peak flow and complete a diary card for two weeks and you will be given a prepaid envelope to return this.

Although your GP has given permission for us to contact some of his/her patients, any information you give me will remain confidential and your treatment will not be affected in any way. You are free to withdraw from the study at any time and will be reimbursed for any travel expenses you incur.

This is a large study involving forty GP practitioners and over two thousand patients, therefore the study will take a long time to complete; However, the results will be made available on completion if you wish.

You are welcome to ask anything at any time about the study and there is a contact telephone number below to contact members of the research team; However, you should contact your GP if you are concerned at any time about your asthma and/or its treatment.

Any questions about the study at any time please telephone :- **01703-794834**

From_____

_____

_____

Community Asthma Study *(Please circle your response)*

I am undecided about my practice being included in your study and would like to meet you to discuss the study further **YES/NO**

I would like my practice to be included in your study and for you to make an appointment to discuss a starting date **YES/NO**

I am willing for you to contact my practice manager to discuss the study further **YES/NO**

Thank you

GP response card

This was printed with the departments' Freepost address on the reverse

IDNO:

QUESTIONNAIRE FOR THE COMMUNITY ASTHMA STUDY

NAME_____

ADDRESS_____

_____

POSTCODE _____

TELEPHONE NUMBER _____EVENING_____

QUESTIONS (please circle your response)

1. Have you been diagnosed as athmatic? **YES/NO**

2. If the answer to number 1. was YES, how long have you had asthma _____

3. Do you take medication for asthma? **YES/NO**

4. If the answer to number 3. was YES, please list the asthma medications you take:

_____

5. Do you suffer with any allergies, e.g. hay fever or eczema? **YES/NO**

6. Are you currently a smoker? **YES/NO**

7. If the answer to number 6. was YES, how many cigarettes/cigars do you smoke per week ? _____ cigarettes per week
   _____ cigars per week

8. Would you like to help us with our research project? **YES/NO**

If you feel unable to help us with our research, would you please tick the box ☐ and return the questionnaire, so that we can take you name off our records. You will not be contacted again.

PLEASE USE THE PREPAID ENVELOPE PROVIDED TO RETURN THE QUESTIONNAIRE.

Not all patients will be required to help further. If you do not hear from us again may we take this opportunity to thank you for your kind assistance.

DIARY CARD

Name _____ Telephone _____

Address _____ D.O.B. _____

_____ Age _____ Height _____

Spirometry FEV_1 Predicted _____

FEV_1 Achieved _____ % of predicted _____

FVC _____ Ratio(FEV_1 / FVC) _____

Personal Details

(Please circle the correct response or put a cross in the appropriate box)

1.Are you in paid employment? a)**YES/NO**

b)If **YES**, what is your job title? _____ or circle **N/A**

c)Are you employed full time? **YES/NO** or circle **N/A**

d)What is your partners occupation? _____

e)If your answer to a) was **NO**, are you...

i)unemployed? ☐ ii)looking after dependants? ☐

iii)a student? ☐ iv)not working because of illness? ☐

v)if not working because of illness, is this due to asthma? ☐

vi)none of the above?**(please specify)** _____

2.If you are **not** a student, what age were you when you left full time education? _____

3.Do you smoke? **YES/NO**

4.If **NO**, does anybody else in your household smoke? **YES/NO**

5.Please tick which of the following applies to your housing;

a)Owner occupier ☐ b) Living in privately rented accommodation ☐

c)Living in property rented from a local authority or a housing assoc. ☐

d)Living with parents ☐

e)Other (please specify) _____

❖ ❖ ❖

IF YOU HAVE ANY PROBLEMS COMPLETING THIS DIARY CARD TELEPHONE

01703-794834

Date card started | | Code | |

KEY

0 = NONE **1 = MILD**
2 = MODERATE **3 = SEVERE**

Please score **SYMPTOMS** below

DAY														
Symptoms on waking ie.cough, wheeze, shortness of breath or chest tightness														
Daytime symptoms ie.cough, wheeze, shortness of breath or chest tightness														
Problems with daily activities														
Nightime symptoms Cough, wheeze, shortness of breath, or chest tightness														
Nightime wakening														
Extra visits/phone calls to GP/PN/Hospital because of asthma (please tick)														

Peak Flow am														
pm														

Please list any **ASTHMA MEDICATIONS** in the numbered boxes below.

Record the **TOTAL** number of puffs /tablets used each day.

[1]														
[2]														
[3]														
[4]														
[5]														

Consent Form for the Community Asthma Study

You should have been given enough time to read the information sheet explaining what this study involves.

(Please circle the appropriate response)

Have you read and understood the Information sheet? **YES/NO**

Have you received satisfactory answers to all your questions? **YES/NO**

Have you received enough information about the study? **YES/NO**

Have you had the opportunity to ask questions? **YES/NO**

Do you agree to your GP being contacted? **YES/NO**

Who has discussed the study with you?_____

Please note:-

- **You are free to withdraw from the study at any time**
- **You do not have to give a reason if you wish to withdraw.**
- **Your medical care will not be affected if you withdraw.**

Do you agree to take part in this study?

YES/NO

If so, please sign after reading this final statement

I _____

(please print your name)

fully and freely consent to participate in the

"Community Asthma Study".

I understand that I may withdraw at any stage.

Signed_____ **Date**_____

Witnessed by_____(name)

Signature of Witness_____

Table 15 (Cont.) Subject Response Rate and Eligibility

	Practice Code	Total Approached	Declined	Non Responders	Response Rate (%)	Not Eligible (Smoker)	Not Eligible (Inactive Asthma)	Withdrawn	Total Seen
21	U	69	9	29	58.0	2	1	0	19
22	V	159	20	85	46.5	8	2	0	27
23	W	195	21	129	33.8	14	0	0	18
24	X	287	37	143	50.2	25	4	0	60
25	Y	324	58	189	41.7	16	2	0	40
26	Z	98	12	61	37.8	2	2	0	17
27	AA	72	10	35	51.4	6	0	0	18
28	BB	74	9	37	50.0	8	0	0	10
29	CC	353	50	205	41.9	27	1	2	43
30	DD	34	5	17	50.0	3	0	1	4
31	EE	99	17	54	45.5	7	0	0	17
32	FF	323	31	228	29.4	16	0	0	36
33	GG	317	44	181	42.9	8	3	0	45
34	II	128	22	60	53.1	7	1	0	27
35	JJ	179	24	80	55.3	12	2	0	48
36	KK	22	0	15	31.8	2	0	0	2
37	LL	63	8	24	61.9	6	1	0	16

Table 15 Subject Response Rate and Eligibility

	Practice Code	Total Approached	Declined	Non Responders	Response Rate (%)	Not Eligible (Smoker)	Not Eligible (Inactive Asthma)	Withdrawn	Total Seen
1	A	307	44	152	50.5	9	3	0	69
2	B	197	24	124	37.1	17	4	0	24
3	C	79	9	43	45.6	6	1	0	16
4	D	42	6	17	59.5	2	0	0	11
5	E	141	17	79	44.0	12	0	0	19
6	F	84	12	32	61.9	10	0	0	25
7	G	139	21	63	54.7	18	0	0	30
8	H	57	12	23	59.6	2	0	0	17
9	I	135	38	36	73.3	14	1	0	39
10	J	93	13	54	41.9	5	0	0	18
11	K	288	38	139	51.7	21	8	0	66
12	L	451	37	316	29.9	19	5	0	56
13	M	288	47	156	45.8	19	5	1	40
14	N	325	68	156	52.0	19	6	2	40
15	O	294	30	152	48.3	22	1	0	52
16	P	187	25	96	48.7	13	2	0	38
17	Q	83	7	55	33.7	3	0	0	11
18	R	250	19	158	36.8	20	3	0	34
19	S	21	4	12	42.9	1	0	0	3
20	T	29	4	19	34.5	2	0	0	3

SYNTAX of Analysis for Thesis

*First look at scatterplots of totadj vs independents, looking for evidence of linear relationships and strong non linear between variables .

```
* Graph of QOL vs clinicians BTS adherence.
GRAPH
  /SCATTERPLOT(MATRIX)=totadj  btsq8_1 btsq9_1 btsq10_1 btsq12_1
  btsq14_1 btsq15_1   /MISSING=LISTWISE .

* Graph of QOL vs practice BTS adherence/ characteristics.
GRAPH
  /SCATTERPLOT(MATRIX)=totadj list_sz pracprot pracequi persman
  /MISSING=LISTWISE .

* Graph of QOL vs PACT.
GRAPH
  /SCATTERPLOT(MATRIX)=totadj iplist iddplist ratiodd patppart
  /MISSING=LISTWISE .
```

*Graph of QOL vs practice organisation.

```
GRAPH
  /SCATTERPLOT(MATRIX)=totadj audit ituse complian reg_per
clinnat spirom skintest nurse  /MISSING=LISTWISE .
```

*Look at the correlations between the outcome variable totadj and the various predictors (BTS adherence and Practice organisation)
*Results were compared with the graphs.

```
CORRELATIONS
  /VARIABLES=totadj list_sz pracprot pracequi persman btsq8_1 btsq9_1
  btsq10_1 btsq12_1 btsq14_1 btsq15_1 iddplist iplist ratiodd patppart audit ituse reg_per
  complian clinnat spirom skintest nurse
  /PRINT=TWOTAIL NOSIG
  /MISSING=PAIRWISE .
```

* The Correlation analysis suggests that 7 variables are important with p <0.2.
*The following aspects of BTS guideline adherence were associated with QOL and have therefore been selected for the
multivariate regression model:-

persman p= 0.166
btsq10 p= 0.013
btsq15 p= 0.078
ratiodd p= 0.056

*The following aspects of Practice Organisation are associated with QOL and have been selected for the multivariate
regression model:-

list_sz p= 0.096

spirom p= 0.026
complian p= 0.055

* First a multivariate regression model has been constructed with the selected BTS guideline adherence variables.
Have performed weighted least squares regression, entering all the above variables;
Weighted by number of SGRQs (n_brea1).

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=ENTER  persman btsq10_1 btsq15_1  ratiodd .
```

* Now the impact of Practice Organisation will be assessed. This will done by constructing a parsimonious model
with the original BTS guideline candidates selected from the correlation analysis and also the selected
Practice Organisation variables.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=ENTER  persman btsq10_1 btsq15_1  ratiodd list_sz spirom complian.
```

*btsq15_1 largest p value (0.747) therefore eliminated:-

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=ENTER  persman btsq10_1 ratiodd list_sz spirom complian.
```

*persman largest p value (0.454) therefore removed:-

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=ENTER   btsq10_1 ratiodd list_sz spirom complian.
```

*spirometer largest p values (0.132) therefore removed:-

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=ENTER  btsq10_1 ratiodd list_sz  complian.
```

*compliance largest p value (0.147) therefore removed:-

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=ENTER  btsq10_1 ratiodd list_sz .
```

*This is now the final model looking at BTS guideline and QOL, taking into account the impact of Practice Organisation.

*The regression and backwards elimination has been re-run getting the computer to do it in order it to compare results.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_brea1
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT totadj
 /METHOD=BACKWARD persman btsq10_1 btsq15_1  ratiodd list_sz spirom complian.
```

*Very comfortingly this produces the same variables in the final model, however their significance is different
(handles missing cases differently - persman lots of missing cases)

**The above process will now be repeated for the secondary outcomes starting with Diurnal variation.

* Graph of Diurnal Variation vs clinicians BTS adherence.

```
GRAPH
 /SCATTERPLOT(MATRIX)=dvactu_1  btsq8_1 btsq9_1 btsq10_1 btsq12_1
 btsq14_1 btsq15_1   /MISSING=LISTWISE .
```

* Graph of Diurnal Variation vs practice BTS adherence/ characteristics.

```
GRAPH
  /SCATTERPLOT(MATRIX)=dvactu_1 list_sz pracprot pracequi persman
  /MISSING=LISTWISE .

* Graph of Diurnal Variation vs PACT.
GRAPH
  /SCATTERPLOT(MATRIX)=dvactu_1 iplist iddplist ratiodd patppart
  /MISSING=LISTWISE .

*Graph of Diurnal Variation  vs practice organisation.
GRAPH
  /SCATTERPLOT(MATRIX)=dvactu_1 audit ituse complian reg_per
clinnat spirom skintest nurse  /MISSING=LISTWISE .


CORRELATIONS
  /VARIABLES=dvactu_1  list_sz pracprot pracequi persman btsq8_1 btsq9_1
  btsq10_1 btsq12_1 btsq14_1 btsq15_1 iddplist iplist ratiodd patppart audit ituse reg_per
  complian clinnat spirom skintest nurse
  /PRINT=TWOTAIL NOSIG
  /MISSING=PAIRWISE .

* The Correlation analysis suggests that 5 variables  are important with p <0.2.
*The following aspects of BTS guideline adherence were associated with Diurnal Variation
 and have therefore been selected for the multivariate regression model:-

persman p= 0.176
btsq14 p= 0.103


*The following aspects of Practice Organisation are associated with Diurnal Variation
and have been selected for the multivariate regression model:-

list_sz p= 0.155
audit p=0.038
spirom p= 0.056

* First a multivariate regression model has been constructed with just the 2  selected
BTS guideline adherence variables.
Have performed weighted least squares regression. Weighted by number of Diary Cards
(n_break).

REGRESSION
  /MISSING LISTWISE
  /REGWGT=n_break
  /STATISTICS COEFF OUTS CI R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT dvactu_1
  /METHOD=ENTER  persman btsq14_1 .


*No statistically significant results and does not appear to be clinically significant.
```

* Now the impact of Practice Organisation will be assessed. This will done by constructing a parsimonious model
with the original BTS guideline candidates selected from the correlation analysis and also the selected
Practice Organisation variables.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT dvactu_1
 /METHOD=ENTER  persman btsq14_1 list_sz audit spirom.
```

*audit largest p value (0.721) therefore eliminated.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT dvactu_1
 /METHOD=ENTER  persman btsq14_1 list_sz  spirom.
```

*persman largest p value (0.518) therefore eliminated.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT dvactu_1
 /METHOD=ENTER  btsq14_1 list_sz spirom .
```

*spirom largest p value (0.336) therefore eliminated.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT dvactu_1
 /METHOD=ENTER  btsq14_1 list_sz .
```

*btsq14 largest p value (0.143) therefore eliminated.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
```

```
GRAPH
  /SCATTERPLOT(MATRIX)=dvactu_1 list_sz pracprot pracequi persman
  /MISSING=LISTWISE .

* Graph of Diurnal Variation vs PACT.
GRAPH
  /SCATTERPLOT(MATRIX)=dvactu_1 iplist iddplist ratiodd patppart
  /MISSING=LISTWISE .

*Graph of Diurnal Variation  vs practice organisation.
GRAPH
  /SCATTERPLOT(MATRIX)=dvactu_1 audit ituse complian reg_per
clinnat spirom skintest nurse  /MISSING=LISTWISE .


CORRELATIONS
  /VARIABLES=dvactu_1  list_sz pracprot pracequi persman btsq8_1 btsq9_1
  btsq10_1 btsq12_1 btsq14_1 btsq15_1 iddplist iplist ratiodd patppart audit ituse reg_per
  complian clinnat spirom skintest nurse
  /PRINT=TWOTAIL NOSIG
  /MISSING=PAIRWISE .

* The Correlation analysis suggests that 5 variables  are important with p <0.2.
*The following aspects of BTS guideline adherence were associated with Diurnal Variation
 and have therefore been selected for the multivariate regression model:-

persman p= 0.176
btsq14 p= 0.103


*The following aspects of Practice Organisation are associated with Diurnal Variation
and have been selected for the multivariate regression model:-

list_sz p= 0.155
audit p=0.038
spirom p= 0.056

* First a multivariate regression model has been constructed with just the 2  selected
BTS guideline adherence variables.
Have performed weighted least squares regression. Weighted by number of Diary Cards
(n_break).

REGRESSION
  /MISSING LISTWISE
  /REGWGT=n_break
  /STATISTICS COEFF OUTS CI R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT dvactu_1
  /METHOD=ENTER  persman btsq14_1 .


*No statistically significant results and does not appear to be clinically significant.
```

*The following aspects of Practice Organisation are associated with symptom scores and have been selected for the multivariate
regression model:-

list_sz p= 0.158
IT use p=0.197
spirom p= 0.160

* First a multivariate regression model has been constructed with the 2 selected BTS guideline adherence variables.
Have performed weighted least squares regression, entering all the above variables; Weighted by number of Diary Cards (n_break).

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT sympme_1
 /METHOD=ENTER  persman btsq8_1.
```

*This does not produce statistical or clinically significant results.

***Impact of Practice Organisation on these two variables will be assessed by constructing a parsimonious model.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT sympme_1
 /METHOD=ENTER   persman btsq8_1 list_sz ituse spirom .
```

*persman largest p value (0.520) therefore eliminated.

```
REGRESSION
 /MISSING LISTWISE
 /REGWGT=n_break
 /STATISTICS COEFF OUTS CI R ANOVA
 /CRITERIA=PIN(.05) POUT(.10)
 /NOORIGIN
 /DEPENDENT sympme_1
 /METHOD=ENTER   btsq8_1 list_sz ituse spirom .
```

*When this is re-run all the remaining variables are statistically significant so this is the final model.
*This has been re-run getting the computer to do it.

```
REGRESSION
  /MISSING LISTWISE
  /REGWGT=n_break
  /STATISTICS COEFF OUTS CI R ANOVA
  /CRITERIA=PIN(.05) POUT(.10)
  /NOORIGIN
  /DEPENDENT sympme_1
  /METHOD=BACKWARD persman btsq8_1 list_sz ituse spirom .
```

*Again similar results - same variables, different figures for significance.

Appendix 17 Practice Characteristics

Practice	No. of Patients Registered	No. of Partners (WTE)	No. of Registered Patients/Partner (WTE)	% Patients on Asthma Register
A	15299	7	2185	5
	5300	3	1766	9
C	2997	2	1498	13.26
D	7100	4	1775	4
E	8218	4.50	1826	3
F	6209	3.75	1656	4.90
G	5605	3	1868	13.80
H	3500	2	1750	8.10
I	8507	5.25	1620	9.20
J	6684	3.75	1782	12
K	19150	13.75	1392	5
L	20738	9	2302	8.20
M	12000	6.25	1920	8.50
N	13403	7.50	1787	6.43
O	20472	9	2274	5.10
P	11457	6	1909	11
Q	5222	3	1740	4.70
R	6898	4	1724	10
S	807	1	807	9
T	1602	1	1602	4.93
U	2916	2	1458	10.18
V	8212	4	2053	5.40
W	*	3	*	*
X	11934	5	2386	6
Y	12848	7.25	1772	7.40
Z	4106	2	2053	5.80
AA	3763	2	1881	6.48
BB	3380	2	1690	8.90
CC	20019	9.30	2152	12.89
DD	*	1	*	*
EE	6752	3	2250	5.70
FF	15456	7.75	1994	5.90
GG	10769	5.75	1794	8.50
II	9443	5	1888	7.40
JJ	7413	4	1853	6.10
KK	3134	1	3134	3.50
LL	4060	3	1353	4.90

KEY
* Data not available
WTE = whole time equivalent

Patients per Partner
range 807 - 3134
mean 1853

% on Asthma Register
range 3.0 - 13.8
mean 7.43

Appendix 18 (i) **Frequency of Cough, Shortness of Breath and Wheeze in the Preceding year**

Frequency	Cough	Short of Breath	Wheeze
	Number (%)	Number (%)	Number (%)
Most days a week	169 (16.0%)	134 (13.0%)	53 (5.0%)
Several days /week	184 (17.5%)	225 (21.0%)	119 (11.0%)
A few days a month	328 (31.5%)	511 (49.0%)	478 (46.0%)
With chest infection	327 (31.0%)	139 (13.0%)	268 (26.0%)
Not at all	44 (4.0%)	44 (4.0%)	130 (12.0%)
TOTAL	1052	1055	1050

Appendix 18 (ii) **Reported Duration of the Worst Attack of Chest Symptoms in the Preceding Year**

Duration of Worst Asthma Attack	Number(%)
Not applicable, no severe attacks	318 (30.2%)
Less than a day	233 (22.1%)
1 or 2 days	150 (14.2%)
3 or more days	153 (14.5%)
A week or more	199 (18.9%)
TOTAL	1053 (100.0%)

Appendix 18 (iii) **Reported Number of 'Good Days' in an Average Week**

Number of good days	Number(%)
0 good days	154 (14.6%)
1 or 2 good days	670 (63.6%)
3 or 4 good days	164 (15.6%)
Nearly every day is good	55 (5.2%)
Every day is good	10 (0.9%)
TOTALS	1053 (100%)

Appendix 18 (iv) **Proportion of Patients Reporting Morning Wheeze in the Preceding Year**

Morning Wheeze	Number(%)
Not applicable, no wheeze	76 (7.2%)
No, do not wheeze in morning	586 (55.7%)
Yes, wheeze in morning	391 (37.1%)
TOTAL	1053 (100%)

Appendix 18 (v) **ctivities Associated with Breathlessness**

Activity associated with breathlessness	Number(%) agreeing with statement
Sitting or lying still	77 (7.3%, *n* = 1049)
Getting washed or dressed	29 (2.8%, *n* = 1049)
Walking around the home	42 (4.0%, *n* = 1045)
Walking outside on the level	99 (9.5%, *n* = 1041)
Walking up a flight of stairs	444 (42.2%, *n* = 1050)
Walking up hills	749 (71.3%, *n* = 1050)
Playing sports or games	856 (81.3%, *n* = 1044)

Appendix 18 (vi) **Patients Description of Their Chest Condition**

Statement	Number (%) agreeing with statement
It is the most important problem I have	48 (4.6%)
It causes me quite a lot of problems	81 (7.7%)
It causes me a few problems	740 (70.5%)
It causes me no problem	181 (17.2%
Missing	9 (0.3%)
TOTALS	1053 (100.0%)

Appendix 18 (vii) **Problems Associated with Breathing**

Problems with common activities associated with breathing	Number (%) agreeing with statement
I take a long time to get washed or dressed	17 (1.6%, n = 1052)
I cannot take a bath or shower/take a long time	16 (1.5%, n = 1051)
I walk slower than other people/stop for rests	200 (19.1%, n = 1049)
Jobs /housework take a long time/have to rest	160 (15.3%, n = 1048)
If I walk up one flight of stairs I have to go slowly/stop	208 (19.8%, n = 1049)
If I hurry or walk fast, I have to stop or slow down	440 (41.9%, n = 1050)
My breathing makes it difficult to do such things as walk up hills, carrying things up stairs, do light gardening such as weeding, dance, play bowls or golf	312 (29.7%, n = 1050)
My breathing makes it difficult to do such things as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim	494 (47.2%, n = 1047)
My breathing makes it difficult to do such things as very heavy manual work, run, cycle, swim fast or play competitive sports	714 (68.3%, n = 1045)

Appendix 18 (viii) **Impact of Chest Trouble on Employment**

Statement	Number (%) agreeing with statement
Not applicable, never worked	23 (2.2%)
My chest trouble does not affect my work	842 (81.7%)
My chest trouble interferes with my work, or made me change my work	162 (15.7%)
My chest trouble made me stop work altogether	26 (2.5%)
TOTALS	1053 (100.0%)

Appendix 18 (ix) **Activities Associated with Breathlessness and Cough**

Problem	Number (%) agreeing with statement
My cough hurts	183 (17.6%, n = 1042)
My cough makes me tired	224 (21.3%, n = 1046)
I am breathless when I talk	223 (21.2%, n= 1045)
I am breathless when I bend over	120 (11.4%, n = 1040)
My cough/breathing disturbs my sleep	530 (50.4%, n = 1051)
I get exhausted easily	340 (32.3%, n = 1048)

Appendix 18 (x) **Impact on Social Functioning**

Statement	Number(%) agreeing with statement
My cough or breathing is embarrassing in public	180 (17.1%, n = 1052)
Chest trouble is a nuisance to my family, friends or neighbours	124 (11.8%, n = 1052)
I get afraid or panic when I cannot get my breath	368 (35%, n = 1050)
I feel that I am not in control of my chest problem	157 (15.0%, n= 1046)
I do not expect my chest to get any better	486 (46.8%, n = 1039)
I have become frail or invalid because of my chest	24 (2.3%, n = 1050)
Exercise is not safe for me	59 (5.6%, n = 1048)
Everything seems too much of an effort	66 (6.3%, n = 1049)

Appendix 18 (xi) **Impact of Medication**

Statement	Number(%) agreeing with statement
My medication does not help me very much	65 (6.2%, n = 1018)
I get embarrassed using my medication in public	241 (23.6%, n = 1020)
I have unpleasant side effects from my medication	104 (10.2%, n = 1022)
My medication interferes with my life a lot	41 (4.0%, n = 1021)

Appendix 18 (xii) **Impact of Chest Condition on Daily Activities**

Statement	Number(%) agreeing with statement
I cannot play sports or games	153 (14.6%, n = 1047)
I cannot go out for entertainment/recreation	16 (1.5%, n = 1049)
I cannot go out of the house to do the shopping	6 (0.6%, n = 1051)
I cannot do housework	17 (1.6%, n = 1048)
I cannot move far from my bed or chair	2 (0.2%, n = 1051)

Appendix 18 (xiii) **Impact of Chest Condition on Life**

Statement	Number (%) agreeing with statement
It does not stop me doing anything I would like to do	625 (59.4% n = 1053)
It stops me doing one or two things I would like to do	407 (38.7% n = 1053)
It stops me doing most things I would like to do	17 (1.6% n = 1053)
It stops me doing everything I would like to do	4 (0.4% n = 1053)

	N	Symptoms	Range/SD	Activities	Range/SD	Impact	Range/SD	Total	Range/SD
A	56	41.16	6.75-84.88 (16.38)	24.90	0.0-66.95 (15.58)	14.01	0.0-46.74 (11.08)	21.78	4.14-57.52 (10.84)
B	14	48.99	8.8-82.26 (19.4)	30.85	0.0-73.04 (25.21)	23.67	5.52-55.18 (16.17)	30.03	4.58-59.57 (16.95)
C	15	50.49	25.12-83.11 (17.56)	39.85	5.96-66.19 (18.57)	19.09	0.0-47.74(13.92)	30.60	9.62-57.57 (13.50)
D	9	46.77	23.22-46.77 (16.82)	21.44	0.0-66.96 (21.21)	14.63	4.15-51.90 (16.01)	22.03	8.14-58.07 (16.98)
E	15	41.29	13.34-77.07 (20.22)	23.17	0.0-80.43 (20.50)	15.75	1.63-65.03 (15.83)	22.25	3.08-69.39 (16.73)
F	17	41.58	17.27-76.0 (16.89)	26.20	0.0-79.67 (23.18)	16.43	0.0-68.54 (18.39)	23.57	4.53-73.15 (17.81)
G	27	51.22	8.8-97.48 (19.78)	35.11	0.0-100.0 (25.19)	20.03	0.0-88.6 (19.71)	29.76	6.22-93.53 (19.32)
H	14	45.88	23.79-86.10 (19.22)	24.22	0.0-74.5 (23.63)	15.50	0.0-49.49 (14.63)	23.18	7.8-63.15 (16.63)
I	31	40.95	6.6-72.30 (16.59)	26.01	0.0-59.46 (16.06)	16.56	0.0-46.74 (12.91)	23.47	5.28-50.91 (11.84)
J	17	48.82	14.19-94.94 (21.14)	25.43	0.0-79.74 (23.16)	16.22	1.57-43.94 (14.19)	24.43	6.62-59.9 (15.99)
K	53	40.71	6.6-88.08 (18.26)	21.47	0.0-54.21 (15.14)	13.50	0.0-36.82 (9.63)	20.38	1.1-42.03 (10.32)
L	45	47.46	15.8-86.54 (16.08)	29.05	0.0-67.84 (17.65)	16.83	0.0-67.3 (13.21)	25.61	7.55-61.84 (13.27)
M	35	46.15	0.0-100.0 (23.65)	30.09	0.0-79.03 (21.60)	20.42	0.0-87.63 (20.64)	27.57	3.02-87.08 (19.67)
N	30	43.27	4.42-75.88 (18.53)	23.38	0.0-73.74 (19.96)	16.63	1.63-54.04 (12.35)	23.09	6.91-63.64 (12.49)
O	47	45.45	10.78-84.41 (17.65)	28.48	0.0-64.07 (18.43)	17.06	1.63-52.34 (14.33)	25.23	3.42-60.78 (13.67)
P	31	45.50	4.24-92.75 (25.91)	29.26	0.0--73.58 (22.16)	20.75	0.0-71.37 (19.18)	27.43	2.36-73.76 (19.88)
Q	8	52.04	17.90-85.58 (22.94)	37.08	5.96-83.23 (28.62)	20.20	0.0-71.37 (19.99)	30.62	7.29-72.84 (22.18)
R	27	48.90	13.21-83.11 (17.54)	29.47	5.96-66.19 (14.97)	17.97	0.0-62.56 (13.0)	26.57	8.29-63.42 (11.97)
S	2	53.61	47.43-59.80 (8.75)	39.24	17.43-61.05 (30.85)	28.76	1.63-59.66 (7.88)	36.06	25.46-46.66 (15.0)
T	3	47.77	35.67-59.83 (12.08)	15.93	0.0-35.6 (18.10)	9.24	23.18-34.33 (7.44)	17.67	6.79-27.49 (10.29)
U	18	44.39	14.05-86.37 (18.73)	30.45	0.0-60.27 (18.21)	14.47	1.63-16.5 (12.75)	24.56	7.55-56.23 (13.44)
V	25	50.86	14.02-90.45 (19.11)	29.70	0.0-60.25 (19.56)	18.91	1.63-49.35 (9.32)	27.50	7.5-50.04 (11.89)
W	17	47.61	11.95-82.52 (20.37)	27.26	0.0-100.0 (27.08)	21.04	1.63-35.31 (20.3)	27.28	3.19-81.07 (20.34
X	53	46.72	5.49-87.98 (15.16)	26.99	0.0-81.32 (19.49)	15.47	1.43-70.27 (12.65)	24.14	2.6-62.28 (13.01)
Y	34	44.54	8.8-83.80 (18.05)	22.32	0.0-85.66 (18.32)	11.39	0.0-59.5 (11.55)	20.18	1.46-66.99 (13.29)
Z	13	56.13	25.22-87.98 (16.85)	27.95	0.0-66.19 (20.14)	20.22	0.0-51.05 (10.41)	28.50	6.46-48.41 (12.54)
AA	2	41.31	17.72-64.91 (33.36)	32.81	17.12-48.5 (22.19)	15.11	0.0-40.19 (13.56)	24.82	11.06-38.58 (19.46)
BB	8	39.35	23.22-73.37 (16.57)	20.80	0.0-66.19 (21.88)	17.55	5.52-24.69 (13.41)	22.09	8.12-51.15 (15.14)
CC	33	38.12	13.48-75.11 (16.83)	20.56	0.0-60.35 (16.76)	10.94	1.63-41.66 (8.82)	18.31	2.38-37.5 (10.07)
DD	1	55.77	(N/A)	47.70	(N/A)	11.89	(N/A)	30.03	(N/A)
EE	14	38.53	4.42-63.39 (14.93)	24.70	0.0-59.46 (18.41)	11.23	0.0-30.75 (8.94))	19.78	0.68-44.08 (11.64)
FF	28	50.05	15.58-97.48 (19.83)	33.75	0.0-79.81 (20.66)	17.80	0.0-91.39 (17.14)	28.00	8.02-88.89 (16.21)
GG	38	40.72	7.71-76.63 (17.92)	23.59	0.0-73.00 (17.95)	13.12	0.0-37.03 (9.96)	20.83	4.93-50.64 (11.92)
II	25	38.18	0.0-71.59 (18.91)	25.33	0.0-66.19 (18.21)	12.85	0.0-35.15 (10.2)	20.81	0.73-49.64 (12.33)
JJ	40	47.85	8.8-74.70 (15.24)	25.62	0.0-82.49 (18.56)	14.81	0.0-44.2 (11.63)	23.49	6.34-53.47 (12.14)
KK	2	64.79	54.49-75.09 (14.57)	29.31	29.31 (N/A)	14.24	1.63-26.84 (17.83)	27.20	22.22-32.18 (7.04)
LL	12	45.49	23.06-77.00 (16.22)	29.31	0.0-54.42 (20.49)	11.92	0.0-28.79 (8.94)	22.77	9.33-40.66 (11.23)

Appendix 18 (xiv) **George's Respiratory Questionnaire Component and Total Scores per Practice**

Appendix 19 **Summary Statistics for Secondary Outcome Variables per Practice (cont'd over leaf)**

	n=	Diurnal mean + median	Variation range + SD	n=	Symptom mean+ median	Score range + SD	n=	F E mean + median	V_1 range + SD
A	56	6.59 (4.82)	1.48-24.36 (4.51)	57	1.33 (0.86)	0.0-5.93 (1.39)	56	97.63 (95.84)	45.6-160.3 (20.23)
B	15	9.73 (6.84)	2.22-33.67 (8.48)	14	2.28 (2.14)	0.0-6.43 (1.93)	15	93.34 (93.14)	53.9-129.1 (20.97)
C	15	7.32 (6.50)	1.5-17.19 (4.35)	15	1.98 (1.36)	0.0-5.29 (1.80)	15	98.63 (100)	42.9-124.4 (18.77)
D	9	6.09 (5.22)	3.03-9.25 (2.26)	9	1.75 (1.14)	0.21-4.71 (1.49)	9	95.22 (90.96)	83.2-116.3 (11.66)
E	15	9.00 (6.36)	0.95-31.2 (8.44)	15	1.31 (0.78)	0.0-5.43 (1.34)	15	96.38 (100.35)	76.0-110.2 (11.13)
F	18	7.86 (5.86)	2.18-21.64 (5.73)	18	1.51 (1.14)	0.0-7.0 (1.72)	18	86.19 (90.31)	38.1-114.9 (19.28)
G	28	8.72 (6.35)	0.75-44.12 (8.59)	28	1.99 (1.53)	0.14-6.64 (1.77)	28	91.54 (95.10)	46.9-123.2 (17.72)
H	15	11.60 (8.52)	2.5-43.48 (10.68	16	2.24 (1.57)	0.14-5.36 (1.78)	15	94.29 (93.38)	56.1-118.5 (17.74)
I	31	8.33 (4.57)	0.34-26.86 (7.40	30	1.36 (1.18)	0.0-5.29 (1.2)	31	92.34 (89.07)	58.6-133.5 (17.11)
J	16	12.44 (7.28)	1.69-48.0 (12.76)	16	1.50 (1.50)	0.0-5.86 (1.4)	16	89.17 (92.24)	23.1-121.7 (22.97)
K	56	6.56 (5.27)	0.52-19.84 (4.64)	55	1.32 (0.64)	0.0-5.43 (1.39)	57	102.08 (102.27)	56.7-143.9 (16.37)
L	47	8.02 (5.44)	0.32-25.37 (5.46)	45	1.66 (1.28)	0.0-9.86 (1.84)	45	99.95 (96.95)	60.2-134.5 (15.52)
M	34	7.73 (6.46)	1.29-32.62 (5.89)	37	2.03 (1.07)	0.0-9.93 (2.61)	35	91.85 (93.87)	60.6-121.7 (14.40)
N	31	(5.10)	0.19-22.93 (5.11)	31	1.68 (1.36)	0.0-6.86 (1.56)	31	90.06 (90.62)	43.9-116.1 (15.60)
O	47	8.32 (4.99)	1.42-34.62 (7.52)	47	1.23 (1.00)	0.0-5.43 (1.14)	45	98.52 (99.33)	42.6-141.1 (19.05)
P	32	7.75 (6.33)	0.80-24.31 (5.65)	32	2.02 (1.18)	0.0-10.5 (2.56)	32	96.60 (96.53)	56.4-130.1 (15.31)
Q	8	12.51 (7.46)	1.76-47.79 (15.27)	8	2.97 (2.11)	0.14-11.43 (3.66)	8	78.66 (88.89)	13.5-103.3 (28.94)
R	27	7.41 (5.80)	2.14-28.41 (6.13)	28	1.78 (1.50)	0.14-6.79 (1.43)	28	93.52 (91.70)	67.9-119.8 (12.35)
S	2	12.03 (12.03)	8.36-15.70 (5.19)	2	2.82 (2.82)	1.21-4.43 (2.27)	2	76.41 (76.41)	50.3-102.5 (36.86)

Appendix 19 cont'd **(cont'd) Summary Statistics for Secondary Outcome Variables per Practice**

	n=	Diurnal Variation mean + median	range + SD	n=	Symptom Score mean+ median	range + SD	n=	F E V_1 mean + median	range + SD
T	3	7.02 (5.99)	2.41-12.76 (5.26)	3	1 (1.42)	0.43-1.71 (0.64	2	93.26 (93.26)	83.9-102.6 (13.21)
U	19	5.15 (4.11)	0.74-12.46 (3.45)	20	1.15 (0.57)	0.0-5.0 (1.4)	18	89.26 (91.58)	64.3-114.2 (15.44)
V	25	9.38 (6.56)	2.12-47.34 (10.63)	25	1.77 (1.50)	0.14-5.5 (1.5)	26	93.86 (95.70)	65.9-126.8 (13.62)
W	18	6.45 (5.65)	0.09-16.76 (4.00)	17	1.42 (0.78)	0.0-8.0 (2.04)	18	95.73 (97.89)	52.5-113.4 (16.43
X	53	6.88 (4.58)	1.09-36.75 (6.09)	53	1.62 (1.07)	0.0-5.64 (1.38)	43	100.43 (101.63)	62.7-177.9 (18.25)
Y	35	7.35 (6.17)	1.58-21.59 (4.75)	34	1.39 (1.18)	0.0-5.36 (1.18)	35	96.67 (93.87)	45.7-130.2 (16.14)
Z	14	7.52 (6.89)	1.23-25.52 (5.67)	14	1.77 (1.57)	0.36-4.07 (1.21)	14	96.58 (97.30)	71.5-131.3 (16.05)
A A	13	6.56 (3.83)	0.96-17.39 (5.38)	13	0.74 (0.57)	0.0-2.14 (0.74)	13	92.55 (97.61)	70.2-110 (13.97)
BB	8	8.28 (4.25)	2.97-30.82 (9.43)	8	1.42 (1.39)	0.14-2.57 (0.97)	8	85.71 (87.32)	61.7-101 (13.15)
CC	37	5.80 (4.33)	1.07-20.96 (4.48)	37	1.30 (1.14)	0.0-4.93 (1.17)	36	99.78 (102.24)	77.4-124 (11.35)
DD	1	11.89 (11.89)	N/A	1	1.07 (1.07)	N/A	1	78.40 (78.4)	N/A
EE	14	7.23 (4.53)	1.73-26.40 (7.44)	14	1.53 (0.82)	0.14-4.07 (1.34)	14	93.58 (93.34)	48.8-120.7 (18.57)
FF	29	9.87 (6.61)	0.79-56.16 (11.94)	29	1.82 (1.21)	0.0-8.64 (1.97)	28	92.27 (91.08)	60.4-129.5 (17.25)
GG	39	6.25 (4.66)	1.16-22.88 (4.74)	39	1.38 (0.78)	0.0-7.93 (1.82)	39	99.91 (100.92)	64.1-143.2 (17.70)
II	25	7.87 (5.29)	1.96-35.82 (7.76)	25	1.19 (0.86)	0.0-3.79 (1.08)	25	104.09 (101.99)	69.9-153.7 (17.65)
JJ	41	8.07 (6.13)	1.46-25.43 (5.83)	42	1.87 (1.68)	0.0-8.86 (1.71)	39	92.99 (93.75)	44.1-125.1 (17.16)
KK	2	8.57 (8.57)	5.6-11.53 (4.19)	2	1.79 (1.79)	0.86-2.71 (1.31)	2	105.74 (105.74)	96.6-114.9 (12.95)
LL	12	6.07 (6.05)	1.26-10.41 (3.2)	12	1.26 (1.25)	0.0-3.36 (1.08)	12	91.90 (92.23)	47.2-112.6 (17.37)

Appendix 20 (ii) **Adherence to the BTS Guidelines, Assessed by Practice Equipment, Structure and Resources from Self Report**

Practice Adherence	Potential Max. score	Lowest score	Highest score	Mean score
Equipment	14.00	6.00	13.00	12.08
Structure				
Practice Protocol	10.00	4.00	10.00	6.56
Use of Self Management Plans (SMPs)	100.00	0.00	100.00	45.8
Resources				
Practice Nurse Experience	10.00	1.00	10.00	4.01

Practice	Step 2 T'ment	Use of Rescue Medication	T'ment - Acute Attack	Equipment - Room	Equipment - Home Visits	Drugs - Home Visits
A	2.25	2.00	6.00	3.75	3.38	4.25
B	1.33	2.00	3.33	3.00	2.33	2.33
C	2.50	2.00	6.00	4.50	3.00	5.00
D	1.33	1.33	4.00	3.00	2.25	5.25
E	3.20	2.00	5.60	2.40	2.40	3.40
F	1.25	2.00	6.50	3.25	2.50	3.25
G	1.25	2.00	4.75	3.00	2.50	3.50
H	1.00	2.00	6.50	4.50	2.00	5.00
I	2.33	2.33	6.00	3.83	3.40	4.83
J	1.75	2.00	5.75	3.50	4.00	5.25
K	2.40	2.30	5.10	4.00	2.70	4.20
L	2.20	2.00	5.50	3.70	2.70	3.80
M	3.14	2.00	5.83	4.43	2.83	4.00
N	2.25	2.13	5.00	3.88	3.00	4.13
O	2.57	2.00	5.00	3.14	1.86	3.57
P	2.33	2.17	5.50	4.17	2.00	2.67
Q	3.67	2.67	6.00	4.67	3.50	5.00
R	2.50	1.50	5.25	3.25	3.33	3.75
S	*	*	*	*	*	*
T	3.00	2.00	5.00	3.00	2.00	4.00
U	2.50	2.00	6.00	3.50	3.00	4.00
V	2.75	2.00	6.25	3.25	2.50	4.25
W	*	*	*	*	*	*
X	2.33	2.17	5.67	3.50	3.50	4.00
Y	2.33	2.00	5.50	3.50	2.00	3.83
Z	3.50	3.00	3.50	2.50	2.00	3.00
AA	4.00	2.00	7.00		3.50	3.50
BB	1.00	2.00	3.50	3.00	1.50	4.00
CC	1.90	2.20	5.40	3.20	2.89	4.40
DD	*	*	*	*	*	*
EE	2.33	2.00	5.67	4.33	2.67	5.33
FF	2.83	3.17	6.33	4.00	3.00	4.50
GG	2.17	2.00	6.00	3.50	2.17	4.33
II	1.75	2.00	6.25	3.25	3.00	4.75
JJ	2.00	2.00	6.50	4.00	2.50	4.50
KK	2.00	2.00	4.00	4.00	3.00	3.00
LL	1.33	2.00	5.33	3.67	4.00	5.33

Appendix 20 (iii) **Guideline Adherence Scores by Practice**

Key * no data available

Appendix 21 **Ratio of Inhaled Corticosteroids/Beta Agonist Prescriptions Expressed as Defined Daily Doses**

Practice	IHCS items per Patients as DDDs	Ratio IHCS/Beta Agonist items as DDDs
A	7.3	.64
B	8.72	.44
C	16.92	.69
D	8.2	.57
E	9.83	.59
F	11.52	.63
G	13.18	.73
H	13.67	.62
I	10.29	.66
J	9.07	.64
K	12.17	.75
L	9.22	.69
M	9.08	.67
N	8.79	.79
O	9.10	.68
P	7.40	.64
Q	9.68	.59
R	13.30	.73
S	11.95	.84
T	22.44	.66
U	16.62	.63
V	10.57	.67
W	*	.42
X	8.78	.74
Y	8.93	.58
Z	7.09	.47
AA	1.55	.98
BB	13.86	.49
CC	8.75	.70
DD	*	.47
EE	9.62	.70
FF	8.44	.50
GG	9.55	.83
II	10.74	.67
JJ	9.24	.70
KK	9.2	.75
LL	7.91	.49

Total IHCS
range 7.09 - 22.44
mean 10.62

Ratio IHCS/Beta Agonists
range 0.42 - 0.98
mean 0.65

* = No data available

Appendix 22 **Questions Assessing Practice Organisation (structures in place to qualify for CDM payments)**

Practice	Nature of Asthma Clinic	Audit Level of Activity	Routine Patient Review	IT Use
A	1	0	N	3
B	1	0	N	3
C	1	3	*	2
D	1	3	Y	3
E	2	2	Y	2
F	1	2	*	3
G	1	2	Y	3
H	1	0	Y	3
I	1	2	Y	2
J	1	0	Y	3
K	1	0	Y	2
L	2	1	Y	3
M	3	2	Y	2
N	3	2	*	3
O	3	1	*	2
P	*	0	Y	2
Q	1	0	Y	3
R	2	1	Y	2
S	1	0	Y	1
T	2	2	Y	0
U	1	2	Y	2
V	1	2	Y	3
W	*	*	*	*
X	1	2	Y	2
Y	1	3	*	3
Z	1	0	Y	2
AA	1	0	Y	2
BB	1	0	Y	2
CC	2	2	N	3
DD	*	*	*	*
EE	2	2	Y	3
FF	2	2	Y	3
GG	1	1	Y	3
II	2	1	Y	1
JJ	1	2	Y	3
KK	1	0	Y	2
LL	1	0	N	1

Nature of Asthma Clinic
1= ad hoc
2= set aside
3= both

Audit
1= minimal
2= moderate (process)
3= maximum
(extended or outcomes)

IT Use
1 point for each:
prescriptions, appointments, records

References

Abramson M.J, Bailey M.J, Couper F.J, Driver J.S, Drummer O.H, Forbes A.B, McNeil J.J, and Haydn Walters E; 2001.Victorian Asthma Mortality Study Group. Are asthma medications and management related to deaths from asthma? American Journal of Respiratory Critical Care Medicine. 163 (1):
12-8.

Acheson E. D. 1989. On the state of the Public Health for the year 1988. London: HMSO.

Agresti A., and Finlay B. 1997. Statistical methods for the Social Sciences. London, Prentice Hall.

Aitken M., Anderson D., and Hinde J. 1981. Satistical Modelling in GLIM. Journal of the Royal Statistical Society 144 : 148-161.

Allen R. M., Jones M. P., and Oldenburg B. 1995. Randomised trial of an asthma self- management programme for adults. Thorax 50 :731-738.

Altman D.G. 1992. Practical medical statistics for medical research. London. Chapman and Hall.

American Thoracic Society. 1995. Standards for the diagnosis and care of patients with chronic obstructive pulmonary disease. American Journal of Respiratory Critical Care Medicine 152 (supplement) :s77-s120.

Anderson H. R. 1989. Increase in hospital admissions for childhood asthma: trends in referral, severity, and readmissions from 1970 to 1985 in a health region of the UK. Thorax 44 :614-619.

Anderson H. R., Butland B. K., and Strachan D. P. 1994. Trends in prevalence and severity of childhood asthma. British Medical Journal 308 :1600-1604.

Armstrong D.F.J. and Armstrong, P. 1994. General Practitioners' views of clinical guidelines for the management of asthma. International Journal for Quality in Health Care 6 :199-202.

Aveyard P. 1997. Assessing the performance of general practices caring for patients with asthma. British Journal of General Practice 47 :423-426.

Balarajan R., Yuen P., and Machin D. 1992. Deprivation and general practitioner workload. British Medical Journal 304 :529-534.

Baldwin D. R., Pathak U. A., King R., Vase B. C., and Pantin C. F. A. 1997. Outcome of asthmatics attending asthma clinics utilising self-management plans in general practice. Asthma in General Practice 5 :31-33.

Bara A.I., and Barley E.A., 2000. Cochrane Database. Systematic Review. Caffeine for asthma (2):CD001112.

Barnes G., and Partridge M. R. 1994. Community asthma clinics: 1993 survey of primary care by the National Asthma Task Force. Quality in Health Care 3: 133-136.

Barnes N.C., and Pujet J. C. 1997. Pranlukast, a novel leukotreine receptor antagonist: results of the first European, placebo controlled, multicentre clinical study in asthma. Thorax 52 :523-527.

Barnes P. J., Greening A. P., Neville L., et al. 1982. Single-dose slow-release aminophylline at night prevents nocturnal asthma. Lancet (i) :299-301.

Barnes P. J. 1992. Poorly perceived asthma. Thorax 47 :408-409.

Barnes P.J., and Pauwels R.A., 1994. Thephylline in the management of asthm: time for reappraisal? European Respiratory Journal. (3):579-91.

Barnes P. J. 1995. Inhaled glucocorticoids for asthma. The New England Journal of Medicine 332 :868-875.

Barnes P. J. 1996. Inhaled glucocorticoids: new developments relevant to updating of the Asthma Management Guidelines. Respiratory Medicine 90: 379-384.

Barrit P., and Staples E. 1991. Measuring success in asthma care: a repeat audit. British Journal of General Practice. 41 :232-236.

Barritt P. W. 1992. General practitioners and asthma. Thorax 47 :669-670.

Bateman D.N. 1996. Clearing 'the fog on the Tyne': can the quality of therapeutics be assessed? Clinical Experimantal Pharmacology and Physiology; 23(10-11):1005-9

Bauman A. E., Smith N. A., Braithwaite C., Free A., and Saunders A. 1989. Asthma information: can it be understood? Health Education Research 4 :377-382.

Bauman A. 1993. Effects of asthma patient education upon psychological and behavioural outcomes. Edited by S. Maes, H. Levanthal and M. Johnston. Vol. 2, International Review of Health Psychology. Sydney: John Wisley and Sons.

Bauman A., Cooper C., Bridges-Webb C., Tse M., Miles D., Bhasale A., and Pollock M. 1995. Asthma management and morbidity in Australian general practice: the relationship between patient and doctor estimates. Respiratory Medicine 89 :665-672.

Baur K. 1993 Pharmacodynamic effects of inhaled dry powder formulations of fenoterol and colforsin in asthma. Clinical Pharmacology and Therapeutics. 53;76-83.

Beasley R., Cushley M., and Holgate S. T. 1989. A self-management plan in the treatment of adult asthma. Thorax 44 :200-204.

Bennet N. 1976. Teaching Styles and Pupil Progress. London: Open Books.

Bentley A.M., Hamid Q., Robinson D.S., Schotman E., Meng Q., Assoufi B., Kay A B., and Durham S R. 1996. Prednisolone treatment in asthma. Reduction in the number of eosinophils. T cells, tryptase-only positive mast cells, and modulation of IL-4, IL-5 and interferon- gamma cytokine gene expression within the bronchial mucosa. American journal of Critical Care Medicine 153 :551-556.

Bergner M., Bobbitt R.A., Kressel S., Pollard W.E., Gilson B.S., and Morris J.R. 1976. The Sickness Impact Profile: conceptual formulation and methodological development of a health status measure. International Journal of Health Services 6 :393-415.

Berwick D. M., Enthoven A., and Bunker J. P. 1992. Quality management in the NHS: the doctors role. British Medical Journal 304 :235-239.

Black, N. 1985. Glue ear: The new dyslexia? British Medical Journal. June 29;290 (6486):1963-5.

Bland M. 1997. An introduction to medical statistics. Third edition. Oxford Medical Publications.

Boner A. L., Niero E., Antolini I., Valletta E. A., and Gaburro D. 1985. Pulmonary function and bronchial hyperreactivity in asthmatic children with house dust mite allergy during prolonged stay in the Italian Alps (Misurina). Annals of Allergy 54 :42-45.

Bolton M.B, Tilley B.C., Kuder J. Reeves T. and Schultz L.R. 1991.The cost and effectiveness of an adult education programme for adults who have asthma. Journal of General Internal Medicine. 6: 401-407.

Bosley C.M., Corden Z.M., and Cochrane G..M. 1996. Psychosocial factors and asthma. Respiratory Medicine 90 :453-457.

Bousquet J., Chanez P., Lacoste J. Y., et al. 1990. Eosonophilic inflammation in asthma. New England Journal of Medicine 323 :1033-1039.

Bousquet J. Global initiative for asthma 2000. The Global Intitative for Asthma (GINA) and its objectives. Clinical Experimental Allergy 30: Supplement 1:2-5.

Bradley F., Wiles R., Kinmonth A.-L., Mant D., and Gantley M. 1999. Development of the evaluation of complex interventions in health services research: case study of the Southampton heart integrated care project (SHIP). British Medical Journal 318 :711-715.

Brewis R. A. L. 1991. Patient education, self-management plans and peak flow measurement. Respiratory Medicine 85 :359-363.

BTA (British Thoracic Association). 1982. Death from asthma in two regions of England. British Medical Journal. 285:1251-1255.

BTS (British Thoracic Society), et al. 1990a. Guidelines for the Management of Asthma in Adults: I - Chronic Persistent Asthma. A Statement by the British Thoracic Society, Research Unit of the Royal College of Physicians of London, Kings Fund Centre and National Asthma Campaign. British Medical Journal. 301:651-653.

BTS (British Thoracic Society, et al) 1990b. Guidelines for the Management of Asthma in Adults: II - Acute Severe Asthma. A Statement by the British Thoracic Society, Research Unit of the Royal College of Physicians of London, Kings Fund Centre and National Asthma Campaign. British Medical Journal. 301:767-800.

BTS (British Thoracic Society) 1993. Guidelines for the treatment and management of asthma. Thorax 48 (supplement) :S1-S24.

BTS (British Thoracic Society), National Asthma Campaign, Royal College of Physicians et al,. 1997. The British Thoracic Society Guidelines on Asthma Management: 1995 review and position statement. Thorax 52 :S1 -S21.

BTS-SOCC (The British Thoracic Society Standards of Care Committee) 1997, Guidelines on the management of COPD. Thorax 1997, Vol 52:5. (Supplement)

Britten N. 1994. Why do patient some patients fail to cash their prescriptions? Prescriber 5 :59-60.

Britton J., Pavord I., Richards K., et al 1994. Dietary Magnesium, lung function, wheezing, and airway hyper-reactivity in a random adult population sample. Lancet:344:357-362.

Brown L. A., and Sly R. M. 1980. Comparison of Mini-Wright and standard Wright peak flow meters. Annals of Allergy 45 :72-74.

Bryce F., Neville R., Crombie I., Clark R., and McKenzie P. 1995. Controlled trial of an audit facilitator in diagnosis and treatment of childhood asthma in general practice. British Medical Journal 310 :838-842.

Bucknall C. E. 1991. Who needs referral to the hospital asthma specialist? Respiratory Medicine 85 :453-455.

Bucknall C. E. 1996. Definitions of severity and outcome measures. Respiratory Medicine 90 :447-452.

Burki N. K., Mitchell B. A., and Chaudhary Zechman F. W. 1978. The ability of asthmatics to detect added resistive loads. American Review of Respiratory Disease. 117:71-75.

Burney P. G. J. 1986. Asthma mortality in England and Wales: evidence for a further increase, 1974-84. Lancet ii :323-326.

Burney P.G.J. 1989. The effect of of changing dietary sodiumon the bronchial response to histamine. Thorax; 44:36-41.

Burney P. G. J., Chinn S., and Rona R. J. 1990. Has the prevalence of asthma increased in children? Evidence from the national study of health and growth from 1973 to 1986. British Medical Journal 300 :1306-1310.

Burney P.G.J., Luczynska C., Chinn S., and Jarvis D. 1994. The European Community Respiratory Health Survey. European Respiratory Journal. 7(5):954-60.
Burney P.G.J., Malmberg E., Chinn S., Jarvis D., Luczynska C., and Lai E. 1997. The distribution of total and specific serum IgE in the European Community Respiratory Health Survey. Journal of Allergy and Clinical Immunology 99 :314-322.

Burrows B., Fernando D., Martinez M. D., Halonen M., Barbee R. A., and Cline M. G. 1989. Association of asthma with serum IgE levels and skin test reactivity to allergens. New England Journal of Medicine 320 :271-277.

Bye M. R., Kerstein D., and Barsh E. 1992. The importance of spirometry in the assessment of childhood asthma. American Journal Diseases of Children 146 :977-978.

Campbell J. L. 1996. The reported availability of general practitioners and the influence of practice list size. British Journal of General Practice 46 :465-468.

Campbell M. J., Cogman G. R., Johnstone S. L., and Holgate S. T. 1997. Age specific trends in asthma mortality in England and Wales 1983-1992. British Medical Journal 314 :1439-1441.

Carney T. 1989. Workload of general practitioners. British Medical Journal 299 :753.

Chai H., and Farr R.S. et al. 1975. Standardization of bronchial inhalation challenge procedures. Journal of Allergy and Clinical Immunology 56 :323-327.

Charlton I., Charlton G., Broomfield J., and Mullee M. A. 1990. Evaluation of a peak flow and symptoms only self management plans for control of asthma in general practice. British Medical Journal 301 :1355-1359.

Charlton I., Charlton G., Broomfield J., and Mullee M. 1991a. Audit of the effect of a nurse run asthma clinic on workload and patient morbidity in general practice. British Journal of General Practice 41 :227-231.

Charlton I., Jones K., and Bain J. 1991b. Delay in diagnosis of childhood asthma and its influence on respiratory consultation rates. Archives of Disease in Childhood 66 :633-635.

Charlton I., Charlton G., Broomfield J., and Campbell M. 1992. An evaluation of a nurse-run asthma clinic in general practice using an attitude and morbidity questionnaire. Family Practice 9 :154-160.

Charlton I., Antoniou A. G., Atkinson J., Campbell M. J., Chapman E., Mackintosh T., and Schapira D. 1994. Asthma at the interface: bridging the gap between general practice and a district general hospital. Archives of Disease in Childhood 70 :313-318.

Charlton I. 1997. The contribution primary care (general practice) has made to asthma care in the past twenty years. Asthma in General Practice 5 :18-20.

Clancy L., and Keogan S. 1994. Treatment of nocturnal asthma with nedocromil sodium. Thorax 49 :1225-1227.

Cluzeau, F., Littlejohns P.,Grimshaw, J.M., Feder, G., and Moran, S. 1999. Development and application of a generic methodology to assess the quality of clinical guidelines. International Journal of Quality Health Care,1999; 21-8.

Cochrane G. M., and Clark T. J. H. 1975. A survey of asthma mortality in patients between ages 35 and 64 in the Greater London hospitals. Thorax 30 :300-305.

Cockcroft D. W., and Murdoch K. Y. 1987. Comparative effects of inhaled salbutamol, sodium cromoglycate and BDP on allergen-induced early asthmatic responses, late asthmatic responses and increased bronchial responsivieness to histamine. Journal of Allergy and Clinical Immunology 79 :739-740.

Cogswell J. 1992. How predictive of asthma is atopy? Clinical and Experimental Allergy 22 :597-599.

Cohen J. R. 1977. Statistical power analysis for the behavioural sciences. Vol. Revised Edition. New York: Academic Press.

Conroy M., and Shannon W. 1995a. Measuring and improving physician compliance with clinical practice guidelines. American College of Physicians 122 :277-282.

Conroy M., and Shannon W. 1995b. Clinical guidelines: their implementation in general practice. British Journal of General Practice 45 :371-375.

Crescioli S., Dal Carobbo A., Maestrelli P., Boschetto P., Santagada T., Steinijans V. W., Hurst T. S., Parise G., and Fabbri L. M. 1996. Controlled-release theophylline inhibits early morning airway obstruction and hyperresponsiveness in asthmatic subjects. Annals of Allergy, Asthma and Immunology 77 :106-110.

CSO (Central Statistics Office) 1994. Regional Trends.Volume 29. HMSO.

CTS (Canadian Thoracic Society), et al. 1996. Report on the working groups for the Canadian Asthma Consensus Conference: Canadian Respiratory Journal.

Currie C.J., Evans M., and Morgan C.L. 1997. More adequate systems are needed. British Medical Journal 314 :681.

Dahl R., and Johansson S. A. 1982. Importance of duration of treatment with inhaled steroids on the immediate and late bronchial reaction. European Journal of Respiratory Disease 63 :167-175.

D'Alonzo G.E, Volker W.S, Keller A.1995 Measurements of morning and evening airflow grossly underestimate the circadian variability of FEV_1 and peak expiratory flow rate in asthma. Am J Resp Crit Care Med, 152: 1097-1099.

Davies C.W.H., Cooper N., and Wathen C. G. 1997. General Practitioners' Use of Guidelines. Asthma Journal December :144-145.

Dekhuijzen P.N, Bootsma G.P, Wielders PL, et al.1997 Effects of single-dose zileuton on bronchial hyperresponsiveness in asthmatic patients treated with inhaled corticosteroids. European Respiratory Journal; 10(12):2749-2753.

Dekker F.W., Kaptein A.A., van der Waart M.A., and Gill K. 1992. Quality of self-care of patients with asthma. Journal of Asthma. 29(3): 203-8.

Dekker F.W., Schrier A.C., Sterk P. J., and Dijkman J.H. 1992. Validity of peak expiratory flow measurement in assessing reversibility of airflow obstruction. Thorax 47:162-166.

Dennis S.M., Sharp S.J., Vickers M.R., Frost C.D., Crompton G.K. Barnes P.J., and Lee T.H. 2000. Regular inhaled salbutamol and asthma control: the TRUST randomised study for the Working Group of the National Asthma Task Force and MRC General Practice Framework. Lancet 13;355(9216):1675-9.

Djukanovic R., Roche W., Wilson J. W., et al. 1990. Mucosal inflammation in asthma. State of the art. American Review of Respiratory Disease 142 :434-457.

Djukanovic R., Homeyard S., Gratziou C., Madden J., Walls A., Montefort S., Peroni D., Polosa R., Holgate S., and Howarth P. 1996. The effect of treatment with oral corticosteroids on asthma symptoms and airway inflammation. American Journal of Respiratory Critical Care Medicine 155 :826-832.

DOH (Department of Health). 1989. Working for Patients. London: HMSO.

DOH (Department of Health). 1995. Asthma-An epidemiological overview. London: HMSO.

DOH (Department of Health). 1998a. Towards an evidence-base for health services, public health and social care. London: Department of Health.

DOH (Department of Health) 1998b. Central Research and Development Committee Advisory Group. Indentifying research and development priorities for the NHS on asthma management. Leeds: Department of Health.

DOH (Department of Health). 1998c. Health and Social Services Statistics for England. The Sationary Office.

DOH (Department of Health). 1999 Review of Prescribing, Supply and Administration of Medicines: Final Report. DoH. London.

Dompeling E., Van Shayck C. P., and Van Grunsven P. M. 1993. Slowing the deterioration of asthma and chronic obstructive pulmonary disease observed during bronchodilator therapy by adding inhaled corticosteroids: a four year prospective study. Annals of Internal Medicine 118 :770-778.

Donner A. 1984. Approaches to sample size estimation in the design of clinical trials - a review. *Statistics in Medicine* 3 :199-214.

Dorward M. A. 1994. The role of the practice nurse in asthma managagement. Undergraduate Dissertation (BNSc. hons), University of Southampton.

Dowie, R., Robinson, M. and Jones, R. 2000. Family Practice, 17; February Supplement 1,1-2

Drazen J.M, Israel E, Boushey H.A, Chinchilli V.M, Fahy J.V, Fish J.E, Lazarus S.C, Lemanske R.F, Martin R.J, Peters S.P, Sorkness C, and Szefler S.J. 1996. Comparison of regularly scheduled with as-needed use of albuterol in mild asthma. Asthma Clinical Research Network. New England Journal of Medicine. 19;335(12):841-7.

Drazen J. M., Israel E., and O'Byrne P. M. 1999. Treatment of asthma with drugs modifying the leukotreine pathway. The New England Journal of Medicine 340 :197-206.

D'Souza W., Crane J., Burgess C., Te Karu H., Fox C., Harper M., Robson B., Howden-Chaman, Crossland L., Woodman K., Pearce N., Pomare E., and Beasley R. 1994. Community-based asthma care: trial of a "credit card" asthma self management system. European Respiratory Journal 7 :1260-1265.

D'Souza W., Te Karu H., Fox C., Harper M., Gemmell T., Ngatuere M., Wickens K., Crane J., Pearce N., and Beasley R. 1998. Long-term reduction in asthma morbidity following an asthma self-management programme. European Respiratory Journal 11 :611-616.

Dubois P., Degrave E., and Vandenplas O. 1998. Asthma and airway hyperresponsiveness among Belgian conscripts, 1978-91. Thorax 53 :101-105.

Dunn N., and Pickering R. 1998. Does good practice organisation improve the outcome for diabetic patients? British Medical Journal 48 :1237-1240.

Eastwood A. J., and Sheldon T. A. 1996. Organisation of asthma care: what difference does it make? A systematic review of the literature. Quality in Health Care 5 :134-143.

Eason J., and Markowe H.L.J. 1987. Controlled investigation of deaths from asthma in hospitals in the North East Thames Region. British Medical Journal 294 :1255-1258.

Eccles M., Clapp Z., Grimshaw J., Adams P. C., Higgins B., Purves I., and Russell I. 1996. Developing valid guidelines: methodological and procedural issues from the North of England Evidence Based Guideline Development Project. Quality in Health Care.
5 :44-50.

Ellrodt A. G., Conner L., Riedinger M., and Weingarten S. 1995. Measuring and improving physician compliance with clinical practice guidelines. Annals of Internal Medicine 122 :277-282.

Elmslie C., Grimshaw J., and Templeton A. 1993. Do clinical guidelines improve general practice management and referral of infertile couples? British medcial Journal 306 :1728-1731.

Enright P.L., Lebowitz M.D. and Cockroft D.W. 1994 Physiologic Measures: Pulmonary Function Tests American Journal of Respiratory Critical Care Medicine. Volume 149.p S9-18.

Ernst P., Spitzer W. O., Suissa S., Cockroft D., Habbick B., Horwitz R. I., Boivin J.-F., McNutt M., and Buist S. 1992. Risk of fatal and near-fatal asthma in relation to inhaled corticosteroid use. Journal of the American Medical Association 268 :3462-3464.

ECRHS (Euroean Community Respiratory Health Survey). 1996. Variations in the prevalence of respiratory symptoms, self reported asthma attacks and the use of asthma medication in the European Community Respiratory Health Survey. European Respiratory Journal 9 :687-695.

Evans D. 1993. To help patients control asthma the clinician must be a good listener and teacher. Thorax 48 :685-687.

Evans D. 1996. A stakeholder analysis of developments at the primary and secondary care interface. British Journal of General Practice 46 :675-677.

Farmer A. 1993. Medical practice guidelines: lessons from the United States. British Medical Journal 307 :313-317.

Feder G., Griffiths C., Highton C., Eldridge S., Spence M., and Southgate L. 1995. Do clinical guidelines introduced with practice based education improve care of asthmatic and diabetic patients? A randomised controlled trial in general practices in east London. British Medical Journal 311 :1473-1478.

Fiel S. B., Swartz M. A., Glanz K., and Francis M. E. 1983. Efficacy of short-term corticosteroid therapy in outpatient treatment of acute bronchial asthma. American Journal of Medicine 75 :845-851.

Field M.J., and Lohr K.N. 1992. Guidelines for clinical practice: from development to use. Washington DC. National Academy Press.

Fiore M.C., Smith S.S., Jorenby D.E. et al. 1994. The effectiveness of the nicotine patch for smoking cessation: a meta analysis. Journal of the American Medical Association. 271:1940-1947.

Fischer AR, McFadden CA, Frantz R, et al. 1995 Effect of chronic 5-lipoxygenase inhibition on airway hyper-responsiveness in asthmatic subjects. American Journal of Respiratory Critical Care Med; 152(4 Pt 1):1203-1207.

Fish JE, Kemp JP, Lockey RF, et al. 1997. Zafirlukast for symptomatic mild-to-moderate asthma: a 13-week multicenter study. The Zafirlukast Trialists Group. Clinical Therapy; 19(4):675-690.

Fitzpatrick M. F., Mackay T., Driver H., and Douglas N. J. 1990. Salmeterol in nocturnal asthma: a double blind, placebo controlled trial of long acting inhaled beta2-agonist. British Medical Journal 301 .

Fleming D. M., and Crombie D. L. 1987. Prevelence of asthma and hay fever in England and Wales. British Medical Journal 294 :279-283.

Frank P. I., Ferry S., Moorhead H., and Hannaford P. C. 1996. Use of a Postal Questionnaire to estimate the likely underdiagnosis of asthma-like symptoms in adults. British Journal of General Practice 46 :295-297.

Fried R.A., Miller R.S., Green L.A., Sherrod P. and Nutting P.A., 1995. The use of objective measures of asthma severity in primary care: a report from APSN. Journal of Family Practice. 41(2):139-43.

Furukawa C. T., Duhamel T., Weimer, L., Shapiro C.G., Pierson W.E. and Bierman W. 1988. Cognitive and behavioural findings in children taking theophylline. Journal of Allergy and Clinical Immunology; 81: 83-85.

Gannon P.F.G, Newton D.T, Pantin C.F.A, and Burge P.S. 1998. Effect of the number of peak expiratory flow readings per day on the estimation of diurnal variation. Thorax; 53: 790-792

Garrett J., Mercer Fenwick J., Taylor G., Mitchell E., Stewart J., and Rea H. 1994. Prospective controlled evaluation of the effect of a community basd education centre in a multiracial working class neighbourhood. Thorax 49 :976-983.

Gellert A. R., Gellert S. L., and Iliffe S. R. 1990. Prevalence and management of asthma in a London inner city general practice. British Journal General Practice 40 :197-201.

(The) Georgian Research Society. 1991. The attitude of general practitioners towards practice nurses: a pilot study. British Journal of General Practice 41 :19-22.

Gibson G. J. 1997. The role of spirometry in general practice. Asthma Journal June .

Gibson P.G., Coughlan J., Wilson A.J., Hensley M.J., Bauman A., and Walters E.H. 2000a. The effects of limited (information only) patient education programmes on the health outcomes of adults with asthma. The CochraneDatabase, Systematic Review, Issue 4 (2) CD001005.

Gibson P.G, Coughlan J, Wilson A.J, Abramson M, Bauman A, Hensley M.J, Walters E.H. 2000b.Self-management education and regular practitioner review for adults with asthma (Cochrane Review). In: The Cochrane Library, Issue 4. Oxford: Update Software.

Glennerster H., Matsaganis M., and Owens P. 1992. A foothold for fundholding. A Preliminary Report on the Introduction of Fundholding. London: King's Fund Institute.

Goldstein H. 1995. Multilevel statistical models. Second edition. Kendall's library of statistics 3. London: Edward Arnold.

Grant E.N., Moy N.M., Turner-Roan K and Weiss K.B. (for the Chicago Asthma Surveillance Initiative Project Team). Asthma Care Practices, Perceptions, and Beliefs of Chicago-Area Primary-Care Physicians. Chest. 1999; 116:145S – 154S.

Greenfield S., Stillwell B., and Drury M. 1987. Practice nurses: social and occupational characteristics. Journal of the Royal College of General Practitioners 37 :341-345.

Greenhalgh T. 1997. How to read a paper: the basics of evidence based medicine. Vol. 315. London: BMJ Publishing Group.

Greening A. P., Ind P. W., Northfield M., and Shaw G. 1994. Added salmeterol versus higher-dose corticosteroid in asthma patients with symptoms on existing inhaled corticosteroid. The Lancet 344 :219-224.

Griffiths C., Naish J., and Pereira F. 1996. Prescribing and hospital admissions for asthma in east London. British Medical Journal 312 :481-482.

Griffiths C., Sturdy P., Naish J., Omar R., Dolan S., and Feder G. 1997a. Hospital admissions for asthma in east London: associations with characteristics of local general practices, prescribing and population. British Medical Journal 314 :482-486.

Griffiths C., Sturdy P., J. N., Feder G., Omar R., Dolan S., and Pereira F. 1997b. Outcome measures need to reflect morbidity and quality of care (letter). British medical Journal 314 :681-682.

Grimshaw J. M., and Russell I. T. 1993. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet 342 :1317-1322.

Grimshaw J. F., and N. Wallace, S. 1995. Developing and Implementing Clinical Practice Guidelines. Quality Health Care 4 :55-64.

Grol R. 1992. Implementing guidelines in general practice. Quality in Health Care 1 :184-191.

Grol R. 1993. Development of guidelines for general practice. British Journal of General Practice 43 :146-151.

Grol R., Dalhuijsen J., Thomas S., in't Veld C., Rutten G., and Mokkink H. 1998. Attributes of Clinical Guidelines that Influence the use of Guidelines in General Practice: Observational Study. British Medical Journal 317 :858-861.

Guyatt G. H., Thompson P. J., and Berman L. B., et al. 1985. How should we measure function in patients with chronic lung disease? Journal of Chronic Disease 38 :517-524.

Haahtela T., Lindholm H., Borksten F., Koskenvuo K., and Laitenen L. A. 1990. Prevalence of asthma in Finnish young men. British Medical Journal 301 :266-268.

Haahtela T., Jarvinen M., and Kava T. 1991. Comparison of a beta2-agonist, terbutaline, with an inhaled corticosteroid, budesonide, in newly detected asthmatics. New England Journal of Medicine 325 :388-392.

Haahtela T., Jarvinen M., and Kava T. 1994. Effects of reducing or discontinuing inhaled budesonide in patients with mild asthma. New England Journal of Medicine. 331:700-705.

Hammerquist C., Burr M. L., and Gotzsche P. C. 2000. House dust mite control measures in the management of asthma. Issue 3, 2000, Oxford: Cochrane Library, Update Software.

Hannay D. R., and Usherwood T. P. 1992. Practice organisation before and after the new contract: a survey of general practices in Sheffield. British Journal of General Practice 42 :517-520.

Hannay D. R., Usherwood T., and Platts M. 1992. General practitioner workload before and after the new contract. British Medical Journal 304 :615-618.

Hargreave F. E., Dolovich J., and Newhouse M. T. 1990. The assessment and treatment of asthma: a conference report. Journal of Allergy and Clinical Immunology 85 :1098-1101.

Harm D. L., Kotses H., and Creer T. L. 1985. Improving the ability of peak expiratory flow rates to predict asthma. Journal of Allergy and Clinical Immunology .

Harrison B. D. W., and Nichols J. M. 1995. Results of two surveys in Norfolk of the use of guidelines on asthma management (abstract). Thorax 50 (suppl.2) :AS1.

Harrison B. D. W. 1996. Guidelines in Asthma (editorial). Respiratory Medicine. 90 :375-378.

Harving H., Korsgaard J., and Dahl R. 1994. Clinical efficacy of reduction in house dust mite exposure in specially designed, mechanically ventilated "healthy" homes. Allergy 49:866-880.

Hay I. F., and Higgenbottam T. W. 1987. Has the management of asthma improved? Lancet (ii) :609-611.

Hibble A. 1995. Practice nurse workload before and after the introduction of the 1990 contract for general practitioners. British Journal of General Practice 45 :35-37.

Hickman M., Drummond N., and Grimshaw J. 1994. A taxonomy of shared care for chronic disease. Journal of Public Health Medicine 16 :447-454.

Higgins B. G., Britton J. R., Chinn S., Jones T. D., Jenkinson D., Burney P., and Tattersfield A. E. 1989. The distribution of peak expiratory flow variability in a population sample. American Review of Respiratory Diseases 140 :1368-1372.

Higgins B. G., Brittin J. R., Chinn S., Cooper S., Burney P. G. J., and Tattersfield A. E. 1992. Comparison of bronchial reactivity and peak expiratory flow variability measurements for epidemiologic studies. American Review of Respiratory Diseases. 145:588-593.

Hilton S., Sibbald B., Ross-Anderson H., and Freeling P. 1986. Controlled Evaluation of the Effects of Patient Education on Asthma Morbidity in General Practice. Lancet 1 .

Hilton S. 1993. Management of asthma in general practice - a changing scene, The Royal College of General Practitioners Members' Reference Book. London: RCGP.
Holgate S. T. 1996a. Inhaled sodium cromoglygate. Respiratory Medicine 90 :387-390.

Holgate S. T. 1996b. The efficacy and therapeutic position of nedocromil sodium. Respiratory Medicine 90 :391-394.

Holgate S. T. 1997. The cellular and mediator basis of asthma in relation to natural history. Lancet 350 :5-9.

Horn C. R., and Cochrane G. M. 1989. An audit of morbidity associated with asthma in general practice. Respiratory Medicine 83 :71-75.

Horn C. R., Clark T. J. H., and Cochrane G. M. 1990. Can the morbidity of asthma be reduced by high dose inhaled therapy? A prospective study. Respiratory Medicine. 84:61-66.

Hoskins G., Neville R. G., Smith B., and Clark R. A. 1996. Do self-management plans reduce morbidity in patients with asthma? British Journal of General Practice 46 :169-171.

Hoskins G., Neville R. G., Smith B., and Clark R. A. 1997. Does participation in distance learning and audit improve the care of patients with acute asthma attacks? The general practitioners in asthma group. Health Bulletin of Edinburgh 55 :150-155.

Hoskins G., Neville R. G., Smith B., and Clark R. A. 1998. Structure, Process and Outcomes of Asthma Clinics (abstract). Paper presented at National Asthma Campaign 3rd Conference on the Management of Patients with Asthma, at London, UK.

Hoskins G., Neville R. G., Smith B., and Clark R. A. 1999. The link between practice nurse training and asthma outcomes. British Journal of Community Nursing 4 :222-228.

Hughes J.R, Stead L.F, and Lancaster T. 2000. Antidepressants for smoking cessation (Cochrane Review). Cochrane Database Systematic Review; (4):CD000031

Hunt S., and McKewan P. 1980. The development of a subjective health indicator. Sociology of Health and Illness 2 :231-246.

Huntley A, and Ernst E. 2000. Herbal medicines for asthma: a systematic review. Thorax Nov;55(11):925-9

Huss K., Huss R.W., Squire E.N., Carpenter G.B. Smith L.J., Salata K., Selerno M., and Agostinelli D. 1992. Computer education for asthmatics: what effects? Journal of Nursing Care Quality; 6(3):53-66.

Hyland M. E. 1991. The living with asthma questionnaire. Respiratory Medicine 85 (supplement):13-16.

Hyndman S. J., Williams D. R. R., Merrill S. L., Lipscombe J. M., and Palmer C. R. 1994. Rates of admission to hospital for asthma. British Medical Journal 308 :1596-1600.

Ignacio-Garcia J. M., and Gonzalez-Santos P. 1995. Asthma Self-Management Education Program by Home Monitoring of Peak Expiratory Flow. American Journal of Respiratory Critical Care Medicine 151 :353-359.

Jamison J. P., and Mckinley R. K. 1993. Validity of peak expiratory flow rate variability for the diagnosis of asthma. Clinical Science 85 :367-371.

Janson C., Gislason T., Boman G., Hetta J., and Roos B.-E. 1990. Sleep disturbances in asthma. Respiratory medicine 84 :37-42.

Jarvis D., Lai E., Luczynska C., Chinn S., and Burney P. 1994. Prevalence of asthma and asthma-like symptoms in young adults lining in three East Anglian towns. British Journal of General Practice 44 :493-497.

Jenkinson D., Davidson J., Jones S., and Hawtin P. 1988. Comparison of effects of a self-management booklet and audio cassette for patients with asthma. British Medical Journal 297 :267-270.

Jindal S. K., Gupta D., and Singh A. 1994. Indices of morbidity and control of asthma in adult patients exposed to environmental tobacco smoke. Chest; 106 :662-663.

Johnston S. L., Pattemore P., Sanderson G., Smith S., Lampe F., Josephs L., et al. 1995. Community study of the role of viral infections in exacerbations of asthma in 9-11 year old children. British Medical Journal 310 :1225-1227.

Jones A., and Sykes A. 1990. The effect of symptom presentation on delay in asthma diagnosis in children in general practice. Respiratory Medicine 84 :139-142.

Jones K. 1989. Asthma - still a challenge for general practice. Journal of the Royal College of General Practitioners 39 :254-256.

Jones K. 1991a. Asthma care in general practice. British Journal of General Practice 41 :224-226.

Jones K., Bain D., Middleton M., and Mullee M. 1992a. Correlates of asthma morbidity in primary care. British Medical Journal 304 :361-364.

Jones K., Charlton I., Middleton M., and Mullee M. 1992b Targeting asthma care in general practice using a morbidity index British Medical Journal 304 :1353-1356.

Jones K. 1992. Impact of an interest in asthma on prescribing costs in general practice. Quality in Health Care 1 :110-113.

Jones K.P. 1995 The role of measuring forced expiratory volume in one second in determining therapeutic changes made in an asthma clinic in general practice. Respiratory Medicine March ;89 (3);171-174.

Jones K. P., and Mullee M. A. 1995a. Lung function measurement in general practice: a comparison of the Escort spirometer with the micromed turbine spirometer and the mini-Wright peak flow meter. Respiratory Medicine 89 :657-663.

Jones K., and Mullee M. 1995b. Proactive, nurse-run asthma care in general practice reduces asthma morbidity: scientific fact or medical assumption? British Journal of General Practice 45 :497-499.

Jones K., Mullee M., Middleton M., Chapman E., Holgate S. T., and British Thoracic Society Research Committee. 1995. Peak flow based asthma self-management: a randomised controlled study in general practice. Thorax 50 :851-857.

Jones K. and Gruffyd-Jones K. 1996 Management of acute asthma attacks associated with respiratory tract infection: a postal survey of general practitioners in the U.K. Respiratory Medicine 90, 419-425.

Jones, K., Cleary, R. and Hyland, M. 1999, Predictive value of a simple asthma morbidity index in a general practice population. British Journal of General Practice. 49, 23-26

Jones P. W., Baveystock C. M., and Littlejohns P. 1989. Relationships between general health, measured with the Sickness Impact Profile and respiratory symptoms, physiological measures and mood in patients with chronic airflow limitation. American Review of Respiratory Disease 140 :1538-1543.

Jones P. W. 1991b. The St. George,s Respiratory Questionnaire. Respiratory Medicine 85 (supplement B) :S25-S31.

Jones P. W., Quirk F., Baveystock C., and Littlejohns P. 1992c. A self-complete measure for chronic airflow limitation - the St. George's Respiratory Questionnaire. American Review of Respiratory Disease 145 :1321-1327.

Juniper E. F., Guyatt G. H., Epstein R. S., Ferrie P. J., Jaeschke R., and Hiller T. K. 1992. Evaluation of impairment of health related quality of life in asthma: development of a questionnaire for use in clinical trials. Thorax 47 :76-83.

Juniper E. F., Guyatt G. H., Ferrie P. J., and Griffith L. E. 1993. Measuring quality of life in asthma. American Review of Respiratory Disease 147 :832-838.

Kaur B., Anderson H. R., Austin J., Burr M., Harkins L. S., Strachan D. P., and Warner J. O. 1998. Prevalence of asthma symptoms, diagnosis and treatment in 12-14 year old children across Great Britain (ISAAC, UK). British Medical Journal 316 :118-124.

Kendrick A.H., Higgs C.M.P., Whitfield M.J., and Laszlo G. 1993. Accuracy of perception of severity of asthma: patients treated in general practice. British Medical Journal 307 :422-424.

Khot A., and Burn R. 1984. Seasonal variation and time trends of deaths from asthma in England and Wales. British Medical Journal 289 :233-234.

Kibbe D. C., Kaluzny A. D., and McLaughlin C. P. 1994. Integrating guidelines with continuous quality improvement: Doing the right thing, the right way to achieve the right goals. Journal on Quality Improvement 20 :181-191.

Kitzinger J. 1995. Introducing Focus Groups. British Medical Journal 311 :299-302.
Konig P. 1981. Hidden asthma in childhood. American Journal Disease in Children 135 :1053-1055.

Lahdensuo A., Haahtela T., Herral J., Kava T., Kiviranta K., Kuusisto P., Peramaki E., Poussa T., Saarelainen S., and Svahn T. 1996. Randomised comparison of guided self management and traditional treatment of asthma over one year. British Medical Journal 312 :748-752.

Laitenen L. A., Laitenen A., and Haahtela T. 1993. Airway mucosal inflammation even in patients with newly diagnosed asthma. American Review of Respiratory Disease 1993 :697-704.

Lane D.J. 1991. Chronic persistent asthma: nebulizers and therapy additional to inhaled beta-agonists and steroids. Respiratory Medicine 85 :359-363.

Lebowitz M..D., Krzyzanowski M., Quackenboss J.J., and O'Rourke M.K. 1997, Diurnal Variation of PEF and its use in epidemiological studies. European Respiratory Journal;10. Supplement 24, 49s-56s.

Lee D A., Winslow N.R., Speight A.N.P., and Hey E.N. 1983. Prevalence and spectrum of asthma in childhood. British Medical Journal 286 :1256-1258.

Levy M., and Hilton S. 1992. Asthma in Practice. London: The Royal College of General Practitioners.

Levy M.L., Couriel J.M. Clark R.A. Holgate S.T. and Chauhan A.J. 1997. Shared care for asthma. Oxford: Isis Medical Media.

Linde K. and Jobst K. 2000. Homeopathy for chronic asthma. Cochrane Database of Systematic reviews (2) CD000353.

Linde K., Jobst K. and Panton J. 2000. Acupuncture for chronic asthma. Cochrane Database of Systematic reviews (2) CD000008.

Littlejohns P., and MacDonald L. D. 1993. The relationship between severe asthma and social class. Respiratory medicine 87 :139-143.

Littlejohns P., and Cluzeau, F., 2000. Guidelines for Evaluation. Family Practice, 17; February Supplement 1,3-6

Lomas J., Anderson G. M., Domnick-Pierre K., Vayda E., Enkin M. W., and Hannah W. J. 1989. Do practice guidelines guide practice? The New England Journal of Medicine 321: 1306-1311.

Maiman L. A., Green L. W., Gibson G., and MacKenzie E. J. 1979. Education for self treatmentby adult asthmatics patients. Journal of the American Medical Association 241:1919-1922.

Majeed F., and Voss S. 1995. Performance indicators for general practice. British Medical Journal 311 :209-210.

Majeed A., Evans N., and Head P. 1997. What can PACT data tell us about prescribing in general practice? British Medical Journal 315 :1515-1519.

Malo J. L., Boulet L. P., and Dewitte J. D. et al. 1993. Quality of life of patients with occupational asthma. Journal of Allergy and Clinical Immunology 91 :1121-1127.

Mant D., and Fowler G. 1990. Urine analysis of glucose and protein: are the requirements of the new contract sensible? British Medical Journal 300:1053-1055.

Marks G. B., Dunn S. M., and Woolcock A. J. 1992. A scale for the measurement of quality of life in adults with asthma. Journal of Clinical Epidemiology 45 :461-472.

Martys C. 1992. Asthma care in Darley Dale: general practitioner audit. British Medical Journal 304 :758-760.

Maxwell M., Heaney D., Howie J. G. R., and Noble S. 1993. General practice fundholding: observations on prescribing patterns and costs using the defined daily dose method. British Medical Journal 307 :1190-1194.

Mayo P. H., Richman J., and Harris H. W. 1992. Results of a programme to reduce admissions for adult asthma. Annals of Internal Medicine 112 :864-871.

Mazzuca S. A. 1982. Does patient education in chronic disease have therapeutic value? Journal of Chronic Disease 35 :521-529.

McAlister N. H., Covvey H. D., Tong C., Lee A., and Wigle E. D. 1986. Randomised controlled trial of computer assisted management of hypertension in primary care. British Medical Journal 293 :670-674.

McColl A, Smith H, White P, Field J. 1998. General practitioner's perceptions of the route to evidence based medicine: a questionnaire survey. British Medical Journal. 316(7128):361-5.

McCorick A., Fleming D., and Charlton J. 1995. Morbidity statistics from general practice-fourth national study: HMSO.

McGinn P. 1988. Practice standards leading to premium reductions. American Medical News, December 2nd, 1.

McGovern V., and Crockett A. 1996. 1993 BTS guidelines: impact and shortfall. Asthma Journal 1 :30-31.

McKee M., and Clarke A. 1995. Guidelines, enthusiasms, uncertainty and the limits to purchasing. British Medical Journal 310 :101-104.

MRC (Medical Research Council). 1956. Controlled trial of cortisone acetate in chronic asthma. Lancet 2 :798-803.

Miller R. M., Dickinson S. A., and Hitchings D. J. 1992. The accuracy of portable peak flow meters. Thorax 47 :904-909.

Modell M., Harding J., Horder E., and Williams P. 1983. Improving the care of asthmatic children in general practice. British Medical Journal 286 :2027-2030.

Mohan G., Harrison B. D. W., Badminton R. M., Mildenhall S., and Wareham N. J. 1996. A confidential enquiry into deaths caused by asthma in an English health region: impliactions for general practce. British Journal of General Practice 46 :529-532.

Moldofsky H, Broder I, Davies G, Leznoff A. 1979. Videotape educational program for people with asthma. Canadian Medical Association Journal. 17;120(6):669-72.

Morgan D.L. 1992. in, Tools for primary care research. Edited by M. Stewart, F. Tudiver, M. J. Bass, E. V. Dunn and P. G. Norton. 6 vols. Vol. 2, Research methods for primary care. London: Sage Publications: 177 to 193.

Morgan, M. 2000. Family Practice, 17; February Supplement 1,21-25

NAC (National Asthma Campaign). 1996. The Impact of Asthma. Uxbridge: Allen and Hanburys Limited.

Nagendra HR, Nagarathna R. 1986. An integrated approach of yoga therapy for bronchial asthma: a 3-54-month prospective study. Journal of Asthma. 23(3):123-37.

Naish J., Sturdy P., and Toon P. 1995. Appropriate prescribing in asthma and its related cost in east London. British Medical Journal 310 :97-100.

NHS (Management Executive). 1993. GP contract health promotion package: guidance on implementation. Department of Health. FHSL, 3.

NHSE (National Health Service Executive). 1996. Clinical guidelines, using clinical guidelines to improve patient care within the NHS. Leeds: DOH.

NHLBI (National Heart Lung and Blood Institute). 1995. Global Initiative on Asthma: A Practical Guide for Public Health Officials and Health Care Professionals. Bethesda: National Institutes of Health.

NEAGDP (North of England Asthma Guideline Development Group). 1996. North of England evidence based guidelines development project: summary version of evidence based guidelines for the primary care management of asthma in adults. British Medical Journal 312 :762-766.

Neville E., Gribbin H., and Harrison B. D. W. 1991. Acute severe asthma. Respiratory Medicine 85 :463-474.

Neville R. G., Hoskins G., Smith B., and Clark R. A. 1996. Observations on the structure, process and clinical outcomes of asthma care in general practice. British Journal of General Practice 46 :583-587.

Neville R. 1996. Patient education and guided self-management plans. Respiratory Medicine 90 :385-386.

Newton J., Knight D., and Woolhead G. 1996. General practitioners and clinical guidelines: a survey of knowledge, use and beliefs. British Journal of General Practice. 46:513-517.

North of England Study of Standards and Performance in General Practice. 1992. Overview of the Study. Newcastle-upon-Tyne: Centre for Health services research.

OPCS (Office of Population Censuses and Surveys). 1989. General Household Survey. London: HMSO.

ONS (Office of National Statistics). 1998. Key health statistics from general practice. Series MB6, No1. London: The Stationary Office.

ONS (Office of National Statistics). 1999. The Source; Online Governement Statistical Service: Office of National Statistics.

Osman L. M., Abdalla M. I., Beattie J. A. G., Ross S. J., Russell I. T., Friend J. A., Legge J. S., and Douglas J. G. 1994. Reduced hospital admission through computer supported education for asthma patients. British Medical Journal 308 :568-571.

Osman L. M., Robertson R., Friend J. A. R., Legge J. S., and Douglas J. G. 1995. Nurses role in general practice asthma review. European Respiratory Journal 19 :463s.

Osman L. M., Godden D. J., Friend J. A. R., Legge J. S., and Douglas J. G. 1997. Quality of life and hospital re-admission in patients with chronic obstructive pulmonary disease. Thorax 52 :67-71.

Osman L., Calder C., Robertson R., Friend J. A. R., and Legge J. S. 2000. Symptoms, quality of life and health service contact among young adults with mild asthma. American Journal of Respiratory and Critical Care Medicine 161/2 :498-503.

Palmer J. B. D., and Hyland M. E. 1991. Salmeterol in clinical practice: comparator and safety studies, quality of life studies. European Respiratory Journal 1 :301-303.

Paterson C, Britten N. 2000. Organising primary health care for people with asthma: the patient's perspective. British Journal of General Practice. 50(453):299-303

Patterson M. 1997. A comparison of the effects of inhaled steroid and salmeterol prescribing on exacerbations, symptom control and lifestyle in 2,432 patients with asthma in primary care using PACT data. European Respiratory Journal 10 :104s.

Pearce L, Matthews H, Dolding M, and McCarthy P. An assessment of training needs of East Norfolk primary care asthma nurses, on behalf of the Norfolk Respiratory Interest Group. Asthma in General Practice: Journal of the GPs in Asthma Group. Dec 1997;5 (2): 26.

Pearlman D. S., Chervinski P., LaForce C., Seltzer J. M., Southern D. L., and Kemp J. P. et al. 1992. A comparison of salmeterol with albuterol in the treatment of mild to moderate asthma. New England Journal of Medicine 327 :1420-1425.

Pearson M. G., Neville R., Richards N., Patience J., Sondhi S., Wagstaff B., and Wells N. 1995. Distribution of Asthmatics at Each Guideline Step and Use of Beta Agonists in General Practice. Thorax 50 :P3.

Peat. J.K., Haby M., Spijker, Berry G. and Woolcock A. Prevalence of asthma in adults in Busselton, Western Australia. 1992. British Medical Journal; 305:1326-9.

Perks W. H., Tams I. P., Thompson D. A., and Prowse K. 1979. An evaluation of the mini-Wright peak flow meter. Thorax 34 :79-81.

Peroni D. G., Moner A. L., Vallone G., Antolini I., and Warner J. O. 1994. Effective allergen avoidance at high altitude reduces allergen-induced bronchial hyperresonsiveness. American Journal of Respiratory Critical Care Medicine. 149: 1442-1446.

Peter A. 1993. Practice nursing in Glasgow after the new general practitioner contract. British Journal of General Practice 43 :97-100.

Picken H. A., Greenfiel S., Teres D., Hirway P.S. and Landis J.N. Effect of local standards on the implementation of national guidelines for asthma 1998. Journal of General Internal Medicine 13 (10), 659-663.

Pill R., Jones A., and Adams S. 2000. Professional and Patient perspectives on Guided Self Management for Asthma in Primary Care: a qualitative pilot study. Paper presented at Academic and University Departments of General Practice(AUDGP), Annual Scientific Meeting, at Bournemouth.

Platts-Mills T.A., Thomas W.R., Aalberse R.C., and Chapman M.D. 1992a. Dust mite allergens and asthma; report of a second international workshop. Journal of Allergy and Clinical Immunology 89 :1056-1060.

Platts-Mills T. A., Tovey E.R., Mitchell E.B., Moszoro H., Nock P., and Wilkins S.R. 1992b. Reduction of bronchial hyperreactivity during prolonged allergen avoidance. Lancet ii :675-678.

Prescribing Research Unit. 1995. Defined, Prescribed and Standard Daily Doses. Leeds: Universty of Leeds.

PPA (Prescription Pricing Authority). 1998. PACT Standard Report, Quarter Ending June 1998. PPA : Newcastle-Upon-Tyne

Pringle M., Stewart-Evans C., Coupland C., Williams I., Allison S., and Sterland J. 1993. Influences on control of diabetes mellitus: patient, doctor, practice or delivery of care? British Medical Journal. 306 :630-634.

Price D. B., McGovern V., Mead M., and Ryan D. 1995. GP Prescribing Trends in Asthma : Meeting the Challenge of the Guidelines. Thorax 50 :P5.

PSSRU (Personal, and Social Services Research Unit) 1997. Unit costs of health and social care. University of Kent and Canterbury.

Quirk F. H., and Jones P. W. 1990. Patients' perception of distress due to symptoms and effects of asthma on daily living and an investigation of possible influential factors. Clinical Scientist 79 :17-21.

Reddel H., Jenkins C., and Woolcock A. Diurnal variability - time to change asthma guidelines? British Medical Journal 1999;319:45-47.

Raw M., McNeill A., and West R. 1999. Smoking cessation: evidence based recommendations for healthcare professionals. British Medical Journal. 318(7177):182-5.

Reed C. E. 1990. Aerosol glucocorticoid treatment of asthma: adults. American Review of Respiratory Disease 140 :S82-S88.

Rees J., and Price J. 1995. ABC of Asthma. 3rd edition ed. London: BMJ publishing.

Renwick D.S., and Connolly M.J., 1996. Impact of obstructive airways disease on quality of life in older adults. Thorax; 51:520-525.

Ridgeway N.A., Harvill D.R., Harvill L.M., Falin T.M., Forester G.M., Gose O.D. 1999. Improved control of type 2 diabetes mellitus: a practical education/behaviour modification program in a primary care clinic. Southern Medical Journel ; 92(7):667-72.

Ringsberg K. C., Wiklund I., and Wilhelmsen L. 1990. Education of adult patients at an "asthma school": effects on quality of life, knowledge and need for nursing. European Respiratory Journal 3 :33-37.

Robertson R., Osman L. M., and Douglas J. G. 1997. Adult asthma review in general practice: nurses' perception of their role. Family Practice 14 :227-232.

Robinson D.S., Hamid Q., Ying S., Bentley A.M., Assoufi B., Durham S.R., and Kay A.B. 1993. Prednisolone treatment of asthma is associated with modulation of bronchoalveolar lavage cell interleukin4, interleukin-5 and interferon-gamma cytokine gene expression. American Review of Respiratory Disease 148 :401-406.

Roland M. 1999. Quality and efficiency : enemies or partners. British Journal of General Practice 49 :140-143.

Rona R. J., Chinn S., and Burney P. G. J. 1995. Trends in the prevalence of asthma in Scottish and English schoolchildren 1982-1992. Thorax 50 :992-993.

Ross L. 1997. Research Methods in Primary Care. Edited by Y. Carter and C.Thomas. Abingdon: Radcliffe Medical Press; 39-48.

Rowe B. H., and Oxman A. D. 1993. Performance of an asthma quality of life questionnaire in an outpatient setting. American Review of Respiratory Diseases. 148 :675-681.

RCGP (Royal College General Practitioners). 1993. Guidelines for the care of patients with asthma. London: Royal College General Practitioners.

RCGP (Royal College General Practitioners). 1993. Guidelines for the care of patients with diabetes. London: Royal College General Practitioners.

RCR (Royal College of Radiologists). 1993. Making best use of a department of clinical radiology. Guidelines for doctors. London: RCR.

Rubinfeld A.R., and Pain M.C. 1976. Perception of asthma. The Lancet I: April 24:882-884.

Ryan G., Latimer K. M., Dolovitch J., and Ha F.E. 1982. Bronchial responsiveness to histamine; relationship to diurnal variation of peak flow rate improvement after bronchodilator and airway. Thorax 37 :423-429.

Sackett D.L., 1995. Applying overviews and meta-analyses at the bedside. Journal of Clinical Epidemiology;48(1):61-6.

Samet J. M. 1987. Epidemiologic approaches for the identification of asthma. Chest. 91 :74s-78s.

Sears M.R., Rea, H.H., and Heaf, P. 1986 Observations on recent increase in mortality from asthma. British Medical Journal, 293:1342-45

Sears M.R., Taylor D.R., Print C.G., Lake D.C., Li Q., Flannery E.M., et al. 1990. Regular inhaled b-agonist treatment in bronchial asthma. Lancet 336 :1391-1396.

Sears M. R. 1995. Is the routine use of inhaled beta-adrenergic agonists appropriate in asthma treatment? - No. Journal of Respiratory Critical Care Medicine 151 :597-599.

Seaton A. Godden D.J., and Brown K. 1994. Increase in asthma: a more toxic environment or a more susceptible population? Thorax; 49(2): 171-4.

Sefton C. 1991. Huge variations over number of GP clinics. Pulse 51 :7.

Selroos O., Backman R., Forsen K., Lofroos A.-B., Niemisto M., Pietinalho H., and Riska H. 1994. When to start treatment of asthma with inhaled steroids. European Respiratory Journal 7 (suppl 18) :151s.

Shapiro S. M., Hendler J. M., Ogirala O. G., Aldrich T. K., and Shapiro M. B. 1991. An evaluation of the accuracy of Assess and MiniWright peak flow meters. Chest 99 :358-362.

Sheffer A. L. 1991. Guidelines for the diagnosis and management of asthma. National heart Lung and Blood Institute, National Asthma Education Programme, Expert Panel Report. Journal Allergy and Clinical Immunology 88 :425-534.

Shelley M., Croft P., Chapman S., and Pantin C. 1996. Is the ratio of inhaled corticosteroid to bronchodilator a good indicator of the quality of asthma prescribing? Cross sectional study linking prescribing data to data on admissions. British Medical Journal 313 :1124-1125.

Shelley M, Croft P, Chapman S, Pantin C. Is the quality of asthma prescribing, as measured by the general practice ratio of corticosteroid to bronchodilator, associated with asthma morbidity? 2000 Journal of Clinical Epidemiology. 53(12):1217-21

Shepherd G.L., Hetzel M.R. and Clark T.J. 1981. Regular versus symptomatic aerosol bronchodilator treatment of asthma. British Journal of Diseases of the chest. 75(2): 215-7.

Shivpuri D.N., Singhal S.C., and Parkash D. 1972. Treatment of asthma with an alcoholic extract of *Typhori Iindica*: a crossover, double blind study. Annal of Allergy, 30:407-412.

Siersted H.C., Mostgarard G., Hyldebrandt N., Hansen H S., Boldsen J., and Oxhoj H. 1996. Interrelations between diagnosed asthma, asthma-like symptoms, and abnormal airway behaviour in adolescence: the Odense schoolchild study. Thorax 51 :503-505-509.

SIGN (Scottish Intercollegiate Guidelines Network). 1998. Primary Care Managegement of Asthma : A National Clinical Guideline.: SIGN Secretariat, Royal College of Physicians, Edinburgh

Silagy C., Mant D., Fowler G., et al. 1994. Meta analysis on efficacy of nicotine replacement therapies in smoking cessation. Lancet 343 :139-142.

Singh V., Wisniewski A., Britton J., and Tattersfield A. 1990. Effect of yoga breathing exercises (pranayama) on airway reactivity in subjects with asthma. Lancet 335 :1381-1383.

Siriwardena A. N. 1995. Clinical guidelines in primary Care: a survey of general practitioners' attitudes and behaviour. British Journal of General Practice 45 :643-647.

Sly R. M. 1975. Evaluation of a sound-slide programme for patient education. Annals of Allergy 34 :94-97.

Sly P. D., Cahill P., Willet K., and Burton P. 1984. Accuracy of peak flow meters in indicating changes in lung function in children with asthma. British Medical Journal. 308:572-574.

Sly O D., Landau L.I., and Weymouth R. 1985. Home recording of peak expiratory flow rates and perception of asthma. American Journal of Diseases in Children 139 :479-482.

Smeele I.J, Grol R.P, van Schayck C.P, van den Bosch W.J, van den Hoogen H.J, Muris J.W 1999. Can small group education and peer review improve care for patients with asthma/chronic obstructive pulmonary disease? Quality in Health Care. June 8(2):92-8

Smith H., Gooding S., Brown R., and Frew A. 1998. Evaluation of readability and accuaracy of information leaflets in general practice for patients with asthma. British Medical Journal 317 :264-265.

Sowden A., Sheldon T., and Alberti G. 1995. Shared care in diabetes: better evaluation is needed. British Medical Journal 310 :142-143.

Speight A.N. 1978. Is childhood asthma being underdiagnosed and undertreated? British Medical Journal. 2(6133):331-2.

Speight A. N., Lee D. A., and Hey E. N. 1983. Underdiagnosis and treatment of asthma in childhood. British Medical Journal 286 :1253-1256.

Spector SL, Smith LJ, Glass M. 1994. Effects of 6 weeks of therapy with oral doses of ICI 204,219, a leukotriene D4 receptor antagonist, in subjects with bronchial asthma. ACCOLATE Asthma Trialists Group. American Journal of Respiratory Critical Care Medicine; 150(3):618-623.

Spelman R. 1993. Recent asthma guidelines, what are the implications for patient management? Irish Medical Journal 86 :165-167.

Spiegal N., Murphy E., Kinmonth A-L., Ross F., Bain J. and Coates R. 1992. Managing change in general practice: a step by step guide. British Medical Journal 304: 231-234

Sporik R., Chapman M. D., and Platts-Mills T. A. E. 1992. House dust mite exposure as a cause of asthma. Clinical Experimental Allergy 22 :897-906.

Starfield B. 1994. Is primary care essential? Lancet; 344(8930):1129-33.

Stearn R., and Sullivan F. M. 1993. Should practice nurses be involved in diabetic care? British Journal of Nursing 2 :952-956.

Steven K., Morrison J., and Drummond N. 1998. A qualitative investigation of the treatment goals of adult asthmatics. Paper presented Academic and University Departments of General Practice (AUDGP), Annual Scientific Meeting,, Edinburgh.

Storr J., Barrrell E., and Lenney W. 1988. Rising asthma admissions and self referral. Archives of Disease in Childhood 63 :774-779.

Sturdy P., J. N., Pereira F., Griffiths C., Dolan S., and Toon P. et al. 1995. Characteristics of general practices that prescribe appropriately for asthma. British Medical Journal 311:1547-1548.

Tang J. L., Law M., and Wald N. 1994. How effective is nicotine replacement therapy in helping people to stop smoking? British Medical Journal 308 :21-26.

Tattersfield A. E., and McNicol M. W. 1987. Respiratory Disease. In Treatment in Clinical Medicine. London: Springer-Verlag.

Tattersfield A. E., and Holmes W. 1995. Who should look after asthma? Thorax 50 :597-599.

Taylor D.R., Sears M.R., Herbison G.P., Flannery E.M., Print C.G., and Lake D.C. et al. 1993. Regular inhaled beta-agonist in asthma: effect on exacerbations and lung function. Thorax 48 :134-138.
Taylor R. D. 1997. Making the diagnosis of asthma. British Medical Journal 315 :4-5.

Tettersell M. J. 1993. Asthma patients knowledge in relation to compliance with drug therapy. Journal of Advanced Nursing 18 :103-113.

Thapar A. 1994. Educating asthmatic patients in primary care: a plot study of small group education. Family Practitioner 11 :39-43.

Thomas K., Fall M.; and Parry G et al. 1995 National Survey of access to complementary health care via general practice. Medical Care Research Unit, Sheffield Centre for Health and Related Research, University of Sheffield.

Thomas L. 1998. Systematic review of the effectiveness of clinical guidelines in nursing, midwifery and other professions allied to medicine. Newcastle upon Tyne: Centre for Health Services Research.

Thoonen B.P.A., Jones K.P., van Rooij H.A., van den Hout A.C., Smeele I., Grol R., and van Schayck C.P. 1998. Self-treatment of asthma: possibilities and perspectives from the practitioner's point of view. Family Practice, Vol. 16, No.2, 117-122.

Tirimanna P. R. S., van den Boom C., van Schayck C. P. P., den Otten J. J., van Weel C., van Herwaarden C. L. A., van Grunsven P. M., and van den Bosch W. J. H. M. 1996. Prevelance of Asthma and COPD in General Practice in 1992: Has it changed since 1997? British Journal of General Practice 46 :277-281.

Trautner C., Ritcher B., and Berger M. 1993. Cost-effectiveness of a structured treatment and teaching programme on asthma. European Respiratory Journal 6 :1485-1491.

Turner-Warwick M. 1989. Nocturnal Asthma: A Study in General Practice. Journal of the Royal College of General Practitioners 39 :238-243.

UKCC (United Kingdom Central Council) 1999. Fitness for Practice. UKCC, London.

Ullman A., and Svedmyr N. 1988. Salmeterol, a new long acting inhaled b-2 adrenoceptor agonist: comparison with salbutamol in adult asthmatic patients. Thorax 43 :674-678.

Usherwood T., and Barber J. 1988. Audit of process and outcome in a mini-clinic for children with asthma. Family Practitioner 5 :289-293.

Van Schayck CP 1996. Diagnosis of asthma and chronic obstructive pulmonary disease in general practice. British Journal of General Practice March; 46, (4040 193-197.

Vaughan M.T.R., Weber C.R.W., and Nelson H.S. 1989. Comparison of PEFR and FEV1 in patients with varying degrees of airway obstruction. Chest 95 :558-562.

Wanner A. 1995. Is the routine use of inhaled beta-adrenergic agonists appropriate in asthma? American Journal of Respiratory Critical Care Medicine. 151(3 part 1):597-9.

Wardlaw A.J., Dunnette S., Gleich G.J., Collins J.V., and Kay A.B. 1988. Eosinophils in bronchoalveolar lavage in subjects with mild asthma. American Review of Respiratory Disease 137 :62-69.

Wardman A.G., Cooke N.J., Horder E.J., Binns V., and Clayden A.D. 1985. The use of prophylactic drugs for asthma in general practice. Journal of the Royal College of Physicians London 19 :45-47.

Ware J. E., and Sherborne C. D. 1992. The MOS 36 item short-form health survey 1: conceptual framework and item selection. Medical Care 30 :473-483.

Warner J. O., Gotz M., and Landau L. L. 1989. Management of Asthma: A Consensus Statement. Archives of Disease in Childhood 64 :1065-1079.

Watkins C., Harvey I., Langley C., Gray S. and Faulkner A. 1999. General practitioners' use of guidelines in the consultation and their attitudes to them. British Journal of General Practice, 49, 11-15.

Watson A., Lim T. K., Joyce H., and Pride N. B. 1992. Failure of Inhaled corticosteroids to modify bronchoconstrictor or bronchodilator responsiveness in middle-aged smokers with mild airflow obstruction. Chest 101 :350-355.

Weiner P., Azgad Y., Ganam R., and Weiner M. 1992. Inspiratory muscle training in patients with bronchial asthma. Chest 102 :1357-1360.

Wells A., Drennan C., Holst P., Jones D., Rea H., and Thornely P. 1992. Comparison of nedocromil sodium at two dosage frequencies with placebo in the management of chronic asthma. Respiratory Medicine 86 :311-316.

Wempe J. B., Tammeling E. P., Postma D. S., Auffarth B., Teengs J. P., and Koeter G. H. 1992. Effects of budesonide and bambuterol on circadian variation of airway responsiveness and nocturnal symptoms of asthma. Journal of Allergy and Clinical Immunology 90 :349-357.

Wensing M., van der Wijden T., and Grol R. 1998. Implementing guidelines and innovations in general practice: which interventions are effective? British Journal of General Practice 48 :991-997.

West E., and Newton J. 1997. Clinical guidelines: An ambitious national strategy. British Medical Journal 315 :324.

White P. T., Pharoah C. A., Anderson A. R., and Freeling P. 1989. Randomised controlled trial of small group education on the outcome of chronic asthma in general practice. Journal of the Royal College of General Practitioners 39 :182-186.

Wilcock M. 1998. Primary non-compliance with prescriptions for inhaler devices. The Asthma Journal, March 1998 .

Wilding P., Clark M., Thompson Coon J., Lewis S., Rushton L., Bennett J., Oborne J., Cooper S., and Tattersfield A. E. 1997. Effect of long term treatment with salmeterol on asthma control: a double blind, randomised crossover study. British Medical Journal. 314:1441-1446.

Wilkens J.H. 1990. Effects of PAF-antagonist (BN 52063) on bronchoconstriction and platelet activation during exercise induced asthma. British Journal of Clinical Pharmacology, 29:85-91.

Wilkinson J., and Holgate S. T. 1996. Candidate gene loci in asthmatic and allergic inflammation. Thorax 51 :3-8.

Williamson J. W., German P. S., Weiss R., Skinner E. A., and Bowes F. 1989. Health Science information management and continuing education of physicians. Annals of Internal Medicine 34 :598-604.

Wilson D.M., Taylor D.W., and Gilbert R. et al. 1988. A randomised trial of a family physician intervention for smoking cessation. Journal of the American Medical Association 260 :1570-1574.

Wilson S.R., German D.F., Lulla S., Chardon L., Starr-Schneidkraut N., and Asham G.M. 1993. A controlled trial of two forms of self management education for adults with asthma. The American Journal of Medicine 94 :564-576.

Wong C., Cooper S., Britton J.R., and Tattersfield A.E. 1993. Steroid sparing effect of nedocromil sodium in asthmatic patients on high doses of inhaled steroids. Clinical Experimental Allergy 1993 :370-376.

Wood R. A., Chapman M.D., Adkinson N.F. jr., and Eggleston P. A. 1989. The effect of cat removal on allergen content in household dust samples. Journal of Allergy and Clinical Immunology 83 :730-734.

Woolcock A., Rubinfield A.R., and Seale J P. 1989. Asthma Management Plans. Medical Journal of Australia 151 :650-652.

Woolf S. H. 1992. Practice guidelines, a new reality in medicine. Archives of Internal Medicine 152 :946-952.

World Health Organisation. 1978. Alma Ata Declaration. Copenhagen: Regional Office for Europe.

World Health Organisation. 1991. Guidelines for Defined Daily Doses. Oslo: World Health Organisation Collaborating Centre for Drugs Statistics Methodology.

Worrall G., Chaulk P., and Freake D. 1997. The effects of clinical practice guidelines on patient outcomes in primary care: a systematic review. Canadian Medical Association. 156 :1705-1712.

Yoon R., McKenzie D. K., Bauman A., and Miles D. A. 1993. Controlled trial evaluation of an asthma education programme for adults. Thorax 48 :1110-1116.

Yuen P., and Balarajan R. 1989. Unemployment and patterns of consultation with the general practitioner. British Medical Journal 298 :1212-1214.

Bibliography

Audit Commission. 1994. A prescription for improvement: towards more rational prescribing in general practice. London: HMSO.

Bowling A. 1997. Measuring Health. Open University: Buckingham Philadelphia.

Bulletin of European Respiratory Physiopatholoy, 1983 Tables for Predicted FEV1, FVC and PEF, 19, Supplement 5 pages 1-95.

Harrison B.D.W. 1995. Guidelines for the management of asthma in adults. Edited by S.T. Holgate. Volume no. 6. Horizons in Medicine. London: Blackwell Science.

Jenkinson C., Wright L., and Coulter A. 1993. Quality of life measurements in health care. A review of measures and population norms for the UK SF-36. Oxford: Health Services Research Unit.

Lane D.J. 1996. Asthma clinical features and management, in Oxford textbook of medicine, edited by D.Wetherall, J.Ledingham and D.Warrell. Volume 2, third ediction. Oxford. Oxford University Press.

Machin D., and Campbell M. 1987. Statistical tables for the design of clinical trials. Oxford: Blackwell.

Mann T. 1996. Clinical guidelines: using clinical guidelines to improve patient care within the NHS. Leeds: NHS Executive.

O'Brien K. 1993. Improving survey questionnaires through focus groups. Edited by D. Morgan, Successful Focus Groups. London: Sage.

Pearson M., Goldacre M., Coles J., Amess M., Cleary R., Fletcher J., Mason A., Dixon P., Eastwood A., (eds). 1999. Outcome Indicators for Asthma: Report of a Working Group to the DOH. Oxford: Centre for Health Outcomes Development.

Polgar S., and Thomas S.A. 1995. Introduction to research in health sciences. Third Ediction. Ed. Melbourne: Churchill Livingstone.

Sackett, D.L., Haynes, R.B.,Guyatt, G.H., and Tugwell, P. 1991 Clinical Epidemiology: A basic science for clinical medicine. Little, Brown and Company, London (2nd Ed.)

Tager I. B., Segal M. R., Speizer F. E., and Weiss S. T. 1988. The natural history of forced expiratory volumes. The effect of cigarette smoking and respiratory symptoms. American Review of Respiratory Diseases 138 :837-849.

Thomas C., Greenfield S., and Carter Y. 1997. Research Methods in Primary Care. Edited by Y. Carter and C. Thomas. Abingdon: Radcliffe Medical Press;49-61.