# MANAGING ASTHMA
# IN
# PRIMARY CARE

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## A TWO YEAR OBSERVATIONAL STUDY OF REAL LIFE MEDICAL PRACTICE

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## DECLARATION

The submission of this thesis represents all my own work and I have acknowledged the assistance given in the collection of some data by year III BSc (Hons) Physiotherapy students under my supervision.

Data obtained from testing the reliability of the Q score were presented at the European Respiratory Society, Annual Congress, Berlin, in September 1997. Data from the initial patient assessment were presented at the British Thoracic Society, Winter Meeting, London in December 1997. This data has also been published in Thorax, the Journal of the British Thoracic Society.

Data from the assessment at year one were presented at the American Thoracic Society, American Lung Association, International Conference, San Diego in April, 1999 and the European Respiratory Society Annual Congress, Madrid, in September 1999.

Data from the assessment at year two were presented at the American Thoracic Society, American Lung Association, Canadian Lung Association, International Conference, Toronto, in May 2000.

## ABBREVIATIONS

| | |
|---|---|
| **AQLQ** | Asthma Quality of Life Questionnaire |
| **BTS** | British Thoracic Society |
| **CDM** | Chronic Disease Management |
| **COPD** | Chronic Obstructive Pulmonary Disease |
| **CRQ** | Chronic Respiratory Questionnaire |
| **DOH** | Department of Health |
| **$FEV_1$** | Forced Expiratory Volume in One Second, measured in Litres |
| **FVC** | Forced Vital Capacity, measured in Litres |
| **GP** | General Practitioner |
| **GRASSIC** | Grampian Asthma Study of Integrated Care |
| **HAD** | Hospital Anxiety and Depression scale |
| **HRQL** | Health Related Quality of Life |
| **LWAQ** | Living with Asthma Questionnaire |
| **NAEP** | National Asthma Education Programme |
| **NHP** | Nottingham Health Profile |
| **NHS** | National Health Service |
| **PEF** | Peak Expiratory Flow, measured in Litres per minute |
| **PEFM** | Peak Expiratory Flow Metre |
| **PEFR** | Pear Expiratory Flow Rate, measured in Litres per minute |
| **QoL** | Quality of Life |
| **RCP** | Royal College of Physicians (London) |
| **SF36** | Short Form 36 |
| **SIP** | Sickness Impact Profile |
| **TLC** | Total Lung Capacity, measured in Litres |
| **WHO** | World Health Organisation |

## ABSTRACT

Guidelines for the management of asthma in the UK have been published (BMJ, 1990, Thorax, 1993 and 1997) and embraced by many GP practices with improved outcome for patients. The study aims to observe and follow a cohort of adult asthma subjects from differing primary health care settings over a two-year period. Also to assess a newly devised patient focused morbidity index (Q score) by comparison to an established asthma specific quality of life questionnaire (AQLQ, Juniper *et al,* 1993).

One hundred and fourteen subjects from four GP Practices, two inner city and two suburban were studied. Morbidity was assessed by AQLQ and Q score (Rimington *et al*, 2001), psychological status by the hospital anxiety and depression (HAD) scale (Zigmond and Snaith, 1983). Spirometry values (forced expiratory volume in one second, $FEV_1$), peak expiratory flow (PEF) and details of current treatment as per BTS guidelines treatment step were recorded as markers of asthma severity. Subjects were assessed at baseline, twelve and twenty-four months. A random sub set of patients was asked to repeat certain elements of the study protocol at two weeks in order to assess the reliability of the Q score.

The Q score correlated from baseline to two weeks ($r_s$=0.61) as did AQLQ symptom score ($r_s$=0.74) both $p<0.01$. At baseline AQLQ symptoms correlated with PEF ($r_s$=0.40, $p<0.001$) and with BTS guidelines treatment step ($r_s$=0.25, p=0.001) as did the Q score. Similar levels of correlation were reported for $FEV_1$ with symptoms. HAD scores also correlated to AQLQ and Q score, but there was little correlation with lung function. At one and two year follow up no significant differences were observed in subjective or objective markers of asthma. There was a significant increase ($p<0.001$) in the number of subjects in the higher BTS guidelines treatment steps from baseline to twelve and twenty-four months while psychological symptoms remained high for inner city patients.

In conclusion the Q score yields similar results to the AQLQ and is quick and

easy to use in any busy clinic. The GP practice, at the forefront of asthma care should be offering appropriate therapy and regular review. The Q score used as a patient focused morbidity index can be a useful audit tool. Altering medication can give the impression of treating asthma but with out short-term reassessment the same levels of morbidity can persist.

# CHAPTER 1

# INTRODUCTION

## 1.1 Study Background

### *1.1.1 Outcome Measures*

Health outcomes may be thought of as changes that can occur in a subjects' health or health related status or risk factors that can affect their health (Pearson & Bucknall, 1999). In asthma changes that occur can be related to the amount or type of therapy prescribed or taken, or the natural progress of the disease.

Outcome measures used to determine the success (or failure) in the treatment of asthma vary widely. For the individual patient an improved outcome may well be a reduction in symptoms enabling them to carry out unhindered activities associated with daily living. An individual may seek a reduction in medication along with stabilisation of symptoms as an improved outcome. In order to achieve either an asthmatic patient would require individual assessment and review in order to monitor for a successful outcome. This is time consuming for the health professional but essential if a successful outcome is to be achieved for the individual patient.

Health professionals do not always monitor the change of the individual patient often preferring to look at outcome measures for a cohort of subjects with the same disease. Positive outcome indicators for asthma have previously been recorded as a reduction in the days lost from work or school, or a decrease in the number of a patients admitted to hospital for acute exacerbation of their asthma (Lahdensuo *et al*, 1998). While these may indicate to the practitioner an overall improvement in care for the asthmatic cohort the needs of the individual patient may not be realised.

Current medical management for chronic respiratory disease involves the use of inhaled medication to reduce symptoms (BMJ, 1990). Previous studies have investigated the long-term use of inhaled medication (bronchodilators and steroids) in Chronic Obstructive Pulmonary Disease (COPD) (Rimington, 1994). This study used a hospital-based cohort of COPD patients. Part of the study looked at the use of inhaled medication in the long-term management of COPD. Subjects with the best outcome (as measured by lung function and survival rate) were those who had a positive response to oral corticosteroids trial and regularly used inhaled steroids as part of their management (Rimington *et al*, 1993a and b). What the Rimington (1994) study did not investigate was how to monitor patient's response to alterations in therapy.

The majority of patients with chronic respiratory disease are managed in primary care (the GP practice) (Neville *et al*, 1999). It is therefore appropriate for the cohort presented in this thesis to be recruited from primary as opposed to secondary care. Previous research reports have tended to use objective markers of care as outcome measures, eg, improved lung function, fewer days absent from school or work or a decrease in the number of acute admissions to hospital. In the past studies have not used subjective markers as outcome measure. Such markers are important to patients eg, any reduction in dyspnoea for the breathless patient can be seen as a positive outcome. The study presented in this thesis intends to use subjective markers of asthma eg, quality of life (QoL), morbidity and psychological status and objective markers of asthma eg, spirometry, lung function and severity of disease as outcome measures over a two-year period. This will be the first two-year follow up study observing asthma management in primary care.

### *1.1.2 Basis of the Study*

Asthma is one of the common chronic respiratory conditions with up to 4% of adults and 6% of children reporting symptoms at present (Department of Health, (DOH) 1995). Currently asthma affects more than three million people in the UK with this number growing daily. The estimated cost to the National Health Service (NHS) for treatment of asthma was some £511 million in 1995/6 (Office of Health Economics, 1997). The number of prescriptions issued for asthma medication has risen by 75% in the past decade. While some 76% of the asthma population reported days lost from work or school due to their respiratory disease (National Asthma Campaign, 1995).

The provision of a high quality, cost-effective asthma service for the general public would seem to be of prime importance in order to reduce the financial burden on the NHS and to improve QoL for asthma patients. The key to success lies with the patient and GP at the primary care interface. Quick and accurate assessment of patients' asthma status could lead to a responsive tool for management and improved outcome. The aim of this study was to observe the management of a cohort of adult asthma subjects in primary care and to evaluate a new patient focused morbidity index (Q score). A further aim of this study was to establish if the Q score reflects current individual status of subjects within the GP Practice as a whole.

## 1.2 Asthma – Definition, Diagnosis and Problems

### *1.2.1 Current Definition*

Dr Henry Slater, a physician at Charring Cross Hospital, London in his 1868 treatise described asthma as "paroxysmal dyspnoea of a peculiar character generally periodic with healthy respiration between attacks (Slater, 1868). This observation of airway obstruction and reversibility stemmed from his own personal

experience as an asthma sufferer and the observation of the few cases within London available for scrutiny at that time. Some one hundred years later a CIBA Foundation Guest Symposium was convened in an attempt to define asthma, the symposium ended without a definition being agreed upon. (CIBA, 1959). Still controversy remains, though in recent years within the UK the British Thoracic Society (BTS) has gone to some lengths to give health professionals a working definition for asthma though it is by no means universally accepted. The BTS contained within its 'Guidelines for the Management of Asthma' their definition of the disease, (Thorax, 1993)

> *"A common and chronic inflammatory condition of the airways whose cause is not completely understood. As a result of inflammation the airways are hyper responsive and they narrow easily in response to a wide range of stimuli. This may result in coughing, wheezing, chest tightness and shortage of breath and these symptoms are often worse at night. Narrowing of the airway is usually reversible, but in some patients with chronic asthma the inflammation may lead to irreversible airflow obstruction".*

Asthma remains a prominent source of morbidity and cause of mortality within the UK. It is the commonest respiratory disease that affects young and old alike in England (National Asthma Campaign, 1995). Steven and Montgomery (1999) estimated there were approximately 3.4 million people with asthma in the UK (an estimated 6% of the population) with up to 2,000 deaths per year attributed to asthma (Keating *et al,* 1984, Burney, 1986, Partridge, 1986, Cochrane, 1993). Asthma remains the only cause of preventable death with a mortality rate that actually rose at one point in time (ratio higher in 1987 than in 1979) despite an increase in the medication available to adequately improve respiratory function (Harrison and Partridge, 1991).

### *1.2.2 The Diagnosis of Asthma*

In its loosest terms the diagnosis of asthma can be based upon the

patient recounting sporadic periods of wheeze associated with breathlessness (Clark *et al,* 1992). Causes for symptoms produced are many and various, what would seem to be important for the patient is the correct diagnosis and management of their symptoms. The diagnosis for asthma is usually based upon the patient's symptoms and a record of their Peak Expiratory Flow (PEF). PEF is the greatest flow that can be sustained for 10 milliseconds on forced expiration when starting from full inspiration (Cotes, 1993). Symptoms, which would indicate asthma would include intermittent wheezing associated with breathlessness, a cough often occurring at night or first thing in the morning, a wheeze related to exercise or respiratory symptoms, disturbed sleep especially in the early hours of the morning. For a more accurate diagnosis PEF readings should be taken over a two-week period, four times per day (first thing in the morning, at lunch, tea and bedtime). If the values recorded are below 70% of the predicted value (for the same age, height and gender) vary by 25% and the lowest scores are first thing in the morning - a diagnosis of asthma can be confirmed. Many subjects taking part in this study will have had their asthma confirmed by the former tool for diagnosis.

For many patients either of the above criteria can be successfully used to obtain a positive diagnosis of asthma. Using a combination of the above a diagnosis of asthma can be given to a patient with assurance. Failure to diagnose asthma correctly and quickly can lead to inappropriate and ineffective treatment (Pearson, 1986).

### *1.2.3 Problems with Asthma Management*

A patient diagnosed with asthma today would have received a very different treatment and management programme some thirty

years ago. Since the 1960's there have been many advances in the development of anti-asthma medication, accompanying this progress has been a change in the management of asthma by health care professionals. Indeed the asthma sufferer of thirty years ago would greatly appreciate these advances (Christie, 1994).

The inflammatory process occurring in asthma used to be dealt with by the use of oral or injected corticosteroids available from the mid 1950s. Side effects associated with the use of oral steroids are well documented (increased appetite, Cushing's syndrome, osteoporosis, peptic ulceration, etc) patients and doctors alike were concerned about such side effects. Inhaled steroids revolutionised the management of asthma in the 1970s. The new inhaled route allowed smaller doses of corticosteroids to be used and delivered to the sites of the inflammatory activity thus reducing systemic side effects. Subsequently inhalation therapy became available for much of the medication used in asthma treatment both bronchodilators and agents other than corticosteroids which reduced inflammation. The means of delivery for all medication altered dramatically in the 1970s. The archaic atomiser sprays used to deliver isoprenaline were replaced by new metered dose inhalers and nebulisers (Christie, 1994).

Hartley *et al* reported in the journal *Nature* for 1968 on a "new class of selective stimulants of adrenergic receptors". This medication relaxed the smooth muscle of the bronchial tree without greatly disturbing the function of the heart. Salbutamol was released in 1969 followed quickly by terbutaline, these were the new adrenergic drugs. Since their development in the late 1960's other agonists have been developed to give longer acting relief of symptoms (Christie, 1994).

In essence the drug therapy for the management of asthma over the past thirty years has consisted of five groups of medication - the cromones, antihistamines, βagonists, theophyllines, and more recently corticosteroids. Treatment has also been improved over the years by the dissemination and implementation of guidelines for the management of the disease. Guidelines have emphasised the increasingly important role of inhaled corticosteroids. The most recently published guidelines were in 1997 (Thorax, 1997). Their advice is probably already outdated with the emerging role of new therapy (leukotriene agonists). The 1997 guidelines comment on the antileukotrienes thus "more studies are needed to provide comparative data before any recommendations can be made".

The publication of national guidelines has lead asthma management to concentrate on the importance of preventative medication (Lipworth, 1999). Inhaled corticosteroids are a powerful anti-inflammatory agent when used in the treatment of asthma. Corticosteroids delivered directly to the airways in relatively small doses (<800 μg/day) can successfully alleviate asthma symptoms (Barnes *et al*, 1998). Cromones also may also be used as preventative medication but are not as effective as corticosteroids. Their use is mainly beneficial to the atopic patient or to the exercise-induced asthmatic. Antihistamines also have a limited role to play being most useful in the management of patients with known allergic trigger factors e.g. fur or pollen. Symptom relief can be alleviated by the use of bronchodilators most commonly agonists but oral theophyllines may still be of use with some patients although their capacity for reversibility is somewhat weak. The anti-inflammatory potential of low dose theophyllines has of late been re-evaluated as a back up to corticsteroids. The slow release preparations can give long acting relief of symptoms for some patients and they remain a useful

adjunct to the management portfolio. However, the main bronchodilator remains the short acting βagonist. This drug is a most effective relaxant of airway smooth muscle. More recently long acting versions have become available. Use of a long acting βagonist can allow the asthma patient to use a lower dose of inhaled cortico steroid producing comparable control to therapy when compared to use of a higher dose of inhaled corticsteroids alone (Pauwels *et al*, 1997).

What may eventually alter guidelines is the effect the newly developed leukotriene agents can have on airway smooth muscle. These agents are effective over a wide spectrum of disease severity and display bronchodilator and anti-inflammatory activity. Unlike other therapy leukotriene agonists can be taken orally which for the non-compliant inhaler patient can be an advantage. Responsiveness does however, vary and as yet there are no definitive recommendations for their inclusion in national guidelines (Lipworth, 1999).

Despite an increase in the variety of medication currently available for the management of asthma and its mode of delivery the control of morbidity and mortality has remained a long-standing problem for the asthma sufferer.

## 1.3 Managing Asthma Today

### *1.3.1 Mortality and Asthma –The Basis for the Development of Guidelines*

Mortality rates for asthma were stable during the first half of the

twentieth century. At the start of the 1960's an increase in recorded mortality was noted in England, Ireland, Scotland, Wales, Australia, New Zealand and Norway (Greenberg, 1965). At the time the increase was thought to be associated with the excessive use of medication delivered by aerosol for the management of asthma. However, Alderson, (1987) noted many reports had since been published suggesting that the increase in mortality was related to an increase in prevalence of the disease, an increase in the severity of the disease, or an increase in the number of episodes reported by patients. At the same time Alderson refuted the link between environmental factors and increased prevalence of asthma. Following Alderson's rebuttal Burney in 1993 restated support for the link between environmental factors contributing to increased prevalence even when taking into account genetic influences over the disease. Opinions constantly change as to the catalyst for the increase in the mortality rates of the 1960's but there remained a significantly raised death rate.

Despite the sudden increase in reported asthma deaths in the 1960's Dirks and Kinsman (1982) stated that asthma mortality remained an infrequent and isolated phenomenon. Janson-Bjerklie *et al* (1992) commented on the under recognition of asthma severity by patient and physician alike as a critical factor in asthma mortality. Acknowledging increased asthma symptoms can be difficult for some patients. They may not wish to visit their GP or present themselves to the Accident and Emergency Department as symptoms increase preferring to manage unaided until such a time as their asthma deteriorates significantly. This is seen as a common phenomenon. Confidential enquiries into asthma mortality have brought to the forefront issues such as those raised by Janson-Bjerklie and others. Many of the reports published over the past thirty years conclude that the majority of

asthma fatalities are preventable citing the less than optimal use of inhaled cortico steroids as a prime cause, (MacDonald *et al,* 1976a, MacDonald *et al,* 1976b, Ormerod and Stableforth, 1980, BTA, 1982, Burney, 1988, Wareham *et al*, 1993, Matsuse *et al*, 1995, Sommerville *et al,* 1995).

The BTS published reports in 1982 and 1984 commenting on the high mortality rates for asthma for two regions from 1979. As opposed to an increase in the use of aerosol therapy the BTS attributed the rise in mortality to be the under use of inhaled corticosteroids (Thorax, 1982, 1984). Sommerville *et al*, (1995) some years later reported findings similar to previous studies. Asthma mortality is preventable and often the result of less than optimal treatment. Sommerville and co-workers concluded that resources should be directed towards primary care, patients, families and the health care professional.

Asthma may be considered as one of the major public health problems in developed countries. Not only is it one of the most common chronic respiratory diseases but prevalence and severity appear to be increasing despite the availability of effective drug therapy. Where asthma mortality rates have been considered unacceptable, national guidelines have been produced and disseminated to health care professionals in primary and secondary care. The following authors have published asthma specific guidelines as a direct result of unacceptably high mortality rates, Woolcock *et al*, 1989, from Australia and New Zealand, Hargreaves *et al*, 1990 from Canada, BTS, 1997 from UK and the National Asthma Education Programme (NAEP), 1997 for USA.

### *1.3.2 The Development of Guidelines for Asthma Management - British Thoracic Society Guidelines for the Management of Asthma, (BMJ 1990, Thorax, 1993 and 1997)*

The BTS guidelines were issued in direct response to the unacceptably high asthma mortality rates (BMJ, 1990). These guidelines were reviewed in 1993 and 1995 (Thorax, 1993 and 1997). Despite the increase in medication available both mortality and morbidity remained high (Pearson, 1986). Following their investigations, the BTS concluded there continued to be over reliance by patients and clinicians on the use of bronchodilator therapy and an under use of both inhaled and oral corticosteroid therapy. Too few objective measurements existed, there was inadequate monitoring of the disease by the health care professions and poor awareness of their severity of asthma by patients (Partridge, 1993).

The guidelines gave a step by step approach to the management of asthma for both adults and children and set the standard for optimal care (Partridge, 1993). The guidelines were also to be used as a basis for patient education in order to establish continuity of care and information. Treatment was based on four components:-

i) objective measurement of airways calibre in order to assess for the correct course of medication and the severity of the patients disease;
ii) optimal use of pharmacology, in order to give the patient genuine relief from their associated symptoms;

iii) environmental control, if trigger factors exist for patients then they are to be isolated and patients advised to avoid the known factor;
iv) patient education.

The emphasis was based upon continuous monitoring by the

health care team of the patients PEF with the minimum of medication required for the maximum relief of symptoms. The forefront for the implementation of the guidelines has been within the primary health care setting. The responsibility for delivery of care lies with the GP and the primary care team. Recent reforms within the NHS have been directed towards chronic disease management in primary care. The majority of GP practices within the UK participate in the chronic disease management programme which now requires GP's to annually review all asthmatic patients (Charlton *et al*, 1991).

In order to comply with the chronic disease management programme asthma clinics have been established within general practice in order to offer patients structured and well-monitored care (Charlton *et al,* 1992). To many GP practices and their health care team, the concept of an asthma clinic has been a radical method of managing patient and condition (Charlton, 1989). The emphasis of care is a partnership between practice and patient. The asthma clinic itself requires little in the way of resources save time and the enthusiasm of a member of the health care team (usually the practice nurse). Patients attending the asthma clinic can expect to be given a self-management plan, this includes how to recognise deterioration in their asthma and when to adjust their medication (Hayward and Levy, 1990). This is normally conducted with the use of peak flow meter and asthma diary cards.

The establishing of asthma clinics created a new role for GP and practice nurse (Charlton, 1989). Rather than prescribe treatment for the patient on a self-referral basis the GP or more commonly practice nurse empowers the patient to take control of their disease. This giving of information by health care professional in

the treatment and management of asthma was a departure from old practices. This alteration in the role of the patient is said to lead to a better outcome (Wilson, 1993) as measured by morbidity and days lost from work or school. This study intends to observe this process of care in the primary care setting.

The publication and promotion of guidelines within the UK has improved the management of asthma in primary care but there would appear to be a discrepancy between the recommendations for management and compliance by clinicians (Neville *et al*, 1997, Legorreta *et al,* 1998, Picken *et al,* 1998).

## 1.4 Assessing Asthma

Success in the management of asthma is often viewed by the clinician in relation to spirometry and PEF. The closer the patient's recorded readings of $FEV_1$ and PEF are to 'normal', the more control the patient has achieved by the use of medication over symptoms. The diagnosis of asthma relates to PEF values as stated in 1.2.2, which can be considered as an objective marker of asthma severity. What may not always be considered by the clinician is the patient's response to other factors associated with their disease process. Juniper *et al* (1998) noted that physicians have come to appreciate the importance of evaluating functional impairment associated with the disease process when assessing patients, although asthma specific QoL scores are known to correlate poorly to objective markers. Juniper and colleagues also commented on the differences observed in QoL scores (emotional, environmental, activity and symptom related values) for subjects with identical objective markers of asthma severity. Subjects with good, near normal lung function may report what they consider to be increased symptoms associated with poor QoL while others will report little interference with QoL. QoL may be viewed as a subjective marker of asthma but for the patient it may be a more relevant indicator of asthma control.

### *1.4.1 Health Related Quality of Life (HRQL)*

The concept of HRQL has in medical terms a brief history. Quality of life was only considered by the World Health Organisation (WHO) in 1947 to be a health component. The WHO viewed QoL in relation to physical, mental and social well being along side other health measures. Quality of life may be considered as a "final health outcome" focusing on the person, not the disease and how that person intrinsically feels despite what objective clinical evidence may be present. HRQL includes the functional status of the patient, assessing their ability to perform activities of daily living of a physical, mental and social nature. The terms "functional status" and "health status" are often used interchangeably with HRQL, and while acknowledging a precise definition does not exist MacKeigan and Pathak, (1992) have proposed a hierarchical structure for these concepts. On the lowest level is "functional status", incorporating physical, psychological and social status. Pashkow (1996) suggested physical function includes self-care, mobility, physical activity and communication; that psychological function encompasses personal relationships, thoughts of the future and feelings about critical life events; and that perceptions of work, social performance, family support and material welfare are important aspects of social functioning. Above "functional status" is "health status", which includes physiological status and patient well being. Above this lies HRQL, encompassing the previous two categories and general life satisfaction.

Others considered HRQL to include physical, psychological and social domains with or without specific consideration for symptoms, perception of general health, role function, cognition or economic factors (Oldridge, 1997). However, Jenkins *et al* (1990) suggested there is a general consensus that HRQL is a multidimensional construct. Jette and Downing, (1994) support Jenkins view but would also suggest that any patient's goal when

complying with therapy is for an improvement in HRQL.

Patient's QoL can be severely affected by their asthma symptoms, emotional state, or exposure to environmental triggers. The impact of asthma on patients QoL varies considerably from a nuisance to life threatening (Steven and Montgomery, 1999). Many asthmatic subjects are concerned about their asthma status according to the National Asthma Campaign Helpline. Patient concerns include their medication and associated side effects, inconsistent advice from their GP and other health professionals and a failure to implement self-management plans. Also a perceived lack of specialist asthma knowledge in some cases, delays and incorrect diagnosis, as well as concerns about the avoidance of trigger factors, symptom control, asthma death and the cost of prescribed medication. Any combination of the above can lead to a deterioration in health related QoL for the asthma patient. There can also be an impact on the family of the asthmatic. Steven and Montgomery (1999) reported that the burden of asthma can be reflected towards other family members and cohabitees of asthma patients who most commonly complain of sleep disturbance.

According to Schmier *et al*, 1998 studies into the relationship of asthma to QoL are recent phenomena; most published work dates from the 1990's. Much of the current understanding of the impact of asthma on QoL originates from work carried out to develop asthma specific QoL tools. Preparation for the development of asthma specific QoL questionnaires was based mainly on clinical observational studies, noting that patients with asthma experienced a wide variety of problems in physical, psychological and social aspects of life. In work carried out by Juniper and colleagues (1992), Juniper commented that asthma patients regardless of severity were concerned with symptoms, exposure to environmental irritants, levels of activity of daily living and emotional problems. Similarly when Marks *et al,* (1992) were developing their asthma specific QoL questionnaire in Australia, they found that patients were concerned about emotional functioning, symptoms, activity restrictions, social interactions and disease control. Hyland *et al,* had already noted earlier (1991) that HRQL was an important issue for asthmatic subjects.

Juniper (1998) stated that HRQL "has emerged as an important component of health care". The QoL of an asthmatic subject can be influenced by clinical intervention, patients seek advice from health professionals if they consider their function to be impaired. Yet clinicians do not include assessment of elements of QoL in routine care. At present there are a number of validated QoL instruments available but many are too long and cumbersome to be used in routine clinical practice.

There are two types of instruments for measuring QoL, the generic QoL questionnaire and the disease specific QoL questionnaire. The generic instrument can be used to assess different diseases with each other and reflect the burden of illness across a variety of conditions. Such generic QoL tools include the

Short Form 36 (SF-36) (Stewart *et al*, 1988), the Nottingham Health Profile (Hunt *et al*, 1980) and the Sickness Impact Profile (SIP) (Berger *et al*, 1981). Such generic tools are by their nature none specific to the problems associated with any one disease and may therefore not highlight patients perceived problems or small but important changes in their QoL. Disease specific tools look at problems and limitations those patients with a particular disease experience on a daily basis. Such tools are normally developed by asking the patient what do they perceive as major impairments linked to their disease (Juniper *et al*, 1998). The St George's Respiratory Questionnaire (Jones *et al*, 1991) is a tool used for measuring QoL in subjects with airways disease as is the Chronic Respiratory Questionnaire (CRQ) (Guyatt *et al*, 1987). Asthma specific QoL measures have also been developed eg, Living with Asthma Questionnaire (LWAQ) (Hyland *et al*, 1991) and the Marks *et al*, AQLQ (1992).

Juniper and co-workers (1992) developed the Asthma Quality of Life Questionnaire (AQLQ) by asking patients to "identify problems that were most troublesome in their day-to-day lives". The AQLQ as previously stated has four domains and the asthma patient considers problem areas, which subsequently may affect their lives on a daily basis: symptoms, emotions, environmental stimuli and activity limitations. Patients using the AQLQ are asked to respond to each of thirty-two items using a seven-point scale (range, 1 totally limited – 7 no limitation). Rutten-van M✱lken *et al* (1995) compared asthma specific and generic QoL tools when assessing the effects of medication on asthma QoL. Rutten-van M✱lken concluded that the AQLQ responded well to improvements in QoL as noted by subjects receiving treatment. Ware *et al* (1998) also commented that when comparing disease specific and general QoL measures, the disease specific tools proved more valid than their generic counter parts. The AQLQ

has been evaluated extensively, showing excellent reliability and responsiveness with strong cross-sectional and longitudinal validity (Juniper *et al*, 1998). The current study presented in this thesis used the AQLQ as a means of assessing QoL in asthma subjects over a two year period and used the symptom domain specifically to evaluate a newly devised morbidity index.

### *1.4.2 Morbidity Indices*

The development of asthma specific QoL assessment tools usually uses subjects with that disease and/or health professionals familiar with the condition as the initial contact. This mixed group is then required to generate items that they consider bothersome or impairs in some way their activities of daily living. Developed asthma specific QoL instruments contain items relating to symptoms of the disease eg, wheeze, breathlessness, sleep disturbance. The increase in morbidity is perceived by asthma subjects to be detrimental to their daily lives, indeed, increased morbidity can often be the precursor to seeking help from the clinician. While developing the AQLQ, Juniper and colleagues noted asthma morbidity proved to be an area of concern for subjects. When devising the symptom domain, symptoms relating to asthma had the highest impact factors with no score less than 2.01 (range 5 extremely important – 1 not important) in comparison to other domains featured in the score (emotional, environmental and activity domains) (Juniper *et al*, 1997). Morbidity indices have been developed in parallel to QoL questionnaires and have been used as an assessment tool in their own right (Jones *et al*, 1992b).

Jones (1991) and Jones *et al*, (1992a) responded to the reported increase in mortality rates by devising the Jones Morbidity Index, that has subsequently been revised (Jones *et al,* 1999). Noting that the majority of asthma subjects were treated in the

community, Jones targeted these subjects. The Jones Morbidity Index was developed using the symptom of wheeze (during day and night) and interference with daily activity by asthma. Jones and co-workers concentrated on the development of a short morbidity index for use in routine clinical interventions, which was useful as an outcome measure when monitoring health care. Jones and co-workers acknowledged that morbidity indices are useful tools but are not as accurate as QoL instruments that examine the subject more fully. However, Jones stated that morbidity indices used at every scheduled visit to clinic could highlight at risk asthma subjects subsequently improving asthma care.

Steen *et al*, (1994) also recognised the importance of symptom based outcome measures as a tool for monitoring health care in general practice. Steen and colleagues developed a ten-item morbidity index that could be used in primary or secondary care and could monitor symptom reduction over time. The development of the ten-item index again used asthma patients and health professionals with a specific interest in asthma to develop the tool in which wheeze and breathlessness were reported as symptoms creating bother for subjects. Steen and colleagues concluded that the ten-item questionnaire may perform as well if reduced to five items and the outcome of a five-item morbidity index was to be trailed at a later date.

The DOH had in 1995 commissioned a panel of experts to examine what outcome measures were currently available for asthma and to recommend what might be useful for future development. The Q score used within this thesis was developed in response to the need for a patient focused morbidity index that was quick and easy to administer in any busy clinical setting. The Q score was devised as described above using health professional

with specialist knowledge of asthma and piloted by members of the original working party. Items, which were deemed to impinge on activities of daily living were similar to those, reported by the Jones team. Nocturnal disturbance, wheeze, breathlessness and interference with activities of daily living proved to be common items raised by the Q score team. Patients using the Q score are asked to estimate disturbance over a one-week period. Recall is said to be more accurate over a shorter period of time. Questions pertaining to recall over short period are thought to have greater reliability than recall over a longer period though up to a month has been suggested as an acceptable time frame (Pearson & Bucknall, 1999). Steen *et al*, (1994) argued that by choosing too small a recall time span there may be problems with patients not being bothered by symptoms chosen for the morbidity index. The Q score team highlighted wheeze and breathlessness as two of the commonest features of asthma and a week is considered a reasonable time frame for recall and symptom identification. The scoring system is simple to calculate and record and gives an indication of symptom control. The Q score also included a question relating to increase use of medication associated with morbidity, increased usage would indicate poor morbidity control (Pearson & Bucknall, 1999).

Recommendations from the Clinical Effectiveness Unit of the Royal College of Physicians (RCP) (Pearson & Bucknall, 1999) were that a suitable outcome indicator for monitoring asthma should contain a minimum of three questions. Questions should relate to nocturnal disturbance, daytime symptoms (including wheeze) and interference with activities of daily living. The Q score contains these three basic questions, although it also contains a fourth. In this thesis it is proposed to assess the Q score over a two-year period using adult (age 16 – 60 years) asthmatic patients and applying the score to subjects regardless of the

severity of the disease process, thus fulfilling further suggestions contained within the RCP report.

### *1.4.3 Psychological Status*

Psychological status is not a routine assessment tool for the adult asthmatic subject and moreover the influence of psychological factors on outcome in asthma would appear to receive little attention at present (Harrison, 1998). It has previously been reported that psychological status can influence exacerbation of the disease and anxiety and depression are thought by many to be a common feature of asthma (Yellowness and Kalucy, 1990, Michel, 1994, Moran, 1994). Little published work has been presented examining the relationship of psychological status to asthma regardless of severity. Dales *et al* (1989) assessed the psychological status of subjects with respiratory disease in a Canadian epidemiological study. Dales concluded that there was an association between symptoms of respiratory disease and psychological status. Janson *et al*, (1994) in a European epidemiological study came to the same conclusions as Dales and co-workers. Many studies have reported the association between near fatal asthma and increased psychological state (Yellowness and Ruffin, 1989, Campbell *et al*, 1995, Harrison, 1998) none have reported the relationship of psychological status regardless of severity.

Anxiety, "the fear of impending adverse events" can be a feature of chronic illness and may indeed contribute to an exacerbation (Morgan, 1994). Some asthma subjects may well have a tendency to sustained states of anxiety, fear of attack further increasing their anxiety state. It has been suggested that such a raised anxiety state may lead to over prescribing of medication (Dahlem *et al*, 1977, Janson *et al*, 1994). High anxiety state patients have been thought to complain of small increases in symptoms more so than

less anxious subjects. Conversely some authors comment on none compliance associated with the denial of asthma symptoms and depressed subjects may well suffer more near fatal attacks of asthma due to their psychological status (Bosley *et al*, 1995). Some clinicians do advocate assessing psychological status, especially for the non-compliant patient, when planning treatment programmes (Bosley *et al*, 1996, Vamos and Kolbe, 1999, Centanni *et al*, 2000). Bosley and colleagues (1995) used the HAD scale to examine psychological status in their asthma cohort when assessing compliance with inhaled medication. They reported a high incidence of anxiety and depression in subjects who were none compliant with their asthma medication. Psychological status can influence how patients react to their asthma, the way in which they cope with asthma and the way in which health professionals respond to them as patients and may therefore affect how they are managed. If patients are noted to have increased psychological status, attention should be given to treatment plans and compliance with this group. Indeed, the relationship between asthma and psychological status remains complex. (Bosley, Corden and Cochrane, 1996).

Zigmond and Snaith, (1983) developed the Hospital Anxiety and Depression Scale (HAD scale) arguing that emotional disorders can be the result of stresses and strains associated with long term disability. Some manifestations of physical disease, which lead the patient seeking a consultation with the clinician, may well be the result of a heightened psychological state and not due to the associated disease process. Conversely, psychological status may be so heightened that small alterations in symptoms can lead to increased distress and a patient who responds poorly to treatment. Although emotional factors are known to influence outcome in asthma the psychological status of the asthma patient cannot always be considered by the clinician in routine clinical practice.

The HAD scale was developed for clinical use to screen patients for any psychiatric disorder. The scale is quick to complete and designed to be self-administered and concentrates on the two most common neuroses, anxiety and depression. The HAD scale contains seven items pertaining to anxiety and seven for depression although Zigmond and Snaith concede that a smaller scale with fewer items may not affect outcome. When totalled, the score is reflective of the subject's current mood and uses three bands grading depression and anxiety. Previous asthma studies have chosen the HAD scale to measure psychological status, Janson *et al*, 1994, Bosley *et al,* 1995, Vamos and Kolbe, 1999. Many asthmatic patients suffer from long term respiratory disease and the study presented in this thesis uses the HAD scale to assess the psychological status of subjects over a two year period.

## 1.5 The Primary Care Setting

### *1.5.1 Development and Organisation of Asthma Care*

The primary care setting may be considered as the GP practice, contact with the GP or primary care health professional such as the practice nurse or asthma nurse. It has been established that the majority of asthmatic subjects (approximately 85%) are routinely managed in the primary care setting (Neville *et al*, 1999, van Schayck, 2001). In 1990, new contracts were negotiated with GPs in England and Wales by the Department of Health and were followed by further government reforms introducing the Chronic Disease Management initiative (CDM) in 1992. Indeed, Jones (1989) advocated monitoring of objective markers of asthma, patient education and assessment of therapy by the health care team but comments that without adequate training and support, few objectives for improvement in care would be achieved.

The CDM initiative required GPs to annually review amongst others, all asthmatic patients (Neville *et al,* 1996). GP practices were required to assess the process of care by creating a register of all asthmatic subjects recording their therapy, monitoring objective markers of asthma (PEF) and noting the number of days admitted to hospital due to disease exacerbation. As early as 1985 Barnes proposed nurse run asthma clinics to improve patient asthma education thus targeting morbidity. In the early 1990's computer access in primary care was limited and it is only since the nation wide introduction of computerised registration for patient and prescription monitoring that practices (and funding bodies) are able to assess the organisation and delivery of asthma care. Despite computerisation, the instigation of the asthma register and the proliferation of nurse run asthma clinics some studies suggest that patients are reluctant to attend for annual review. With less that half the expected number of subjects attending nurse run asthma clinics (Dickinson *et al*, 1997, Gruffydd-Jones *et al*, 1999).

### *1.5.2 Nurse Run Asthma Clinics in Primary Care*

Since the introduction of the 1990 new GP contracts and the CDM initiative, the role of the nurse in primary care has altered considerably and especially in the management of the asthma patient. Nurse-run asthma clinics are now widespread throughout the UK (Robertson *et al*, 1997). In the late 1980's asthma education was considered an important part of care but despite this input morbidity remained unaltered (White *et al*, 1989).

Since the early 1990's, numerous studies have reported the outcome of the nurse run asthma clinic. Charlton *et al* (1991) was one of the first to report on such clinics. The Charlton group commented on the outcome for patients following the

introduction of patient self-management plans, PEF monitoring and the correct use of inhaled medication in nurse run asthma clinics. Self-management plans for asthma usually involve the patient making decisions regarding their asthma therapy on a daily basis. Patients share the responsibility of disease management with the health care professional. Many self-management plans are based on key stages for the subject pertaining to their normal PEF value. How far below the normal PEF value they fall determines the treatment they should instigate. The implementation of self-management plans by patients are usually carried out following intensive training in the use of inhaled medication (Neville, 1998). Charlton's work concluded that nurse run asthma clinics reduced morbidity, GP consultations and time off from work or school. By adhering to published guidelines these clinics increased inhaled steroid therapy and reduced oral steroid and βagonist use. Charlton advocated the use of nurse run asthma clinics as an effective tool for better asthma care. Other groups also published studies advocating the benefits of nurse run asthma clinics (Pearson, 1986, Hoskins *et al,* 1996) but comment that such positive results may be due to "enthusiasm bias".

More recently Dickinson *et al,* (1998) assessed outcomes for asthma patients following a twelve-month intervention of nurse run asthma clinics. Attendance at nurse run asthma clinics was associated with significant alterations in inhaled therapy and subsequently reduced morbidity. Clinics followed BTS guideline resulting in a shift in therapy reducing bronchodilators and increasing inhaled corticosteroids. Dickinson and colleagues endorse the conclusions of Charlton *et al* (1991) concluding the benefits of nurse run asthma clinics in reduced patient morbidity outweigh increased cost in medication or staffing.

However, not all studies report improvements in care, Jones and Mullee (1995) commented on the proliferation of nurse run asthma clinics throughout the UK. Jones and Mullee's study used two GP practices, one with a nurse run asthma clinic and one without. As with Charlton's 1991 study, outcomes included PEF monitoring and the correct use of inhaled medication. Jones and Mullee also included self-reported morbidity and subjects' attitudes to asthma. Their study drew attention to the increased cost incurred by the GP practice by increased use of inhaled corticosteroid and staffing expenditure but with no significant difference for outcomes between the patients attending the nurse run asthma clinic and those that simply attended their GP practice. However, Jones and Mullee did acknowledge the difficulties associated with clinically based research. Their study argued the case for nurse run asthma clinics remaining unproven, however, they accept large scale random control trials of asthma clinics would prove impossible to conduct. Long term observational studies, such as the work presented in this thesis could assess proactive asthma care and its effect upon the patient.

Care of asthma patients in the community requires a major input by health care professionals. The quality of that care can be dependent upon the interpretation and implementation of published guidelines. With the majority of asthma patients managed in the primary care setting, providing nurse run asthma clinics could serve as a mechanism for monitoring care.

According to Neville and Higgins, (1999) what needs to be established is the means for all asthma patients to receive excellence in their asthma management.

### *1.5.3 Published Asthma Guidelines in Primary Care*

Published guidelines in the UK were developed by specialist groups with an interest in asthma (BMJ, 1990, Thorax, 1993,

Thorax, 1997). However most patients with asthma are treated by non specialists in respiratory care and both the GP and the health care professional involved in asthma management within the primary care setting, usually deal with many other diseases. As non-specialists in respiratory medicine this may in part account for some deficiencies of care (as previously reported by the National Asthma Campaign see 1.4.1). Indeed, the majority of hospital asthma admissions and mortalities are preventable (Horne and Cochrane, 1989). Problems remain at the primary care interface with patient and health care professional alike. Many asthma patients do not recognise the severity of their symptoms, presenting difficulties for management by the clinician. Some clinicians are also unaware of the severity of patient symptoms resulting in under treatment. In both scenarios hospital admission can result and also death in a few cases (van Schayck, 2001). Published guidelines alone may not be able to alter the practice of the patient or the clinician. Van Schayck (2001) cites Smeele *et als*, 1999 study where a group of health professionals providing monitoring and feed back of care resulted in a significant improvement in outcome for their asthma patients. The intervention given to patients by the monitoring and feedback group of health professionals included regular opportunity for patient review and recall, feedback on their PEF, comment on their smoking habit and monitoring of medication. This group was supported by a specialist in asthma care. Van Schayck concluded that successful implementation of guidelines can succeed but required support in terms of feedback, especially for patients difficult to treat, if primary care clinicians are to improve care for patients.

Problems associated with the implementation of guidelines in primary care have been acknowledged (Partridge *et al*, 1998). Although Partridge relates a significant improvement in the

management of asthma patients in primary care by following published guidelines, he also noted the need for vigilance and adequate education. Van Schayck (2001) later commented that for the successful implementation of guidelines adequate educational activities designed to increase health professionals' knowledge and understanding of the recommendations are required, if guidelines are to improve outcome for patients. Primary care clinicians can improve their asthma management if education, feedback and support are offered by clinicians with specialist knowledge (Feder *et al,* 1995).

### *1.5.4 Proactive Asthma Care*

Published guidelines have been embraced by many in the primary care sector with some health professionals becoming proactive in the implementation of good quality care and management. Several primary care health professionals and academics have taken part in assessing the implementation of asthma guidelines but have also developed and piloted their own extended care packages.

The Grampian asthma study of integrated care (GRASSIC) group have published several papers (GRASSIC, 1994, Osman *et al*, 1994, Osman *et al*, 1996) that describe their programme for integrated care between the GP practice and the hospital specialist

in conjunction with the introduction of national asthma guidelines. Asthma patients were initially randomised to receive a mixture of care at their GP practice or an integrated care programme by GP and hospital specialist and possibly including regular PEF monitoring and an enhanced education programme. Patients on the integrated care package received detailed questionnaires regarding their asthma care, as did their GP. Prior to consultation GPs received feed back for each patient and suggestions to improve asthma management. Osman and co

workers argued that the shared care initiated by their programme has lead to improved clinical effectiveness in asthma management.

Again in Scotland, a Dundee based group of hospital, university and GP clinicians has developed a proactive programme of care similar to GRASSIC (Hoskins *et al*, 1998). The Tayside asthma management initiative offers GP practices the opportunity to improve their knowledge in relation to asthma management. Asthma workshops and programmes offer approved postgraduate education for all primary care health professionals involved in asthma care. Difficult to treat patients were targeted in each GP practice with the clinician receiving feedback and suggestions for improved patient management. This group used a slightly different approach to the GRASSIC series of studies as clinical education was achieved by distance learning and computerisation. The Tayside group also advocated shared care as a successful means of achieving improved asthma management (Hoskins *et al,* 2000).

Other groups have used different methods to enhance their asthma programmes. The St George's team based in London has used telephone contact to assess patient morbidity and compliance with inhaled medication as a means of improving outcome for patients (Anie *et al*, 1996). Anie *et al* advocated the use of telephone interviews as a means of successfully monitoring the health status of asthma patients in the community.

The above groups have recognised that successful outcomes for patient care can be achieved but requires considerable effort, the publication of guidelines alone cannot lead to improved care. Specialist have been available to give expert advice in problem

cases and GP and other health care staff have availed themselves of postgraduate education to increase their asthma knowledge thus providing optimal care. Health professionals need to communicate their improved knowledge effectively to their patients. Patient education requires simple and repeated information over time and each consultation with any member of the health care team should contain an element of education. Asthma patients themselves have also been actively encouraged to participate in such programmes, patient education and the use of self-management plans can lead to improved care. The patient and clinician need to work together if a better outcome for the asthmatic is to be obtained, while the GP and primary health care worker require access to specialist support in the community (Partridge, 1995).

### *1.5.5 Reporting from Differing Primary Health Care Settings*

As the majority of adult asthma subjects are managed in primary care it is therefore appropriate for the study presented in this thesis to recruit subjects from that setting (Neville *et al*, 1999). A hospital-based population would include more severe patients that require greater monitoring and care by the clinician and would skew the study population. Asthma is a respiratory disease that can affect any member of society and the present investigation chose to recruit from two differing primary health care settings, inner city and suburban situated practices. This should ensure a suitable cross section of society is recruited. The study intends to recruit subjects that are representative of many GP practices throughout the UK.

Many studies carried out in primary care or use hospital based populations are sponsored by large-scale research bodies or drug companies who may wish to influence the research agenda. The study presented here uses unsponsored research staff with GP

practices and subjects who have been recruited without inducement. Randomised control trials are considered by many to be the "gold standard" research tool (Black, 1996). Yet such studies can be prescriptive in nature, recruiting only subjects that clinicians consider may respond suitably to the intervention giving the desired outcome for the trial. Inclusion criteria may be so exclusive that subjects participating (especially in drug trials) are highly selected and compliant giving rise to a positive outcome for the trial. It is proposed to maintain a wide and inclusive inclusion criteria for the study presented from a cross section of society. It is also proposed to observe clinical practice in its natural setting. Observation is said to be the appropriate technique for reflecting on "real life" in the "real world" (Robson, 1994). This observational study intends to explore the effectiveness of asthma care in the primary health care setting.

## 1.6 Aims, Objectives, Hypotheses

### *1.6.1 Study Aims*

The aims of this study are:-

i) to observe and follow up a cohort of adult asthmatic patients from differing primary health care settings over a two-year period.

ii) to assess a newly devised patient focused morbidity index (Q score) for validity, reliability, sensitivity and specificity by comparison to an established asthma-based quality of a life questionnaire (AQLQ) (Juniper *et al,* 1993).

### *1.6.2 Study Objectives*

The objectives of this two-year follow up study of a number of asthmatic patients:-

Assess patient asthma management over the two-year period by:-

i) Assessing if subjects from different socio-economic groups (inner city versus suburban) report differing levels of asthma morbidity (Q score and AQLQ symptom score), severity (BTS Guidelines treatment step) or psychological status (HAD score) when compared to objective markers of asthma (Spirometry and PEF).

ii) Assessing if asthma morbidity (as measured by Q score and AQLQ) responds to changes in asthma status (as measured by BTS Guidelines treatment step).

iii) Examining the changes in asthma morbidity (as measures by Q score and AQLQ) to psychological status (using the HAD score).

iv) Assessing if alteration in medication as recommended by BTS Guidelines reduces reported levels of morbidity (as measures by Q score and AQLQ).

### *1.6.3 Hypotheses*

The Q score, designed to be a simple patient focused index of morbidity is as reliable as the AQLQ symptom score (Juniper *et al,* 1993) when used to monitor asthma management in a primary health care setting.

The Q score is comparable to the AQLQ score when used to assess for asthma severity (as measured by BTS guidelines treatment step) in a primary health care setting.

Patients in suburban areas have better outcomes (as measured by AQLQ, Q score, HAD score and levels of severity) following treatment intervention than their inner city counter parts.

## 1.7 Summary

The lack of decline in morbidity and mortality related to asthma is well documented (Keating *et al,* 1984, Partridge, 1986, BTS, 1990, Cochrane, 1993) the response of the BTS was to assess the then current management of asthma in the primary health care setting and to subsequently publish their asthma guidelines (BMJ, 1990, Thorax, 1993 and 1997). The response of the NHS to the rising morbidity and mortality rates associated with asthma was the encouragement to establish asthma clinics within the primary health care setting. The impact of asthma clinics is reported to be one of reduced symptoms of morbidity, reduced consultation with the asthma clinic and improvement in days lost from work or school (White *et al*, 1989, Charlton *et al,* 1991, Charlton *et al,* 1992, Wilson, 1993, D'Souza *et al,* 1994).

Information is not currently available for outcomes (as assessed by symptoms of morbidity, reduced consultation with the asthma clinic and improvement in days lost from work or school and QoL) in the primary health care setting where asthma clinics are not a feature of general practice and BTS guidelines are not adhered to thus possibly giving rise to poor asthma care. Many GPs do not identify asthma patients quickly, monitor their patients, share information and prescribe appropriate treatment (Keeley, 1993). The aim of this study is to assess patient outcomes for their asthma using a cohort from GP practices in the inner city and suburbs comparing differing socio-economic groups.

Many studies have used outcome measures related to QoL (Marks *et al,* 1992, Juniper *et al,* 1993), morbidity and attitudes (Charlton *et al,* 1992, Steen *et al,* 1994) as their assessment tool for the patient as an individual. Such studies reflect the important indicators the researcher considers to be necessary to demonstrate an improved outcome for the asthmatic patient.

A comprehensive indicator as to the patients' QoL may include:-

* symptoms of morbidity;
* restriction of activities of daily living which may trigger an attack;
* any side effects of medication used to control asthma;
* need to carry medication and awareness for self-management plan;
* patient anxiety, fear of attack, stigmatisation;
* number of hospitalisations per year;
* days missed from work or school.

At present many questionnaires used to assess outcome measures in clinical practice are long and/or cumbersome (QoL questionnaires eg, Marks *et al,* 1992, Juniper *et al,* 1993 and morbidity index questionnaires eg, Charlton *et al,* 1992, Steen *et al,* 1994). Busy GP practices, regardless of the provision for asthma care require a uncomplicated, yet quick and accurate assessment tool for patient response to treatment. This study will assess if a short symptom related questionnaire can be as successful in monitoring patient outcome as compared to an established, reliable and validated questionnaire (Juniper *et al,* 1993). The short questionnaire (Q score) is a rudimentary patient focused index of morbidity that can be used to interpret and monitor the success of treatment. This questionnaire is short and has been specifically designed to be easy and simple to administer.

Outcome measures should be able to detect any change in a patient's health over time (Steen *et al,* 1994). More importantly they should be used to assess patients desired outcomes. According to Steen *et al,* (1994) morbidity-based outcome measures are more likely to accurately reflect any change in a patient's asthma than an assessment related to general health status. It is therefore vital that the patient fully comprehends the importance of asthma as a symptom related respiratory disease if they are to successfully monitor their own disease process.

Poor or non compliance by a patient with their treatment regimen has been thought to be the result of poor understanding of the disease process and the mode of action of prescribed therapy. With this lack of knowledge the patient perceives no benefit in carrying out medical instructions.

Patient compliance may be defined as "the extent to which patient's behaviour coincides with medical advice" (Cochrane, 1993). With the increased awareness of the importance of self-management for the asthma patient (BMJ, 1990, Thorax, 1993 and 1997) the variety of information (printed matter, audiocassette and videotape) available for the patient has greatly increased. Despite this knowledge being readily available for the patient, compliance remains a problem for the health care team. The problem of non compliance must not rest with the patient alone, the health care team are capable of undermining patient confidence (Keeley, 1993) but compliance can be effectively measured by quantifying patient prescribed medication.

Criteria for an adequate treatment outcome study should include:-

* unbiased subject selection;
* standard treatments;
* clear outcome measures;
* long follow ups;
* large numbers of subjects;
* confirmation of asthma as a diagnosis;
* control of severity of the disease;
* control of use of medication (Hyland, 1994).

With the present media interest in asthma, hardly a day passes by without asthma being brought into the public domain. The continuously high rates in asthma morbidity and mortality are a constant reminder to patient and

health care professional alike that instability still exists within the asthma population. Factors which predispose to high incidence of morbidity and mortality include the lack of patient and health care professional compliance with published guidelines (Thorax, 1993).

This study will attempt to examine patient outcomes from differing socio-economic area areas as measured by community wide social deprivation (Jarman, 1983). Do patients who have a better standard of living fare better than those living with poorer facilities? The importance of appropriate interpretation of published guidelines, as a measure of good practice and its outcome for patients is an important area for review. If the use of guidelines can be associated with patient compliance and a reduction in symptoms of morbidity (and mortality rates) then the advantages of such practice can be used to illustrate good models of care. Using outcome measures as part of an audit tool is at present a common means of evaluation in clinical practice. Outcome measures assessing asthma care are dominated by symptoms of morbidity. What have not been scrutinised are the effects other parameters may exert on the patients desired outcome in relation to QoL. For the clinician, desired outcome may well include reduced symptoms but for the patient there may be other indices. There would seem little point in pursuing certain treatment modalities if this did not give the patient the required end point - a possible reason for non-compliance. It is intended to assess the patient's feelings of anxiety and depression with regard to their asthma and to assess patient's desired outcomes. This may well influence how patients perceive their asthma, the effect asthma has on their activities of daily living, their ability to cope with an asthma attack and their concern at any side effects associated with their current medication.

The best outcome for patients with asthma can be achieved by good communication between patient and health professional. The blame for a poor outcome must be divided between patient and the health care professional (Keeley, 1993). Patients with poorly controlled asthma can

be found within GP practices of good asthma care. It remains easy for the asthma patient to 'slip through the net'. The patient can so often be asked blanket questions that do not probe their current symptoms (Keeley, 1993). By developing a suitable short answer questionnaire this study hopes to establish a framework of questions that can be related to a simple morbidity index relevant to patients and health care professionals as an acceptable outcome measure. It is hoped the Q score will prove to be a quick, reliable and objective assessment tool suitable to be promoted as a means of raising the standard of care for patients.

# CHAPTER 2

# METHODS

## 2.1 Design

This study was planned as a two-year observational study following a cohort of known adult asthma patients based in the community. All subjects were assessed at outset and were invited to attend for reassessment at twelve and twenty-four months. A random subset of subjects were asked to repeat certain elements of the study two weeks after the initial data set had been collected in order to assess the reliability of a newly devised patient focused asthma morbidity score (Q score).

Subjects observed in this study were assessed at their own GP practice or place of residence if more convenient. Baseline data was collected over Winter 1996/Spring 1997, final data collection took place over Winter 1998/Spring 1999. Some 114 subjects were recruited (42 males) from the four GP Practices.

## 2.2 Subjects

### *2.2.1 Recruitment of Primary Health Care Centres (GP Practices)*

Subjects were recruited from four GP Practices situated in close proximity to Aintree Chest Centre in north Merseyside. A number of local GP practices were contacted, four agreed to assist in the study. No incentives apart from individual reports at the end of the study were offered as inducements. Each of the four practices regularly referred patients to the local University Teaching Hospital where Aintree Chest Centre is situated and had previously taken part in activities linked to the acute hospital site.

A visit by the researcher was made to each GP practice. The aims and objectives (see section 1.6) of the study were explained and discussed with practice members (usually the GP with an interest in asthma, practice manager, practice or asthma nurse and records manager).

The facilities required by the researcher to be available over the

two-year period (see Appendix I) were also discussed at this time. If the practice management deemed such facilities would be available the practice was entered into the study. All four GP practices that offered to take part in the study agreed to provide the requirements of the Practice Agreement.

### *2.2.2 Subject Selection*

Participating GP practices were asked to supply the researcher with a complete computer listing of all asthma patients (Reade code [five characters] H33). The practice was asked to exclude from that list all known substance abusers and patients with mental illness who would not be able to co-operate fully with the researcher or where it would be unsafe for the researcher to enter the subjects abode unaccompanied. The practice was also asked to exclude all subjects under 16 years of age and over 60 years of age on the date of agreement to take part in the study. Selected practices had up to 450 subjects with an asthma coding. It was proposed to select approximately forty adult asthma patients from each GP practice for observation.

### *2.2.3 Subject Exclusion Criteria*

Subjects on the GP asthma register under sixteen years of age were considered as children and therefore excluded from the study. Subjects were also excluded if they were over sixty years of age and/or if the had a smoking history greater than twenty pack years. This was felt necessary in order to exclude any potential diagnostic confusion with COPD. Increased age and a long term smoking history are established risk factors associated with COPD. Subjects were further excluded if they had existing Bronchiectasis, other lung pathology or cardiac disease.

Subjects were free to exclude themselves from the study at any

time (see Appendix II).

### *2.2.4 Subject Inclusion Criteria*

Subjects were included in the selection process for the study if they were between sixteen and sixty years of age and if they had been receiving treatment for their asthma from their GP for the previous six months. Such treatment could include any prophylactic inhaler or two or more prescriptions for a β agonist inhaler. Each subject was diagnosed by their GP and subsequently placed on the practice asthma register. Each practice had confirmed at interview that they managed all their asthma patients following BTS published guidelines (Thorax, 1997) (see Appendix III). Thus each subject had had their diagnosis for asthma confirmed by criteria drawn from the current BTS guidelines. This included a record of both the patient's symptoms and their PEFR over a two-week period. Symptoms indicating asthma included intermittent wheezing associated with breathlessness, a cough often occurring at night or first thing in the morning, a wheeze related to exercise and respiratory symptoms disturbing sleep especially in the early hours of the morning. PEFR readings were recorded over a two-week period, twice per day (first thing in the morning and last thing at night). Subsequently a record of PEF variability over a two-week period was attempted as part of the data collection (see section 2.4.1).

### *2.2.5 Subject Selection and Recruitment*

The patient list used in this research for recruitment and selection to the study excluded all subjects under sixteen and over sixty and any asthma subject with lung or heart pathology.

At each GP practice, every eighth patient on the asthma register

was selected, in order to exclude members of the same family (systematic sampling technique). The eighth patient on the asthma register had to fulfil all elements of the inclusion criteria. Subjects who had received asthma treatment in the previous six months were selected for telephone contact. Before telephoning, practice records were used in order to exclude those with bronchiectasis or other pulmonary or cardiac disease, substance abusers and patients with mental illness. If the selected person was ruled out or if on phoning reported a smoking history of greater than twenty pack years, or refused to take part, or were unavailable, the next patient (ie, ninth) was contacted. An attempt was made to recruit forty subjects from each of the four GP practices. Initial recruitment was low and a second attempt at recruiting subjects was sought. The list secured from the GP asthma register was used a second time contacting every eighth patient but from bottom up. Again, if the eighth patient was not available or willing to participate the next patient (ninth) was contacted; the next eighth patient from the last successful contact was then contacted. It was anticipated forty subjects from each GP practice would be entered into the study.

Prospective subjects were informed that the research was being conducted by a local university and subjects would be contacted by a researcher from their GP's practice with their GP's permission. Subjects were informed of the observational nature of the study and the two-year follow up, the use of questionnaires and spirometry. Subjects were not offered any inducement to participate in the study.

Almost half the subjects contacted and invited to participate in the study did not. Subjects who refused to enter the study, cited work commitments, inability to attend GP practice in working hours, home or family commitments and an unwillingness to participate

in home visits. Many subjects worked full time and simply were not available for contact during GP practice hours (9.00 am – 6.00 pm in all cases). Other subjects declined to take part for non-specific reasons. Some subjects who agreed to participate had smoking histories in excess of 20 pack years and therefore excluded themselves. Subjects who were not contactable by telephone were also not entered into the study due to time constraints. No information on subjects who refused to participate was collected.

It proved extremely difficult to recruit forty subjects from each of the four practices subsequently the numbers recruited were as follows:-

- Practice W recruited 30 subjects from 229 patients on their asthma register aged 16-60
- Practice Y recruited 20 subjects from 203 subjects
- Practice S recruited 19 subjects from 189 subjects
- Practice R recruited 45 subjects from 285 patients
- Practices S and Y were situated in the suburbs.

After obtaining informed consent, a total of one hundred and fourteen adult asthma patients agreed to participate in the study.

## 2.3 Equipment and Materials

Equipment and materials used in the study consisted of four Micro Medical hand held spirometers, a patient data sheet (see Appendix IV), two previously validated questionnaires the AQLQ (see Appendices VI) and HAD score (see Appendices VII) and the newly devised Q score contained in Appendix IV.

### *2.3.1 Micro Medical Hand Held Spirometer*

Four hand held spirometers were purchased one for each practice

to be used over the two-year period (Micro Medical Ltd, Rochester, Kent). The spirometers measured PEF, $FEV_1$ and FVC by means of a turbine volume transducer. The turbine drives a low inertia vane, when forced expiration initiates rotations of the vane. Movements of the vane are detected by a closed source of infra red light. This light source reflects onto a sensor that generates electrical pulses, which are computerised into the readings obtained from the spirometer. All spirometers were calibrated by Micro Medical prior to purchase. On delivery each spirometer was allocated to a single practice to be used for data collection relating only to the study. Prior to each set of data collection, at baseline, twelve and twenty-four month's calibration was checked by use of a three-litre syringe. The syringe was attached to the mouthpiece of each spirometer the plunger was withdrawn and the content of the syringe was emptied via the mouthpiece. This activity was repeated three times on each spirometer, readings were taken following each use of the syringe. Readings taken remained unchanged throughout the study period The three litre syringe represented a patients forced vital capacity (FVC) the accuracy was within two percent as suggested by Chowienczy and Lawson, 1982.

The hand held spirometers were used to collect subject's spirometry (PEF, $FEV_1$ and FVC) at outset, twelve months and twenty-four months.

■ **Figure 1 Micro Medical hand held Spirometer**


### *2.3.2 The Patient Data Set*

As much information for the patient data set was recorded from the GP computer files as was possible prior to the initial patient contact. All information recorded was checked for accuracy with each subjects at the initial contact. The patient data set included information regarding the subject's name, address and telephone number for contact purposes (see Appendix IV). The subject's GP practice with computer file number was also recorded. This number was used to identify subjects on the research database (to avoid entering subject's names) and subsequently on GP computer files. Date of birth was also recorded in order to establish predicted vales for spirometry measurements.

Subject's smoking habit was recorded, as was their smoking history. Allergy status was entered for each subject and their occupation was noted though this information was not used in the analysis of this study. Patient's asthma medication was obtained from the computer files as was medication dosage and delivery system. With this information the BTS Treatment Step was calculated (Steps 1-5). The number of hospital admissions for asthma in excess of twenty-four hours was entered as was the number of exacerbations for asthma, which required a visit to the GP or Asthma Nurse. The initial data set registered the number of prescriptions issued for oral steroids, inhaled steroids and βagonists in the preceding six months (this formed part of the inclusion criteria). The subjects height was recorded in order to cite predicted spirometric values. This was followed by recording subject's spirometry (PEF, $FEV_1$ and FVC) using a Micro Medical hand held spirometer. Finally the expected outcome for the last GP visit due to asthma exacerbation was recorded (this information could only be acquired at face to face interview).

At twelve and twenty four months the patient data set was repeated including any change in asthma medication since the previous review. The numbers of repeat prescriptions for oral and inhaled steroids and βagonists were recorded from the patient computer files (see Appendix IV).

### *2.3.3 The Asthma Quality of Life Questionnaire - AQLQ (Juniper et al, 1993)*

A copy of the AQLQ, response options and score sheet as used in this study is shown in Appendix VI. The AQLQ was devised in Canada and as such the list of activities which gives rise to breathlessness included shovelling snow. This was omitted in the version used in this study due to the poor snowfall record in the Merseyside area.

Juniper *et al* (1993) noted, asthma outcomes in the main have consisted of monitoring patients PEF and noting the change in morbidity to medication prescribed and such outcomes do not take into account the influence morbidity exerts on patients activities of daily living. Activities of daily living could well be linked to outcomes the asthmatic patient realistically requires for themselves.

The AQLQ covers four areas of importance for the patient. The four domains cover the degree to which asthma limited the patient in the previous two weeks.

These are:-

- *activities* that are limited by their asthma, (11 items)
- *symptoms* of their asthma, (12 items)
- *emotional* aspects related to their disease, (5 items)
- *environmental* stimuli, (4 items).

The patient responses are on a seven point scale to the thirty-two questions, a low score (1) on the seven point system indicates little effect on health status thus indicating good QoL. The mean scores are calculated for each domain, the overall QoL score is obtained by the mean score from all thirty-two items listed.

Juniper considers that data collected using the AQLQ meets the assumptions for parametric testing (Juniper *et al*, 1992). This study considered the AQLQ to yield ordinal level data thus non-parametric testing was used.

### *2.3.4 The Q Score*

This questionnaire was designed to be short and simple to administer in the primary health care setting and consists of four questions relating to morbidity (an example of the Q score is shown in Appendix IV).

During the past week:-

- On how many days have you wheezed or been breathless?
- On how many nights have you woken because of asthma?
- On how many days has your asthma prevented you doing normal activities?
- How many times are you using your *reliever* inhaler each day?

The subject is asked to reflect upon the questions in relation to the past seven days. Subjects are asked to circle one of three options, 0-1, 2-4 or 5-7 (relating to days per week). The scores are calculated as ordinal data, 0-1 scores 0 which equals symptoms well controlled, 2-4 scores 1 which equals reasonable control of symptoms, 5-7 scores 2 which equals poor control of asthma morbidity.

### *2.3.5 The Hospital Anxiety and Depression Scale - HAD (Zigmond and Snaith, 1983)*

The HAD scale is a fourteen point self-assessment scale suitable for administration in any outpatient clinical situation. It is a useful tool for screening for clinically significant anxiety or depression and is a reflection of the patients feelings at that particular intervention. The HAD scale consists of seven questions relating to anxiety and seven to depression.

Participating subjects are asked to underline one of the option

responses under each question. This can be totalled to give a depression score and an anxiety score. Zigmond and Snaith, (1982) further qualify scores by banding subjects into those with no or moderate or definite symptoms. The scoring system for the HAD ranges from 0-7, for little to no disorder, 8-10 is borderline and 11 and over shows significant depression or anxiety. Information may therefore be considered as ordinal data. A copy of the HAD scale is shown in Appendix VII.

## 2.4 Patient Contact

All assessments took place at the GP practice or in the subjects own home. The researcher was given access to clinic rooms with computer facilities in order to access subject files. GP practices are busy areas and room occupancy was at a premium, this caused severe limitation to times and duration available to the researcher. All GP practices were open on a Monday to Friday 9.00 am to 6.00 pm basis only, evening and weekend sessions were not available.

### *2.4.1 Initial Contact - Collecting the Baseline Data*

Prior to the initial contact each subject was sent a letter with an appointment to attend the GP practice (see Appendix VIII). If a home visit was requested a letter confirming date and time was sent to the subject. Subjects were reminded to take their asthma medication as normal on the day of the initial and subsequent assessments. The subject was telephoned on the day prior to the appointment to remind them of their agreement to attend for assessment.

At the initial appointment subjects were greeted, the aims of the project were repeated and informed consent (see Appendix II) was obtained. Personal details collected from the computer files were checked for accuracy (address, telephone number, and age).

One subject was older than her recorded age, being sixty-one years and was subsequently withdrawn from the study. All other information from the patient data sheet previously recorded from the GP computer files was also checked and verified with the subject. Cross checking highlighted inaccuracies in the smoking histories of some subjects. Verification of subjects smoking history had been obtained initially from GP computer files (this had been reviewed at telephone interview but was reviewed again at the initial contact), if at this stage the subject admitted to a smoking history greater that twenty pack years they were withdrawn from the study. This occurred in 15 subjects with smoking histories ranging from twenty two to eighty seven pack years. These subjects were withdrawn from the study.

*Subjects Spirometry*

Spirometry was measured at each session (PEF, $FEV_1$ and FVC). All measurements were taken using a Micro Medical hand held spirometer with all subjects placed in a sitting position to perform the manoeuvre. Subjects were asked to inhale to total lung capacity (TLC), then to place their mouth around the mouthpiece of the spirometer and to exhale fully as fast as they could and for as long as possible. Each measurement was taken following a questionnaire (regardless of the order in which the questionnaires were randomised) in order not to create undue bronchospasm by asking for three attempts at spirometry at once. The best of the three values was recorded on the subject data sheet (Quanjer *et al*, 1993). All operators unfamiliar with procedures for measuring and recording spirometry and PEF received training in the Pulmonary Function Laboratory of the same large teaching hospital prior to data collection.

■ **Figure 2 Subject using Micro Medical hand held Spirometer**

*Order of Administration of Questionnaires*

Subjects were then invited to draw one of three cards, then one of two, leaving a single card. Each card had a number on the reverse; one, represented patient data sheet and Q score, two, represented AQLQ and three, represented HAD questionnaire. The sequence in which a patient drew the cards represented the administrative order used for the questionnaires at that session.

*The Patient Data Set*

Subjects were asked what asthma medication they were currently receiving, dose and delivery mechanism and if they were using oral steroids on a regular basis. Subjects were asked how many

repeat prescriptions they had received in the preceding six months for each type of medication. Subjects' answers were confirmed against computer records of prescription and uptake. If the subjects' response differed from the prescribed medication the computer files were taken as accurate. All GP practices agreed they adhered to BTS Guidelines (Thorax, 1997) this includes patient self-management plans.

Subjects were asked if they had a personal management plan (see section 1.3.2) and their response was recorded. Subjects BTS Guidelines treatment step was allocated following confirmation of their asthma medication by computer records.

Stability of asthma status was assessed by admission to hospital (in excess of 24 hours) and the number of visits to GP or Asthma nurse for asthma related symptoms in the preceding six months to the study. Subjects were also asked following their previous visit to their GP practice what was their expectation for that visit. (See section 2.3.2 for details of other information obtained from patient data set.)

*Completing the Q Score*

The newly devised Q score was contained within the patient data set. Subjects were shown a copy of the score and where asked to "read this score sheet, think about how "your asthma" has been over the past week, then circle the number of days on the right hand side of the page in answer to the four questions".

*Completing the AQLQ*

When subjects were given the AQLQ to score they were reminded of the first three lines on the score sheet, that the list of activities following was merely suggestive, that they may have other activities that they as asthmatics know are limited by their

asthma and they were free to list these instead. Subjects were given the four colour coded cards and again were reminded that each was for a specific question and to ensure they used the correct coloured card for each question. Subjects were left to complete the AQLQ unassisted. If subjects asked for clarity of any question assistance was given.

*Completing the HAD Scale*

Subjects were also given the HAD scale to score. Subjects were asked to read the opening paragraphs of the HAD score and then to proceed as directed. If subjects asked for clarity of any question assistance was given.

If at any point subjects had difficulty reading questionnaires the researcher read out the content of the questionnaires verbatim.

*End of Assessment*

At the end of the initial contact subjects were asked if they had been prescribed a Peak Flow Meter (PFM). Subjects who had a PFM were asked to keep a daily record of their PF over the next two weeks. They were instructed to record the best of three attempts on the score sheet (see Appendix 5) first thing in the morning and before retiring in the evening. All subjects who agreed to record PF were issued with a stamp addressed envelope to return their peak flow diaries to the researcher.

Each subject was informed that a random subset of subjects would be selected in two weeks, in order to assess the repeatability of the Q score. If selected these subjects would receive the Q score and the AQLQ to complete again and would be asked to return the questionnaires in a stamp addressed envelope (see Appendix 8 for contact letter) to the researcher.

### *2.4.2 Initial Data Set for Each Subject*

- record/case sheet number
- address, phone number
- date of birth
- gender
- GP Practice
- current smoking habit plus pack years
- patient allergy status
- asthma medication and prescribing plan
- operation of patient self management treatment plan
- occupation
- number of hospital admissions in past 6 months
- number of exacerbations of asthma in past 6 months (requiring visit to GP)
- number of oral steroid prescriptions in past 6 months
- number of inhaled steroid prescriptions in past 6 months
- number of inhaled bronchodilator prescriptions in past 6 months
- BTS Guidelines treatment step (steps 1-2 or 3-5)
- predicted spirometry (PEF, $FEV_1$ and FVC)
- measured spirometry (PEF, $FEV_1$ and FVC)
- patients expectation for last visit to GP
- Q score
- AQLQ
- HAD

### *2.4.3 Assessing Q Score Reliability at Two Weeks*

In order to assess the reliability and repeatability of the newly

devised Q score against a reliable and validated questionnaire, at two weeks following the baseline assessment a random sub set of subjects was chosen from the initial database. At each GP practice the second subject on the data file was allocated to the sub-group followed by each alternate subject. Seventy subjects were subsequently contacted at home by sending Q scores and AQLQ questionnaires for completion. Subjects were asked to complete the enclosed questionnaires and return them as soon as completed to the researcher in a stamp addressed envelope.

### *2.4.4 Data Collection at Twelve Months*

After twelve months each GP practice was contacted and an appointment was made in order to access the GP computer files. All subjects recruited at the start of the project had their computer files rechecked in order to establish if they were still alive (one subject deceased at twelve months, cause of death was not related to asthma) and were still at the same address. If they had remained with the GP practice they were considered for review. Prior to contact the GP's computer files on each subject were accessed in order to assess if medication of any subject had altered. Any change was recorded along with the subject's respiratory medication prescription (dose and delivery system), and uptake of prescription recorded.

One hundred and thirteen subjects seen at the start of the project were contacted and invited to attend their GP practice for review. Subjects were contacted by telephone in the first instance and were offered an appointment at their GP practice or home if attendance proved difficult. A letter was sent confirming the appointment time and subjects received a telephone call the day before their appointment reminding them of the arrangements. If the subjects did not attend the first appointment, they were contacted again and offered another appointment at their GP

practice or at their own home. If subjects did not attend for a second appointment they were contacted for a third and final time. Subjects who did not attend for a third appointment were sent copies of the three questionnaires (Q score, AQLQ and HAD) with a covering letter asking them to complete the enclosed questionnaires, return them in the stamp addressed envelope and complete the tear off slip (see Appendix X ). The tear off slip asked the subject if the wished to withdraw from the study or would consider a home visit for collection of spirometry and PEF data. Ninety-five subjects attended, seven withdrew from the study at twelve months, eleven refused to attend, were unavailable or did not attend despite repeated contact.

Subjects who attended for the twelve-month review were assessed using the same procedures for the initial collection of the patient data set (see section 2.4.1). A copy of the twelve-month patient data set can be found in Appendix V.

### *2.4.5 Data Collection at Twenty Four Months*

At 24 months the same procedures for contacting the GP practices and reviewing subjects were repeated as indicated in section 2.4.1 and 2.4.4.

One hundred and six subjects seen at the start of the study were contacted and invited to attend their GP practice for review (from the original cohort of 114 subjects 106 subject were left in the study, one died and seven withdrew at twelve months). Ninety subjects attended for review at twenty-four months (seventy-nine of the ninety had also been seen at twelve months) sixteen subjects withdrew or were unavailable. Only one subject had moved away from the area over the two-year follow up period.

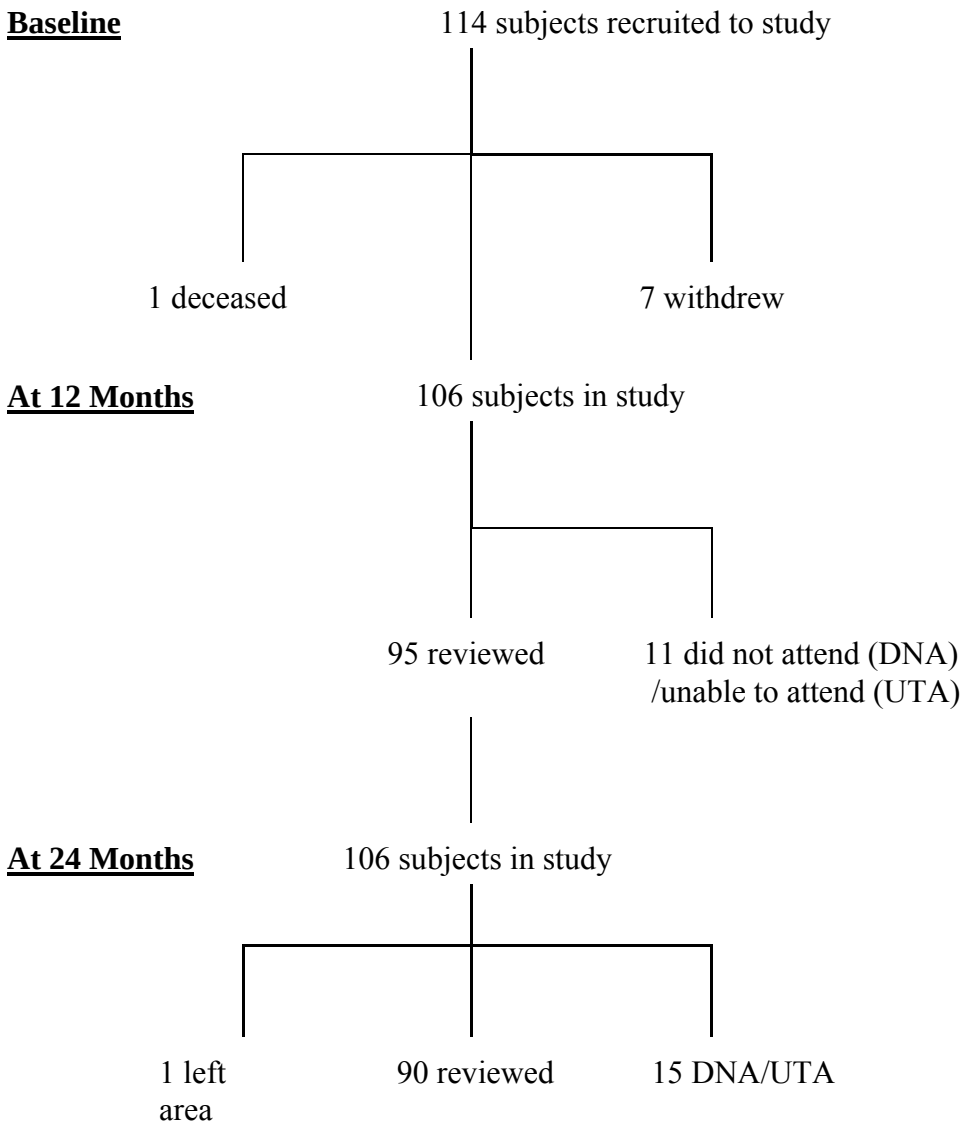
In summary the number of patients starting and progressing

through the study were as follows:-

One hundred and fourteen subjects had been reviewed initially with ninety-five subjects presenting for review at twelve months and ninety subjects presenting for review at twenty-four months. Seventy-nine subjects were assessed at both twelve and twenty-four months. One subjects died within the first twelve months and one moved from the locality.

Each subject was thanked for their contribution to the study and letters of thanks were sent to each GP practice informing them that the study was complete and a report of their individual practice would be available to them upon request.

■ **Figure 3 Flow Chart of Subject Assessment**




**NB: 79 subjects were seen at 12 and 24 months (see Appendix XIII for data)**

## 2.5 Data Analysis

All subject data was transferred from paper data files to SPSS for Windows v 10. To facilitate data analysis five distinct files were created:-

a) baseline data file for 114 subjects
b) twelve months data file for 95 subjects
c) twenty-four month data file for 90 subjects
d) 24 subjects from the baseline data file who withdrew from the study (see Appendix XII)
e) file for 79 subjects with data recorded at baseline, twelve and twenty four months (see Appendix XIII).

Descriptive statistics were used throughout the thesis.

Objective measures of asthma (spirometry and PEF), health status (AQLQ and Q score) psychological status (HAD score) prescribed asthma medication and asthma severity (BTS Guidelines treatment step) were collected throughout the study period (baseline, twelve and twenty-four months). Data were examined for relationships, (correlation design) using Spearman rank order correlation coefficient for non-parametric data. Non-parametric test were used for analysis with the AQLQ, Q score, HAD score and BTS treatment step as scales recorded ordinal level data.

Data were examined for difference, (quasi-experimental design) from baseline to twelve months and baseline to twenty-four months using paired t test or Wilcoxon sign ranks for all subjects or using unpaired t tests or Mann-Whitney U tests for sub-groups.

The level of significance was acceptable at 5% ($p<0.05$).

### *2.5.1 Sub Division of Analysis*

Data from the cohort was subdivided and explored at each stage by the following four sub-groups using experimental analysis.

*Inner City versus Suburban Subjects*

Subjects were divided by their place of residence and locality of GP practice. Two practices were situated in inner city areas with high Jarman (1983) deprivation scores (+18.7 and +13.45), two practices were situated in suburban areas having low scores for deprivation (-19.58 and –18.27). Differences between these two groups in relation to their spirometry and PEF, health status, psychological status and severity were explored by unpaired t test for parametric data or Mann-Whitney U tests for non-parametric data.

*Severity - BTS Guidelines Treatment Step 1-2 versus 3-5*

Severity of asthma was used to further sub divide subjects within the cohort as a whole. Subjects in low BTS treatment step (1 and 2) indicating mild to moderate asthma morbidity were assessed against subjects in the higher treatment steps (3-5) such subjects have less control over their morbidity and require increased medication in order to keep symptoms to a minimum (see Appendix III). Differences between these two groups in relation to their spirometry and PEF, health status, psychological status and place of residence were explored by unpaired t test for parametric data or Mann-Whitney U tests for non-parametric data.

*Depression and Anxiety - Depressed Subjects versus Non-Depressed Subjects*

Zigmond and Snaith, (1983) used three ranges of scores for depression and anxiety. Their scoring system comprised the following scores 0-7, for little to no disorder, 8-10 borderline and 11 plus significant depression or anxiety. In this study the cohort

was subdivided as 0-7 no depression or anxiety, 8 or above, possible depression or anxiety. Differences between these two groups in relation to their spirometry and PEF, health status, severity and place of residence were explored by unpaired t test for parametric data or Mann-Whitney U tests for non-parametric data.

*Medication Changed - Inhaled Steroids Increased versus Inhaled Steroids Reduced/No change*

Subjects' prescription for asthma medication was reviewed at twelve and twenty-four months from baseline. The cohort was sub divided by subjects who had their inhaled steroid prescription increased at the time of the twelve month assessment (twenty-four month assessment) when compared to baseline prescription and subjects with inhaled steroid prescription remaining as at baseline or reduced from baseline. Differences between these two groups in relation to their spirometry and PEF, health status, psychological status, severity and place of residence were explored by unpaired t test for parametric data or Mann-Whitney U tests for non-parametric data.

### *2.5.2 Cross Sectional Data*

*Baseline Data*

Spearman rank order correlation coefficient was used to explore the relationship of subjective measures of asthma such as health status (as measured by Q score to AQLQ) and psychological status (as measured by HAD scale), to spirometry, PEF, severity (as measures by BTS guidelines treatment step) Binary logistic regression analysis was used to identify the variable most strongly linked to morbidity from spirometry, PEF, psychological status and severity.

*Reproducibility of the Q Score*

The reproducibility of the Q score and its' relationship to the

symptom domain of the AQLQ was examined by comparing baseline scores and scores collected from the random sub set of subjects at two weeks using Spearman rank order correlation co-efficient. Q score and AQLQ symptom scores correlate at baseline and at two weeks. The internal consistency of the Q score was measured at baseline and within the sub groups using Cronbach Alpha.

### *2.5.3 Longitudinal Data*

These data were collated at twelve-month intervals throughout the study period (ie, on two subsequent occasions following initial assessment). Differences in spirometry, PEF, health status, psychological status, severity and medication uptake from baseline to twelve and baseline to twenty four months were explored for the whole cohort by paired t test for parametric data or Wilcoxon signed-ranks test for non-parametric data.

Longitudinal data was also explored by the sub-groups in 2.5.1. From baseline to twelve months and baseline to twenty-four months using unpaired t tests for parametric data and Mann-Whitney U tests for non-parametric data.

## 2.6 Ethical Approval

Approval was sort and gained from the local ethics committee, see Appendix XI for copy of letter of approval.

# CHAPTER 3

# Initial Assessment of One Hundred and Fourteen Adult Asthmatics

## 3.1 The Data

This chapter describes the baseline data collected from 114 subjects recruited for the study. This baseline information includes the initial patient data set, the AQLQ, Q score and HAD scale. The data is subdivided as stated in section 2.5.1 by inner city versus suburban subjects, severity as measured by BTS Guidelines treatment step and depression scores. Relationships between established objective measures of assessing asthma (spirometry and PEF) are explored against health and psychological status and severity. The relationship of the Q score to the AQLQ symptom score is also examined at baseline and at two weeks noting the reproducibility of the Q score. All results are discussed within this chapter.

At the initial contact the patient data set was completed for all subjects, as was the AQLQ, Q score and HAD scale, (see sections 2.4.1 and 2.4.2). Spirometry and PEF were also recorded at this stage. At two weeks a random sub set of subjects were asked to repeat the AQLQ and Q scores (see section 2.4.3 and 3.4 where the results are presented).

## 3.2 Exploring the Baseline Data

The baseline data for the population is reported initially for the whole cohort and then to examine relationships within the data set, the cohorts are sub divided as described in 2.5.1. Differences between groups are discussed.

**Table 1: Baseline Values for 114 Asthma Subjects**

| *Variable* | *N=114* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 42 (12) |
| Gender (Males) | 42 | 37 | |
| Subjects living in Inner city | 74 | 65 | |
| Current Smoking | 31 | 27 | |
| Current smokers pack years | | | 3.3 (6.4) |
| Currently using β agonist | 106 | 93 | |
| Currently using inhaled steroid | 95 | 83 | |
| Currently using oral steroids | 8 | 7 | |
| BTS Guidelines Treatment Step (3-5) | 34 | 30 | |
| PEF | | | 353L/min (126) |
| Predicted PEF | | | 463L/min (89) |
| $FEV_1$ | | | 2.23L (0.89) |
| Predicted $FEV_1$ | | | 2.99L (0.62) |
| FVC | | | 2.90L (0.98) |
| Predicted FVC | | | 3.81L (0.72) |
| $FEV_1$/FVC | | 76 | |
| AQLQ score | | | 4.7 (1.2) |
| AQLQ symptom score | | | 4.6 (1.4) |
| Q score | | | 2.7 (2.4) |
| HAD Anxiety | | | 8.3 (4.3) |
| HAD Depression | | | 5.1 (3.9) |

### *3.2.1 An Asthmatic Population*

Table 1 illustrates the initial baseline data for the 114 asthmatic subjects. There were more female subjects recruited than males (72/42) and more subjects were recruited from inner city GP practices than suburban (74/40). Little over a quarter of subjects still smoked (31/114) their mean pack years remaining low (3.3± 6.4).

*BTS Guidelines Treatment Step*

Step 1 - Inhaled βagonists were used by 93% of the population with 18% (21/114) using this type of therapy alone.

Step 2 - Inhaled steroids were used by the majority of subjects with 52% (59/114) of the population using low dose inhaled steroids.

Steps 3-5 - Subjects in these treatment steps, 3-5 accounted for

30% of the population (34/114). There were 22/114 (20%) of subjects in step 3, these subjects required high dose inhaled steroids. With 6/114 (5%) of subjects each in treatment steps 4 and 5.

Few subjects used other prescribed medication for their asthma on a regular basis (theophylline, anticholinergics or sodium cromoglycate).

The population was comprised of relatively stable asthmatics with only two subjects admitted to hospital in excess of 24 hours for their asthma in the preceding six months prior to the commencement of the study. Sixty percent (68/114) of the population did not experience an exacerbation of their asthma in the same period and of the subjects who did, 63% (29/46) received one or more courses of oral steroids for relief of symptoms.

If subjects attended their GP practice for their asthma, subjects were asked what their expectations were for the visit. Fifty percent of the population required better control of their asthma symptoms with 10% complaining specifically of sleep disturbance.

The GP practice was also assessed at the outset of the study as to adherence to and awareness of current guidelines recommended for practice with asthma. All practices said they adhered to current guidelines eg, by prescribing peak flow meters for patients, issuing patients with self-management plans and advice on increasing medication. No practice had a dedicated GP for asthma or an asthma nurse, though all practices had a GP with an interest in asthma management. The practice nurse at each practice ran specific asthma clinics but only one practice ran clinics on a regular basis as recommended.

Spirometry and PEF were recorded for all subjects and were compared to predicted values for age, height and gender (Cotes, 1993). Recorded values for spirometry and PEF were less (though not significantly so) than predicted with $FEV_1$/FVC at 76% of predicted.

Mean values for health status scores as measured by AQLQ and the newly devised Q were 4.7 and 2.7 respectively. The AQLQ score ranges from 1-7, the lower the score the greater the infringement on health status, the baseline score (4.7) indicates only moderate interference in QoL for the cohort. Q score ranges from 0-8, the higher score represents increased morbidity, mean value for the cohort was 2.7 mirroring the AQLQ score and indicating a relatively active population.

Psychological status was assessed by the HAD scale. The mean depression value for the cohort was below the threshold of eight ($5.1 \pm 3.9$) indicating no depression while the mean anxiety score was recorded as ($8.3 \pm 4.3$) just over the threshold of eight points which would indicate slight anxiety.

### *3.2.2 Relationship of Quality of Life Measures to Lung Function and Psychological Status*

Spearman's rank order correlation coefficients for relationships in the baseline data are illustrated in Table 2. The newly devised Q score inversely correlates ($p<0.01$) to the established AQLQ symptom score and overall AQLQ (both $p<0.01$) reflecting the similar levels of patient health status (see Figures 4 and 5).

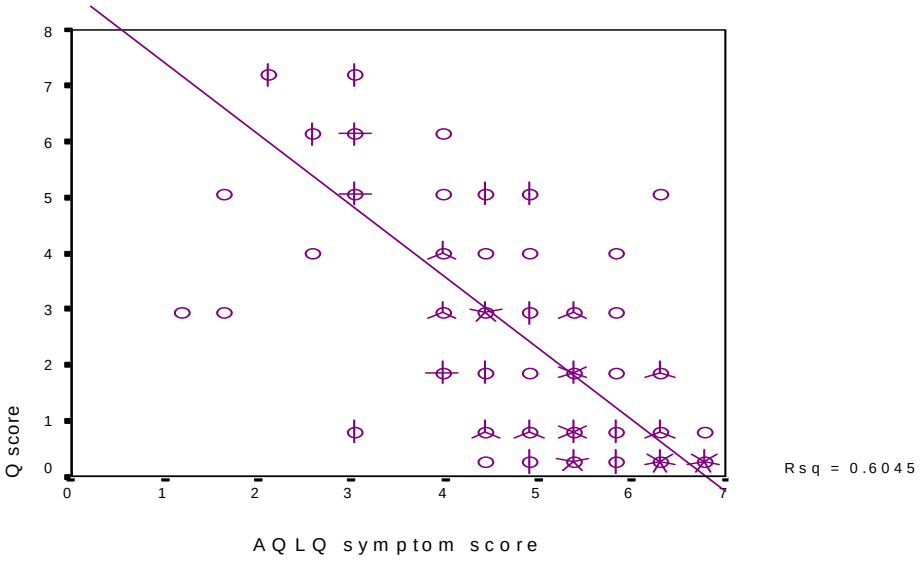
**Table 2: Spearman's Rank Order Correlation Coefficients for the Baseline Data**

| | ***HAD Depression*** | ***HAD Anxiety*** | ***PEF*** | ***$FEV_1$*** |
|---|---|---|---|---|
| PEF | -.160* | -0.095 | | .812** |
| $FEV_1$ | NS | -0.01 | .812** | |
| AQLQ total | -.359** | -.359** | .310** | .316** |
| AQLQ symptom | -.433** | -.352** | .396** | .351** |
| Q score | -.371** | 0.238** | -.444** | -.417** |
| BTS (3-5) | -.240** | NS | NS | NS |
| HAD Depression | | .602** | -.160* | NS |
| HAD Anxiety | .602** | | NS | NS |

| | ***AQLQ Total*** | ***AQLQ Symptom*** | ***Q Score*** | ***BTS (3-5)*** |
|---|---|---|---|---|
| PEF | .316** | .396** | -.444** | NS |
| $FEV_1$ | .316** | -.417** | -.417** | NS |
| AQLQ total | | .898** | -.678** | .217* |
| AQLQ symptom | -.898** | | -.762** | .248** |
| Q score | -.678** | -.762** | | -.415** |
| BTS (3-5) | .217* | .248** | .414** | |
| HAD Depression | -.509** | -.433** | .371** | -.240** |
| HAD Anxiety | -.359** | -.352** | .238** | NS |

Key ** = p<0.01, * = p<0.05, NS = not significant.

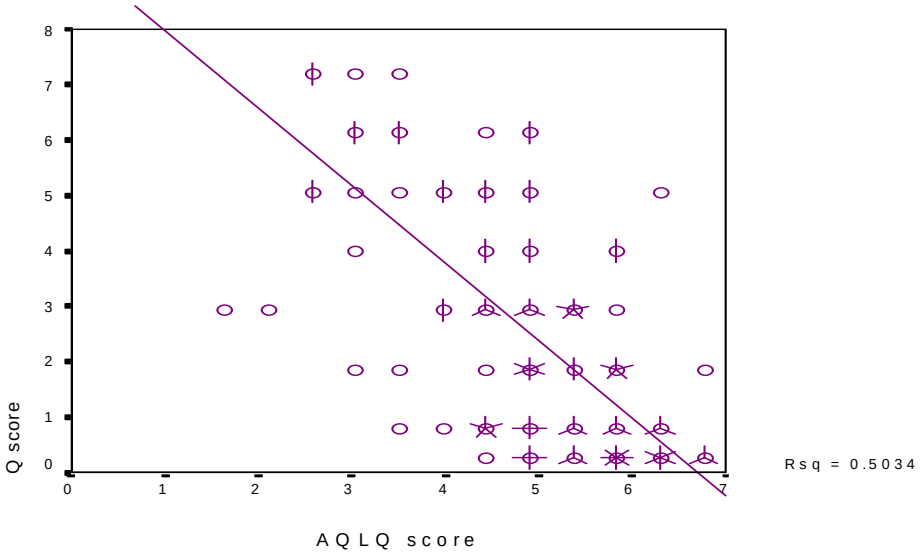
■ **Figure 4** - Scatterplot of the Q scores relationship to AQLQ symptom score (p<0.01).




Key: circle and each subsequent point on all scatterplots denotes one subject.

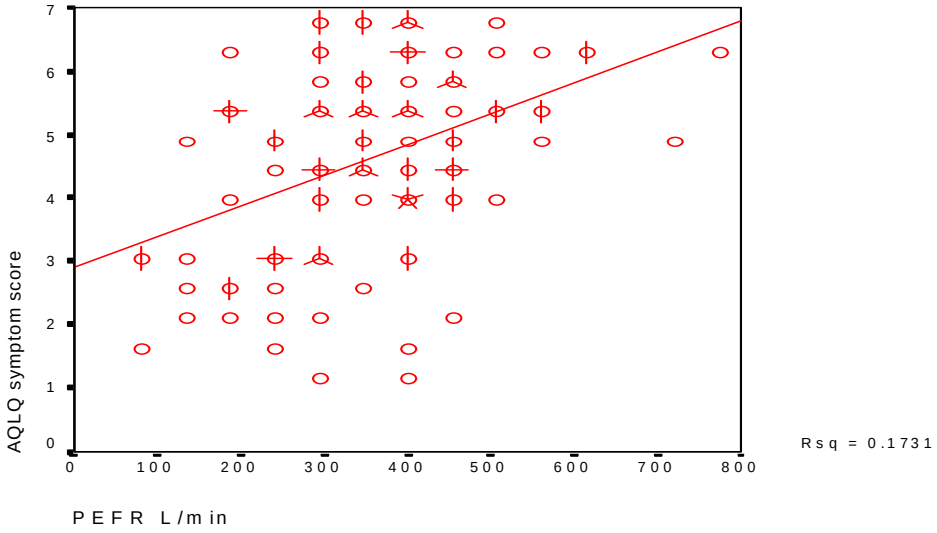
■ **Figure 5 –** Scatterplot of the Q scores relationship to AQLQ

score ($p<0.01$).

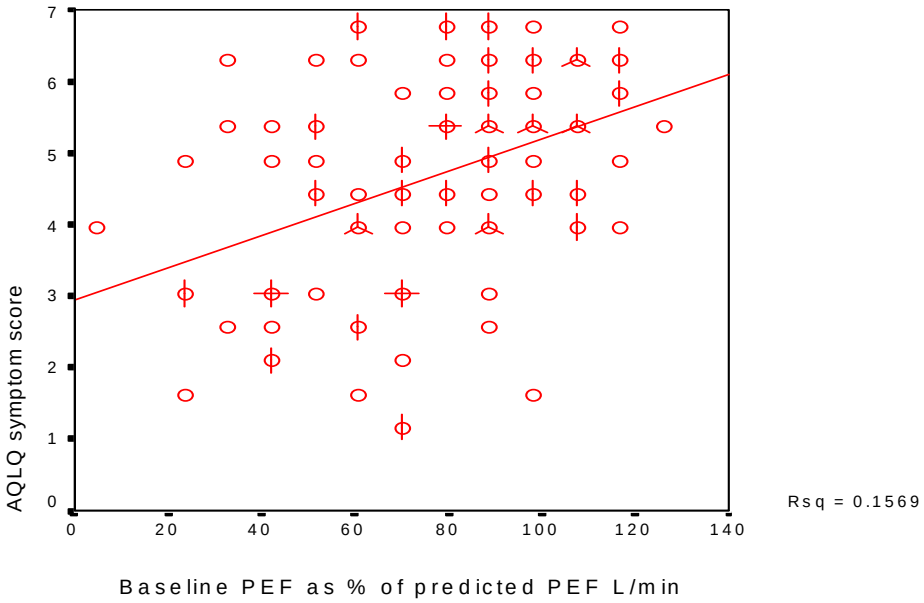



AQLQ total score and symptom score directly correlate significantly (all $p<0.01$) to worsening levels of PEF and $FEV_1$. Subjects with reduced spirometry and PEF i.e. poor lung function due to poor control of the disease process and their associated morbidity have increased symptom scores indicating reduced health status. Figures 6, and 7 illustrate the relationship of morbidity as measured by AQLQ symptom score to PEF and $FEV_1$. Figures 6a, and 7a illustrate the relationship of morbidity as measured by AQLQ symptom score to predicted PEF and $FEV_1$.

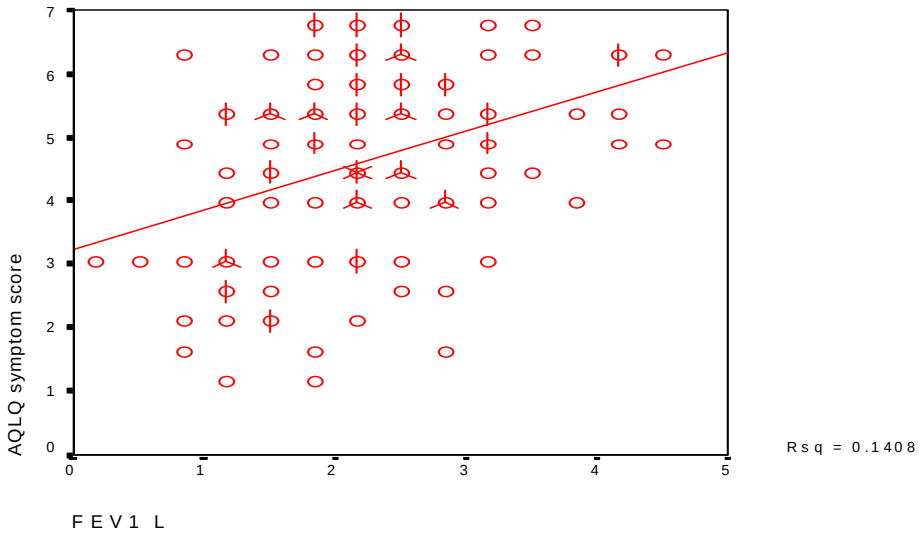
■ **Figure 6** – Scatterplot of lung function (as measured by PEF) to morbidity (as measured by AQLQ symptom score) (p<0.01).



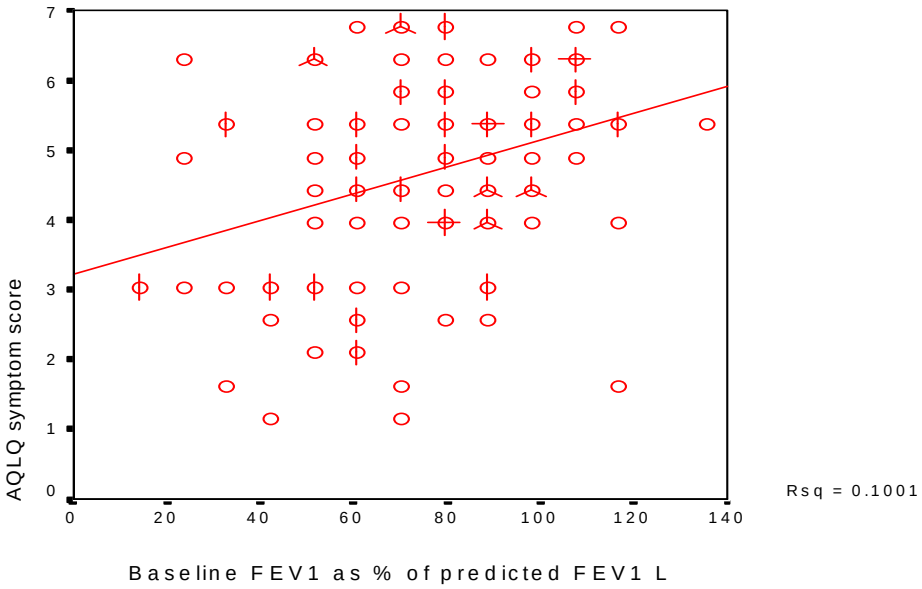

■ **Figure 6a** - Scatter plot of baseline PEF as a percentage of predicted PEF to morbidity (as measured by AQLQ symptom score) (p<0.01)



■ **Figure 7** – Scatterplot of lung function (as measured by $FEV_1$) to morbidity (as measured by AQLQ symptom score) ($p<0.01$)




■ **Figure 7a** - Scatterplot of baseline $FEV_1$ as a percentage of predicted $FEV_1$ to morbidity (as measured by AQLQ symptom score) ($p<0.01$)



Health status as measured by AQLQ inversely correlated ($p<0.05$) with increased levels of treatment as measured by BTS Guidelines treatment step (Steps 3-5) indicating subjects with increased levels of treatment have reduced QoL. Increased levels of morbidity (low AQLQ symptom score) inversely correlated with increased treatment step ($p<0.01$), (see Figures 8 and 9).

Subjects requiring more medication to control symptoms registered higher scores on the morbidity indices used. Although lung function ($FEV_1$) and PEF correlated to the overall AQLQ and morbidity scores, they did not correlate to increased levels of treatment (not significant for both).

■ **Figure 8** – Scatterplot of BTS Guidelines Treatment Step to AQLQ score ($p<0.01$)

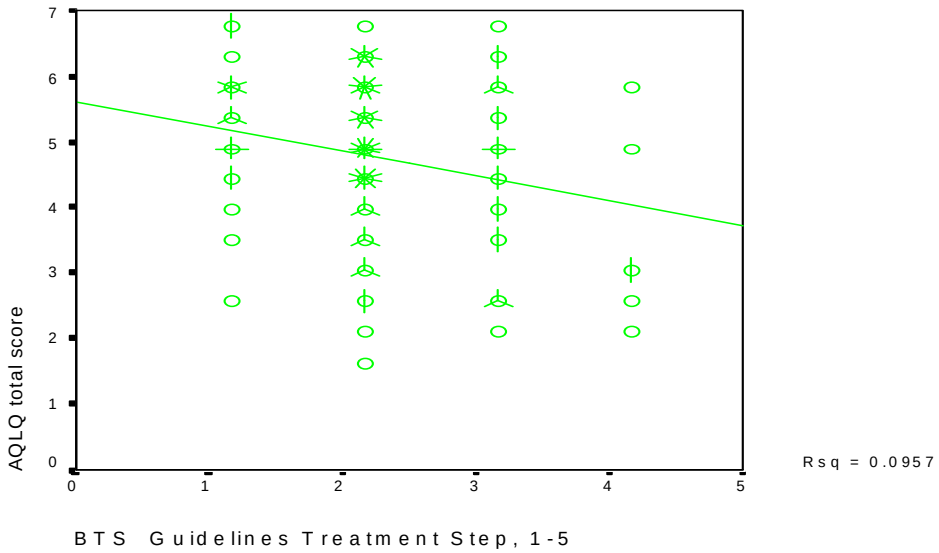
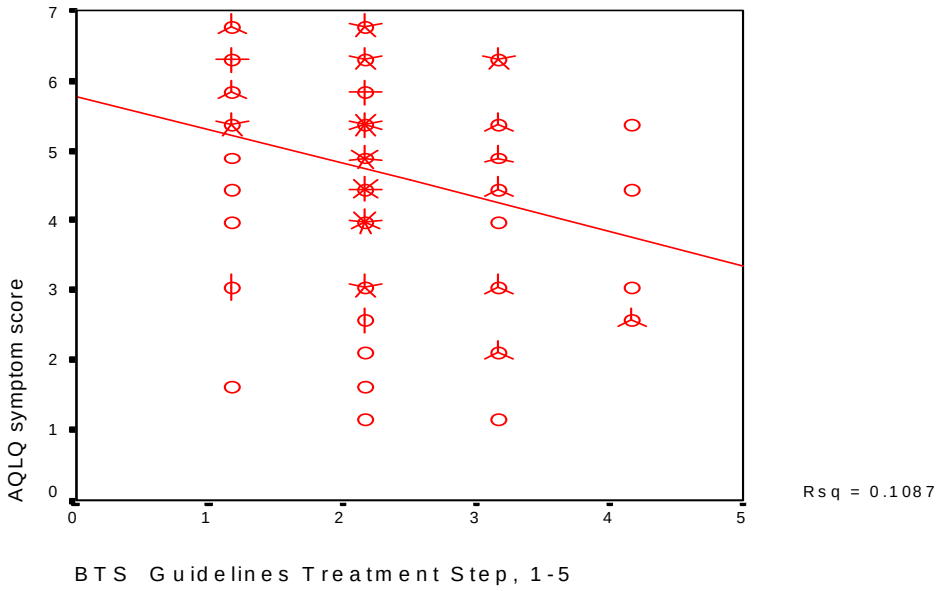


**Figure 9** Scatterplot of BTS Guidelines Treatment Step to AQLQ symptom score ($p<0.01$)

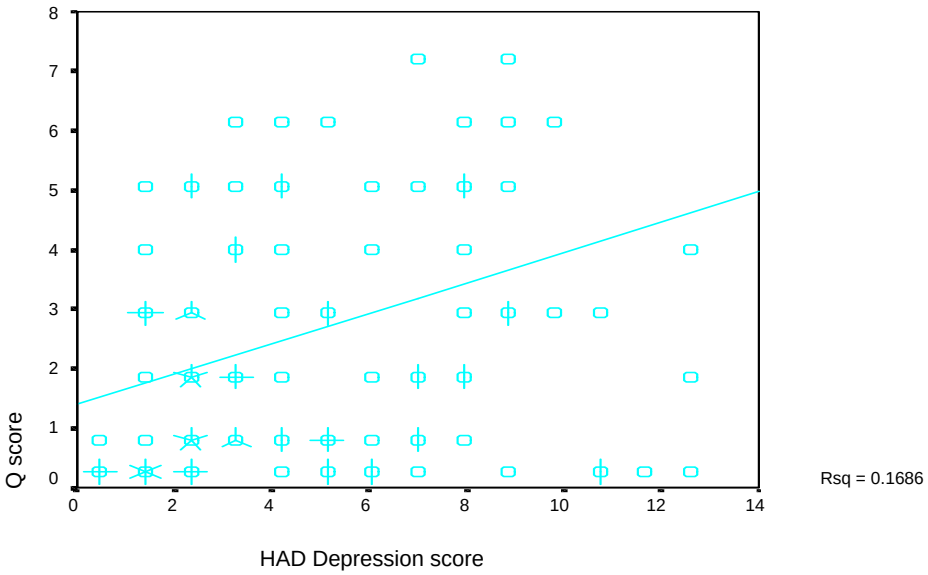



The higher the AQLQ scores the fewer the symptoms of asthma and the greater the QoL. BTS treatment step 1-2 requires low dose medication to keep asthma symptoms to minimal, higher dose treatment steps 3-5 requires more medication to keep symptoms to minimum.

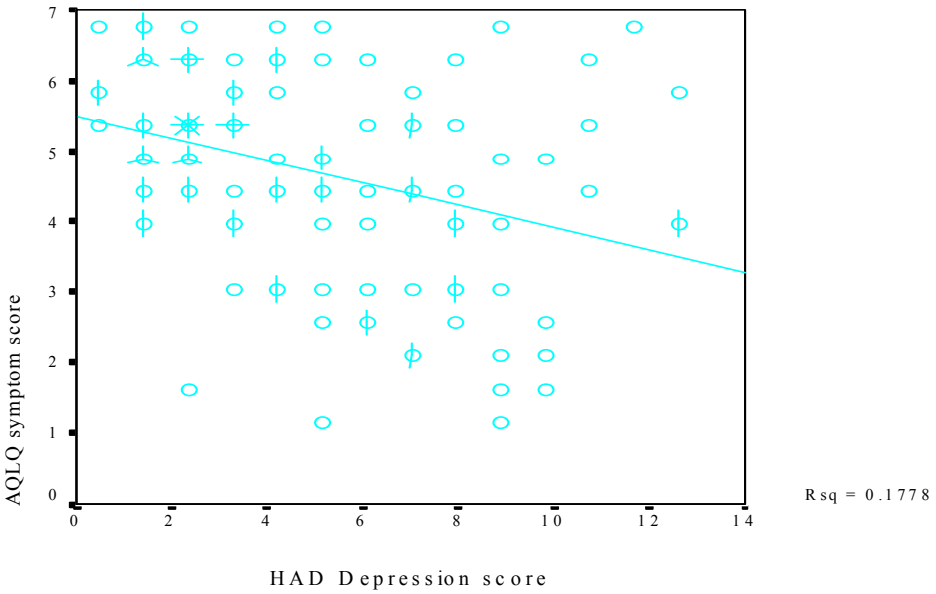
Depression scores correlated with health status (AQLQ) and morbidity (inversely with AQLQ symptom score and directly with Q score) and severity of asthma (treatment steps 3-5) all $p<0.01$ but weakly correlated to levels of PEF ($p<0.05$).

Figures 10 and 11 illustrate the relationship of subjects with increased symptom scores to higher depression scores (see also Figure 12, this illustrates mean HAD depression scores for patients with different Q scores and shows that subjects with more symptoms of asthma i.e., higher Q scores exhibit higher HAD depression scores). Levels of anxiety as measured by the HAD score also correlate to QoL scores (all $p<0.01$) but not to levels of lung function or asthma severity.

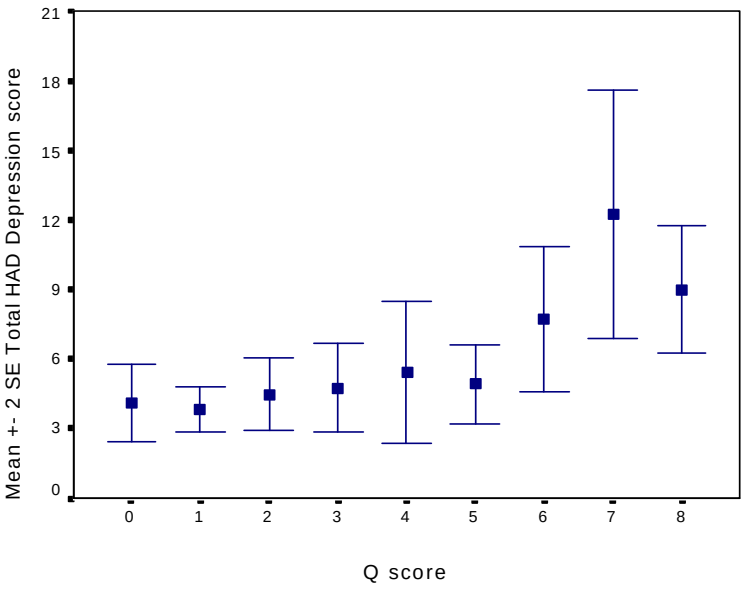
■ **Figure 10** - HAD Depression score correlates directly to increased morbidity as measured by Q score ($p<0.01$).




■ **Figure 11 –** HAD depression score correlates inversely to increased morbidity as measured by AQLQ symptom score ($p<0.01$).



■ **Figure 12 –** Mean HAD depression scores for subjects with different Q scores.




Binary logistic regression analysis was used to determine the influence of psychological status on reported symptoms after controlling for lung function and BTS treatment step. Symptoms were measured by Q score (≤ 4 or > 4) and by AQLQ symptom score (≤ median of 4.9, > median). Whichever score was used to measure morbidity, after controlling for lung function and severity both anxiety and depression added significantly to the predictiveness of the model (Table 3 gives a summary of the relationship between HAD depression and morbidity after adjustment for PEF and severity).

**Table 3: Summary statistics for symptoms (Q score and AQLQ symptom score) by PEF, BTS Guidelines treatment step and HAD depression**

| | | | *Q Score* | | *AQLQ Symptom score* | |
|---|---|---|---|---|---|---|
| ***PEF*** | ***BTS Step*** | ***HAD Depression*** | ***% ≥4*** | ***Mean Score (SE)*** | ***% ≤ median of 4.9*** | ***Mean score (SE)*** |
| ≤359 | 1-2 | ≤ 4 | 20% (4/20) | 2.3 (0.4) | 35% (7/20) | 5.2 (0.2) |
| | | > 4 | 47% (8/17) | 3.6 (0.7) | 77%(13/17) | 3.8 (0.4) |
| | 3-5 | ≤4 | 40% (2/5) | 3.2 (0.8) | 40% (2/5) | 5.0 (0.6) |
| | | > 4 | 79%(11/14) | 5.3 (0.7) | 93% (13/17) | 3.1 (0.3) |
| ≥359 | 1-2 | ≤4 | 14% (3/22) | 1.3 (0.4) | 27% (6/22) | 5.4 (0.3) |
| | | > 4 | 6% (1/17) | 1.5 (0.3) | 53% (9/17) | 5.0 (0.5) |
| | 3-5 | ≤4 | 43% (3/7) | 3.3 (0.6) | 29% (2/7) | 5.3 (0.5) |
| | | > 4 | 50% (3/6) | 4.3 (1.4) | 67% (4/6) | 4.0 (0.8) |

The higher the Q score, or the lower the AQLQ symptom score the greater the symptoms. Also the higher the depression score the worse the depression.

PEF is split by the overall median of 359.

HAD Depression is split by over all median of 4.

### *3.2.3 The Population by Place of Residence*

Four GP Practices were recruited, two were situated in inner city areas and two in suburban areas, this reflects a differing socio-economic subgroup based on Jarman scores (Jarman, 1983) for the wards the GP practices cover. The population was divided by their place of residence, inner city versus suburban. Table 4a and b illustrate the baseline data for this sub division. Sixty-five percent (74/114) of the original cohort resided and attended GP practices within the inner city, while thirty-five percent (40/114) of the original cohort resided and attended GP practices within the suburbs. The internal consistency of the Q score within the sub-groups was assessed by Cronbach Alpha (Alpha = 0.8367 for inner city subjects and 0.6283 for suburban subjects). Reliability of the Q score was below the accepted level of 0.75 for the suburban sub-group.

**Table 4a: Baseline Data for Inner City Subjects**

| *Variable* | *N=74* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 41 (12) |
| Gender (Male) | 26 | 35 | |
| Currently Smoking | 27 | 37 | |
| Currently using β agonist | 68 | 92 | |
| Currently using inhaled steroid | 63 | 85 | |
| Currently using oral steroids | 4 | 5 | |
| BTS Guidelines Treatment Step (3-5) | 20 | 27 | |
| PEF | | | 348L/min (131) |
| Predicted PEF | | | 461L/min (86) |
| $FEV_1$ | | | 2.20L (0.94) |
| Predicted $FEV_1$ | | | 2.99L (0.61) |
| AQLQ score | | | 4.5 (1.3) |
| AQLQ symptom score | | | 4.3 (1.5) |
| Q score | | | 3.0 (2.6) |
| HAD Anxiety | | | 9.46 (4.1) |
| HAD Depression | | | 5.9 (4.2) |

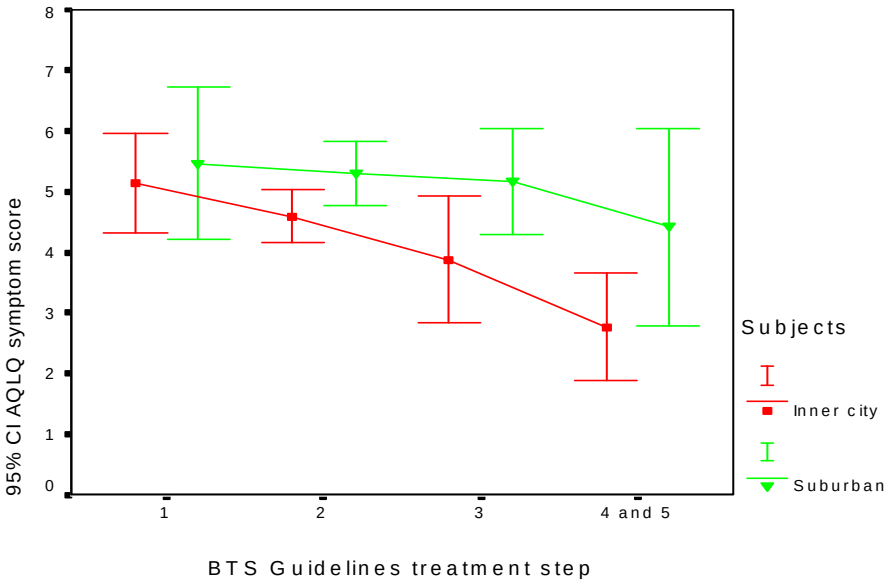
**Table 4b: Baseline Data for Suburban Subjects**

| *Variable* | *N=40* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 42 (12) |
| Gender (Male) | 16 | 40 | |
| Currently Smoking | 4 | 10 | |
| Currently using β agonist | 38 | 95 | |
| Currently using inhaled steroids | 32 | 80 | |
| Currently using oral steroids | 4 | 10 | |
| BTS Guidelines Treatment Step (3-5) | 14 | 35 | |
| PEF | | | 363L/min (116) |
| Predicted PEF | | | 469L/min (95) |
| $FEV_1$ | | | 2.3L (0.89) |
| Predicted $FEV_1$ | | | 3.0L (0.64) |
| AQLQ score | | | 5.1 (0.94) |
| AQLQ symptom score | | | 5.1 (1.2) |
| Q score | | | 2.1 (1.7) |
| HAD Anxiety | | | 6.1 (3.8) |
| HAD Depression | | | 3.7 (2.7) |

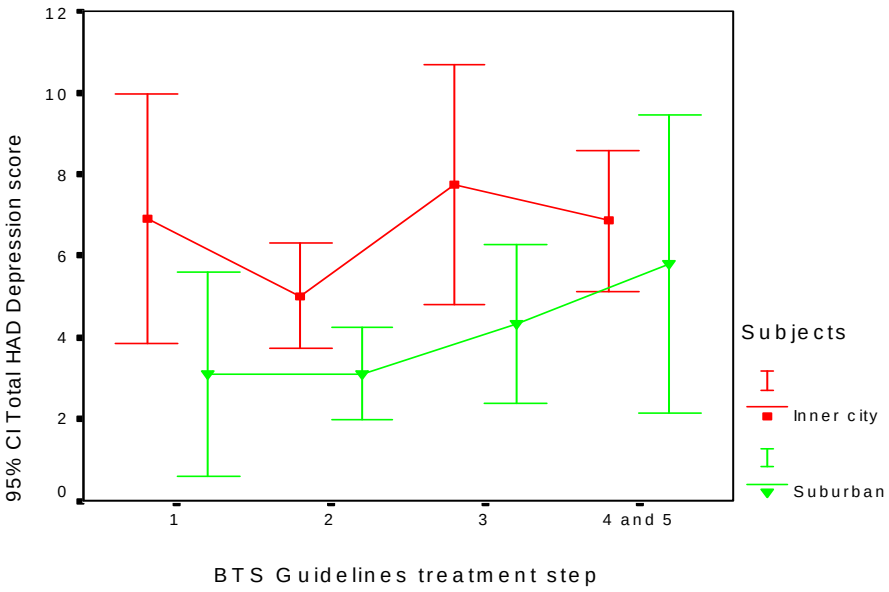
Although there were more subjects recruited from the inner city (74/40) no significant differences were noted in levels of recorded spirometry, PEF, prescribed medication, severity, QoL or morbidity. At each level of treatment (steps 1-5) inner city patients recorded higher morbidity scores and depression scores (see Figures 13, 14 and 15). The inner city cohort was however

significantly more anxious ($p<0.001$) more depressed ($p<0.01$) and consumed more cigarettes ($p<0.01$) than their suburban neighbours.

■ **Figure 13 –** Mean AQLQ symptom score plotted against BTS Guidelines treatment step for subjects from inner city and suburban areas.

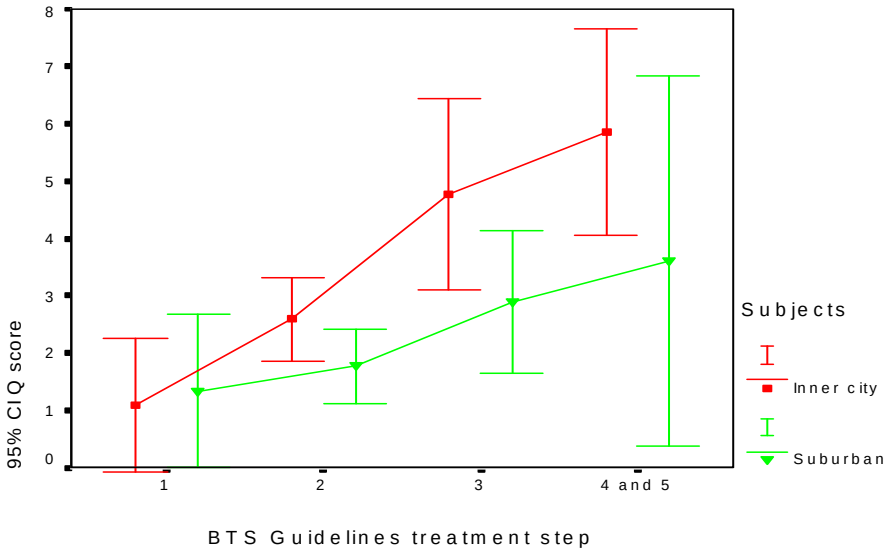



■ **Figure 14 -** Mean HAD Depression score plotted against BTS Guidelines treatment step for subjects from inner city and suburban areas




■ **Figure 15** – Mean Q score plotted against BTS Guidelines

treatment step for subjects from inner city and suburban areas.




### 3.2.4 *Psychological Status and the Asthmatic, Depressed versus Non-pressed Subjects*

The psychological status of the cohort was assessed using the HAD scale, subjects were subdivided into two groups of non-depressed subjects with scores of 7 or less and depressed with scores of 8 or more according to the HAD scale. The HAD scale allows for borderline depression with scores of eight and above. Subjects with scores of eight or higher on the HAD scale were assigned to the depression group, 27% (30/113) subjects from the original cohort were regarded as depressed. Subjects with scores of seven or less on the HAD scale were assigned to the non-depressed group, 73% (83/113) subjects from the original cohort were regarded as non-depressed. Data for the two groups is presented in Table 5a and b. The internal consistency of the Q score within the sub-groups was assessed by Cronbach Alpha (Alpha = 0.8293 for inner city subjects and 0.7598 for suburban subjects). Reliability of the Q score was greater in the depressed sub-group than the non-depressed although both were above the accepted level of 0.75.

**Table 5a: Baseline Data for Depressed Subjects**

| *Variable* | *N=30* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 46 (10) |
| Gender (Male) | 11 | 37 | |
| Currently Smoking | 10 | 33 | |
| Currently using β agonist | 27 | 90 | |
| Currently using inhaled steroids | 25 | 83 | |
| Currently using oral steroids | 3 | 10 | |
| BTS Guidelines Treatment Step (3-5) | 12 | 40 | |
| PEF | | | 331/min (143) |
| Predicted PEF | | | 461L/min (92) |
| $FEV_1$ | | | 2.16L (0.92) |
| Predicted $FEV_1$ | | | 2.90L (0.65) |
| AQLQ score | | | 4.0 (1.35) |
| AQLQ symptom score | | | 4.0 (1.61) |
| Q score | | | 3.82 (1.61) |
| HAD Anxiety | | | 12.10 (4.11) |
| HAD Depression | | | 10.5(2.77) |

**Table 5b: Baseline Data for Non-Depressed Subjects**

| *Variable* | *N=83* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 41 (12) |
| Gender (Male) | 31 | 37 | |
| Currently Smoking | 21 | 25 | |
| Currently using β agonist | 78 | 94 | |
| Currently using inhaled steroids | 69 | 83 | |
| Currently using oral steroids | 5 | 6 | |
| BTS Guidelines Treatment Step (3-5) | 21 | 25 | |
| PEF | | | 360L/min (119) |
| Predicted PEF | | | 466L/min (89) |
| $FEV_1$ | | | 2.25L (0.84) |
| Predicted $FEV_1$ | | | 3.04L (0.61) |
| AQLQ score | | | 5.02 (1.07) |
| AQLQ symptom score | | | 4.96 (1.32) |
| Q score | | | 2.24 (2.14) |
| HAD Anxiety | | | 6.92 (3.51) |
| HAD Depression | | | 3.24 (2.08) |

The majority of the cohort (73%, 83/113, one subject's HAD scores were not recorded) were not depressed having a mean score of 3.24, this was significantly lower than the depressed group of 10.5 ($p<0.001$), as was their anxiety score of 6.92 compared to 12.10 ($p<0.001$). This sub division revealed little difference in the observations between the two groups for

spirometry, PEF, prescribed medication, severity, QoL, and morbidity or smoking habit (all weakly significant, $p>0.05$).

### *3.2.5 Severity of Asthma According to BTS Guidelines Treatment Step, Groups 1-2 versus 3-5*

Baseline data for subjects divided by BTS guidelines treatment step 1 to 2 and 3 to 5 is shown in tables 6a and 6b. Asthma subjects requiring minimal medication to reduce symptoms, BTS Guidelines Treatment Step 1-2 are shown in table 6a. Asthma subjects requiring moderate use of medication to minimise symptoms, BTS Guidelines Treatment Step 3 to5 are shown in table 6b**.** The internal consistency of the Q score within the sub-groups was assessed by Cronbach Alpha (Alpha = 0.7416 for subjects in steps 1-2 and 0.7872 for subjects in steps 3-5). Reliability of the Q score was just below the accepted level of 0.75 in steps 1-2.

**Table 6a: Baseline Data for Subjects as per BTS Guidelines Treatment Step 1 and 2**

| *Variable* | *N=80* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 40 (12) |
| Gender (Male) | 27 | 34 | |
| Currently Smoking | 23 | 29 | |
| Currently using β agonist | 72 | 90 | |
| Currently using inhaled steroids | 61 | 76 | |
| PEF | | | 358L/min (117) |
| Predicted PEF | | | 461L/min (89) |
| $FEV_1$ | | | 2.28L (0.80) |
| Predicted $FEV_1$ | | | 3.0L (0.61) |
| AQLQ score ($p<0.05$) | | | 4.9 (1.1) |
| AQLQ symptom score ($p<0.01$) | | | 4.9 (1.3) |
| Q score ($p<0.001$) | | | 2.0 (2.0) |
| HAD Anxiety | | | 8.2 (4.6) |
| HAD Depression ($p<0.05$) | | | 4.6 (4.0) |

**Table 6b: Baseline Data for Subjects as per BTS Guidelines Treatment Steps 3 to 5**

| *Variable* | *N=34* | *%* | *Mean (SD)* |
|---|---|---|---|
| Age (Years) | | | 46 (10) |
| Gender (Male) | 15 | 44 | |
| Currently Smoking | 8 | 24 | |
| Currently using β agonist | 34 | 100 | |
| Currently using inhaled steroids | 34 | 100 | |
| Currently using oral steroids | 6 | 18 | |
| PEF | | | 340L/min (145) |
| Predicted PEF | | | 471L/min (90) |
| $FEV_1$ | | | 2.10L (0.90) |
| Predicted $FEV_1$ | | | 2.95L (0.65) |
| AQLQ score | | | 4.2 (1.3) |
| AQLQ symptom score | | | 4.0 (1.5) |
| Q score | | | 4.3 (2.4) |
| HAD Anxiety | | | 8.5 (4.5) |
| HAD Depression | | | 6.3 (3.5) |

Table 6a and b illustrate that the majority of subjects (71%) are contained in BTS step 1-2, requiring the use of βagonists alone or with low dose inhaled steroids. Again little difference was exhibited in the observations between the two groups for spirometry, PEF, prescribed medication or smoking habit (all

$p>0.05$). Symptom scores as measured by Q score ($p<0.001$) and AQLQ symptom score ($p<0.01$) were significantly different between the two groups as was the HAD depression score ($p<0.05$) but not anxiety. Subjects who's asthma was more unstable (group 3-5) required more medication to minimise their symptoms and symptom scores recorded were higher for the Q score (4.3 versus 2.0) and AQLQ symptom score (4.9 versus 4.0). Subjects with poor symptom control were slightly more depressed (HAD depression, $p<0.05$).

## 3.3 The Reliability of the Q score as a Simple Patient Focused Morbidity Index

Reporting and symptoms monitoring play a key role in modern asthma management. The clinician should inquire regularly as to the patients' current symptom status. By regular monitoring an attempt can be made to reduce symptom levels to those acceptable to the patient when coping with activities of daily living. The problem remains that health professionals do not always ask the correct questions at an appropriate time (Keeley, 1993). Patients can present for repeat prescription without monitoring of symptoms or indeed attend the GP practice (seeing either nurse or doctor) without having their asthma symptoms checked or recorded.

Although there are a number of respiratory and asthma specific questionnaires within the current literature that contain sections relating to morbidity many are too long to be of use in the busy clinic setting (Hyland *et al*, 1991, Juniper *et al*, 1992). The Q score asks those questions that the clinician should use in order to assess symptoms. The Q score rather like the Jones' score (Jones *et al*, 1992b) is quick and easy to administer in any routine clinical intervention. In order to assess the validity of the Q score in the clinical setting it was administered at the same time as the AQLQ, a reliable and validated questionnaire. Internal consistency of the Q score was assessed at baseline for the whole cohort

(Alpha = 0.8006) indicating good internal consistency within the four questions.

The Q score was developed following consultation with a variety of health professionals with a specific interest in asthma management. As stated by Steen *et al*, 1994 "the key problem with the estimation of validity is that there is no gold standard to act as criterion". This study used an "expert panel" to select questions and an asthma specific tool to assess the newly devised Q score's validity.

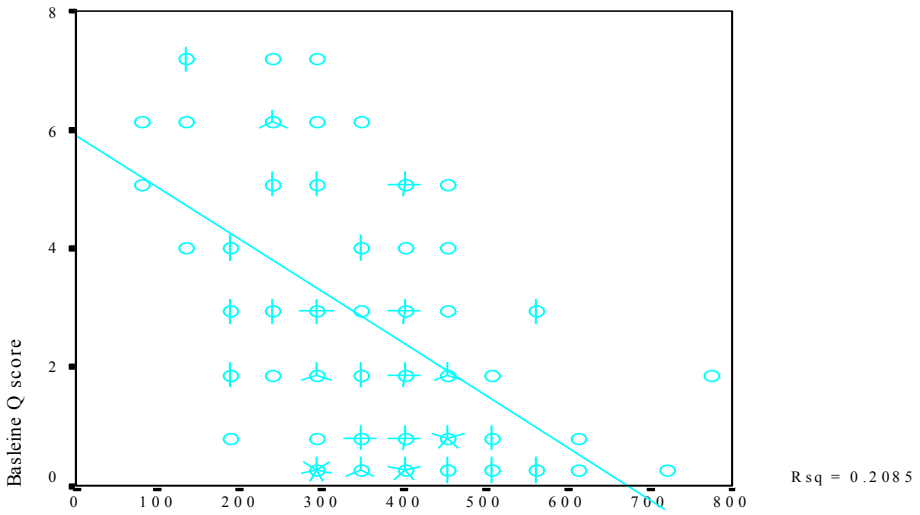
### *3.3.1 The Relationship of the Q score to the AQLQ*

Section 3.2.2 (Figures 4 and 5) illustrates the relationship of the baseline Q score for the cohort of subjects to the AQLQ. The Q score correlates to the AQLQ symptom score ($p<0.01$) and the complete AQLQ that assesses the subjects HRQL ($p<0.01$). Subjects who have poor control of symptoms with the Q score also record increased symptoms when assessed by the AQLQ symptom domain and subjects with high Q scores recorded poorer QoL scores. Symptoms of wheeze and breathlessness are common to both scores as well as disturbed sleep and interference in activities of daily living. The Q score would seem to relate well to an already validated asthma specific questionnaire.

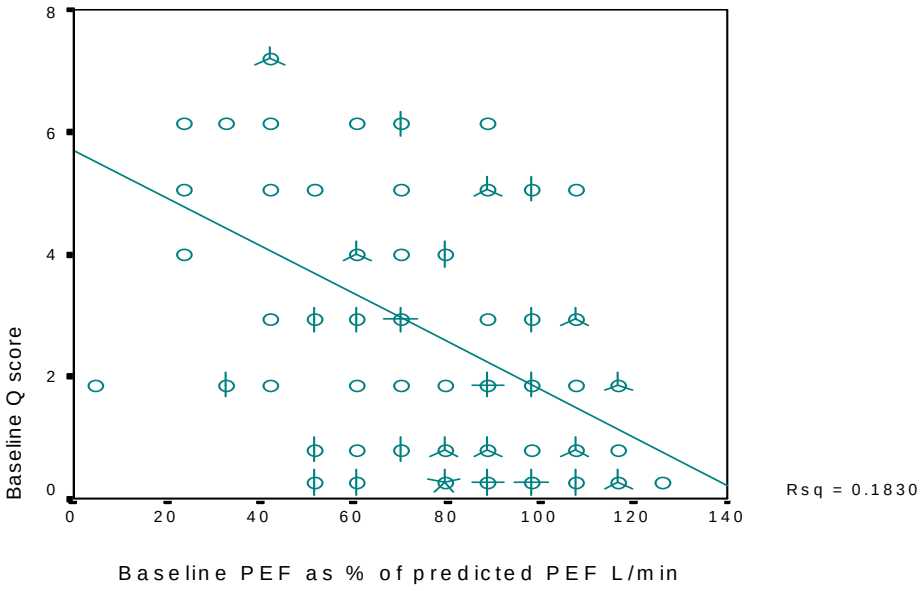
The relationship of symptoms to PEF and severity was explored in section 3.2.2 using the AQLQ symptom score (see Figures 6 and 7 and 8 and 9). Morbidity when assessed by AQLQ symptom score correlated to severity and PEF (both $p<0.01$). According to Jones and Mullee, (1995) when health related questionnaires are seeking validity, they should ensure scores are related to the severity of the disease itself. When assessed by the Q score the relationship to PEF and severity is similar (see Figures 16 and 17, both $p<0.01$ and 18) to those of the AQLQ symptom score thus fulfilling Jones recommended requirements. Figures 16a and 17a

show the relationship of the Q score at baseline to predicted lung function and spirometry.

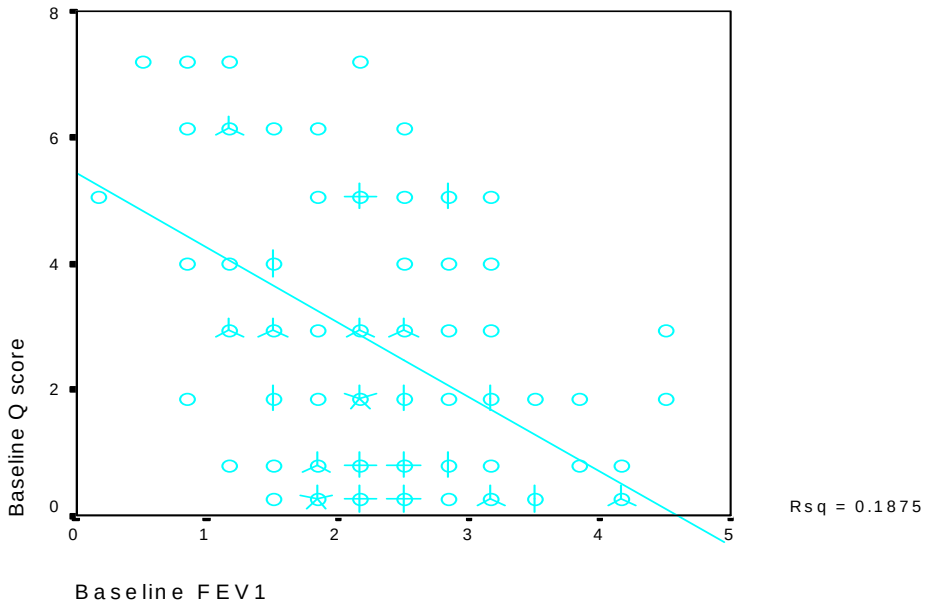
■ **Figure 16 –** Scatterplot of Q score's relationship to PEF at baseline ($p<0.01$).



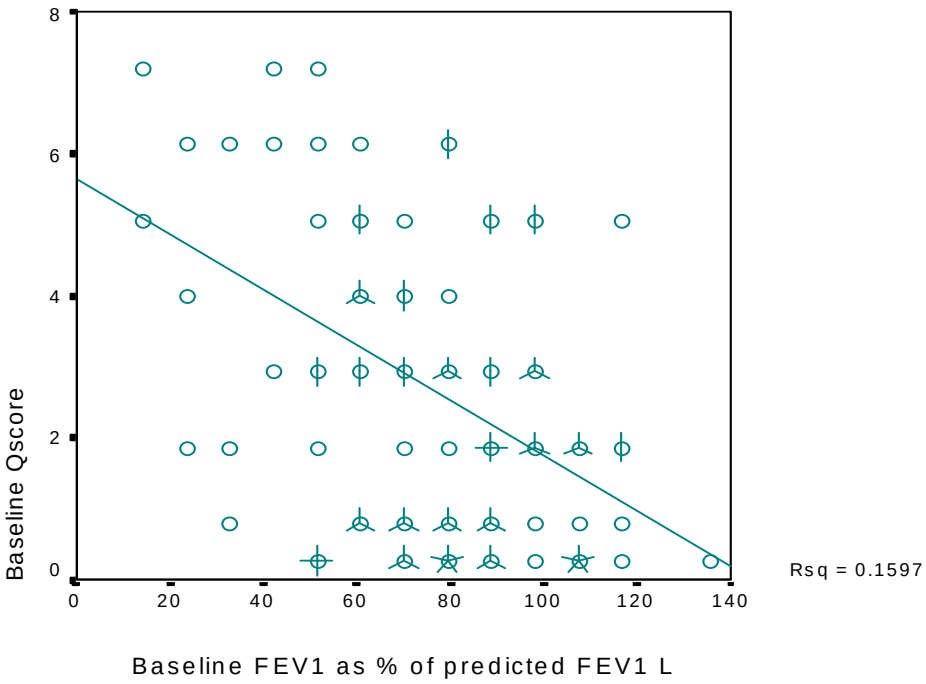

■ **Figure 16a** - Scatterplot of baseline PEF as a percentage of predicted PEF to morbidity (as measured by Q score) ($p<0.01$)



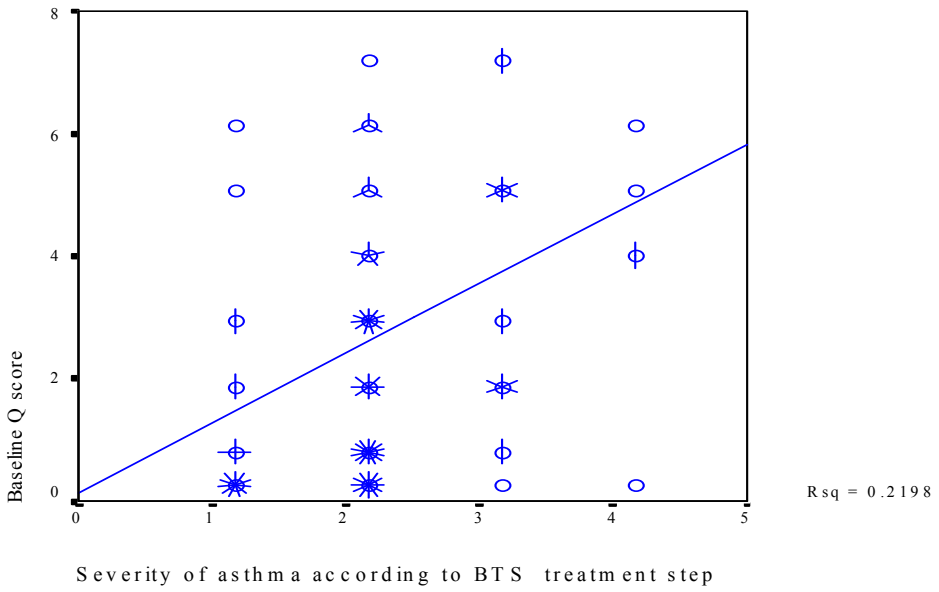
■ **Figure 17 -** Scatterplot of Q score's relationship to lung function ($FEV_1$) at baseline ($p<0.01$)




■ **Figure 17a -** Scatterplot of baseline $FEV_1$ as a percentage of predicted $FEV_1$ to morbidity (as measured Q score) ($p<0.01$)



■ **Figure 18** – Scatterplot of relationship of baseline Q score to BTS Guidelines treatment steps 1 to 5 ($p<0.01$).

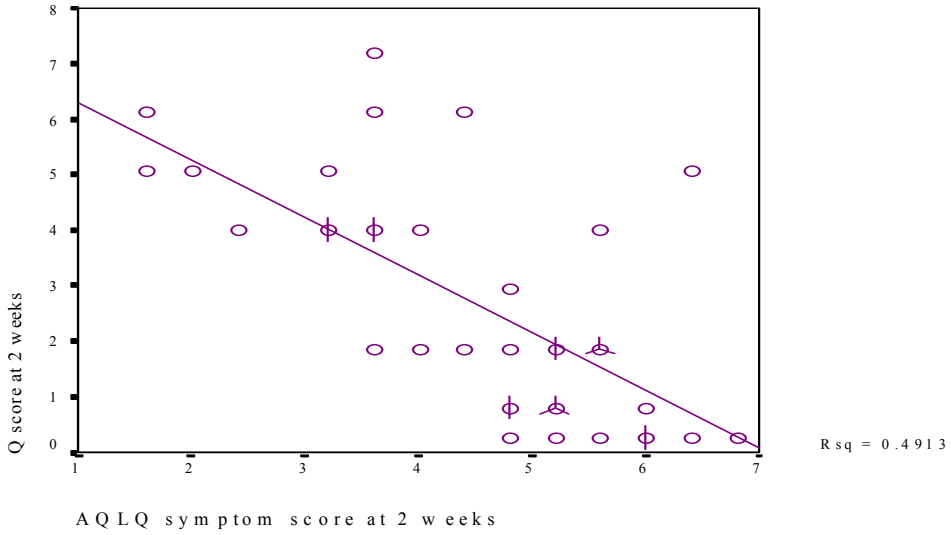



### *3.3.2 Test Re-test Reliability*

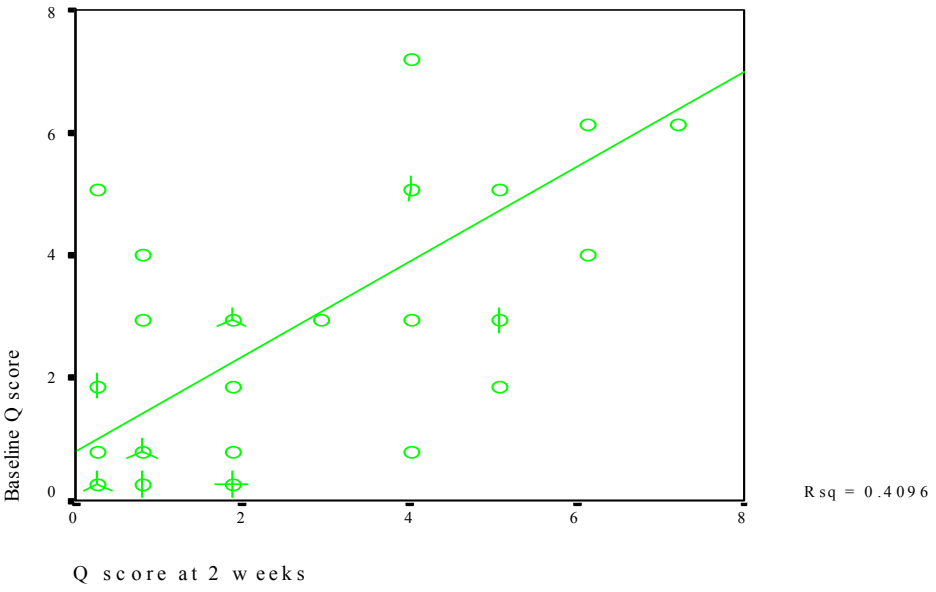
The reliability of the Q score was assessed by test re-test reliability (see section 2.4.3). Following the collection of baseline data a random sub set of subjects were selected (every alternate subject) and sent a copy of the Q score and AQLQ score at two weeks. Thirty-nine subjects (39/70) returned their questionnaires. The repeat Q score at two weeks correlated with initial determinations with a correlation coefficient of 0.61. In 25% (10/39) of repeat cases the Q score was exactly the same as first reported. In 54% (21/39) it agreed to within one unit and in 82% (32/39) it agreed to within two units. However, it should be noted the Q score reflects upon symptoms in the past week while the AQLQ has a two week reflective period. The AQLQ score runs from 1 to 7 and correlation was 0.67 with 67% (26/39) agreement to within one unit and 92% to within two units. Allowing for the variable nature of asthma the Q score would appear to be almost as reliable as the AQLQ. The Q score does not assume to be as sensitive a tool for assessing outcome as the longer AQLQ. It can however be considered as an indicator thus the proximity of the

relationship to the AQLQ would appear to be satisfactory. Scatterplots in figures 19, 20 and 21 illustrate the relationship of Q score to AQLQ symptoms score at two weeks and baseline Q score to re test Q score and baseline AQLQ symptom score to re test AQLQ symptom score.

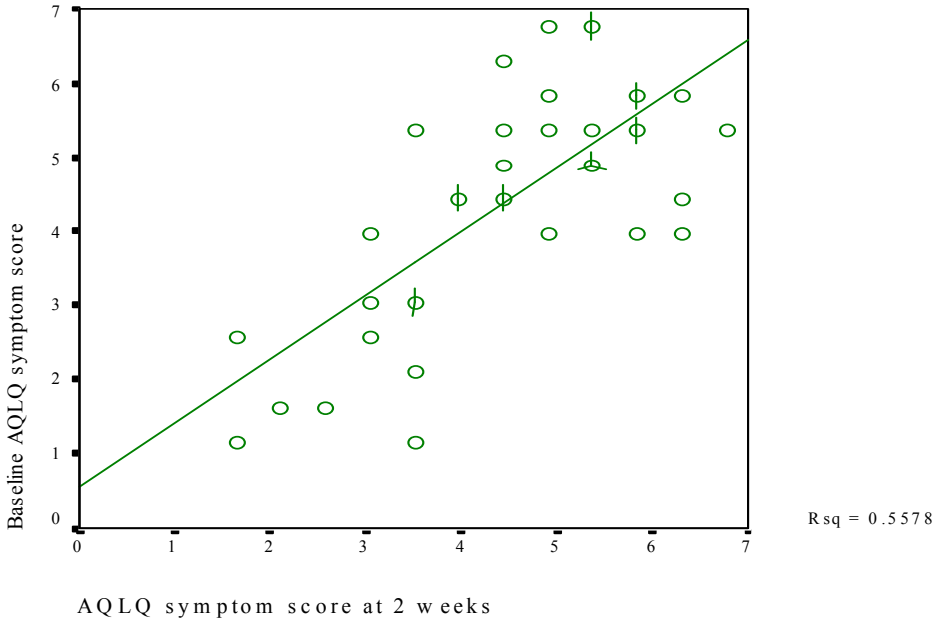
■ **Figure 19 -** The relationship of Q score to AQLQ at two weeks ($p<0.01$).




■ **Figure 20 -** Scatterplot illustrates the relationship of baseline Q score to re test at two weeks ($p<0.01$)



■ **Figure 21** - Scatterplot illustrates the relationship of baseline AQLQ to re test at two weeks ($p<0.01$)




### 3.3.3 *The Use of a Simple Patient Focused Morbidity Score – The Way Forward for the Q Score*

The AQLQ reflects morbidity and it can be seen that the Q score also reflects morbidity in the same way (see Figures 4 and 5). The Q score correlates to the AQLQ symptom score at baseline and at two weeks and reflects PEF and severity in a similar manner (see Figures 16, 17, 19, 20, and 21). The Q score is a simple questionnaire as it asks only four questions. It is patient focused, asks questions that are relevant to the patient and is specific to their asthma symptoms. The result gives the clinician and patient an indicator as to the patient's control of asthma morbidity. The Q score is not a sensitive tool but does indicate whether the patient requires further assessment.

Asthma management as advised by current guidelines looks at symptom reduction as a positive outcome for patients. If patients can understand the objectives of management sharing in the goals of treatment then patients are far more likely to comply with treatment plans. Desired outcome by the clinician must also be

those desired by the patient if any success is to be achieved. Therefore, an outcome measure that asks questions the patient deems important is more likely to elicit an objective response from the patient. Questions must be relevant to asthma and the patient. Patients will often visit their GP only when symptoms become a problem that interferes or disturbs their activities of daily living. Sleep disturbance can be an important factor in the management of asthma morbidity. In the study population 52% of subjects visited their GP because asthma symptoms prevented sleep. The reduction of sleep disturbance must be considered as an important outcome measure for patients.

The Q score is asthma specific and aims to indicate whether the patient has a satisfactory health outcome (few symptoms) or an unsatisfactory health outcome (increased symptoms) at a given point in time. The Q score is intentionally brief and three of the four questions have been identified in a recent publication by the Royal College of Physicians, Clinical Effectiveness Unit (Pearson and Bucknall, 1999) and are considered relevant to patient assessment.

The Q score can be used as a crude assessment tool, indicating patient control of asthma symptoms. Scores greater than four can indicate poor control reflecting incorrect treatment step while scores below four can indicate good symptom control. Such assumptions could act as a filter eg, when patients' contact GP practices by telephone requesting repeat prescriptions and any known asthma patient could be assessed by the Q score. Positive (low) scores would allow repeat prescriptions while high scores could be used to advise patients to attend the practice for further assessment and review in order to reduce morbidity.
Resulting scores could be collected on a regular basis thus creating an opportunity to monitor subjects and the practice over

long periods. The potential exists to not only monitor a single patient or practice but any patient who attends any GP practice, outpatient clinic. If collected on a national basis the Q score could be used as part of a larger more complex tool assessing overall quality of asthma management and the response to published national guidelines. The delivery of appropriate care and the development of "good practice" (as found in published guidelines) in the primary care setting could be promoted if outcome measures such as the Q score were adopted for routine practice. This should be carried out in association with PEF monitoring although the problems associated with continuos monitoring have previously been noted.

A simple straightforward measure for outcome is more likely to be accepted in routine practice by patient and health care professional (Keeley, 1999). The measure needs to accurately record the patients' symptoms at that intervention. The information recorded must be simple in order to be correctly recorded and interpreted by all members of the health care team. The Q score is practicable to collect at every consultation and gives the professional worthwhile feedback with regard to the patient's asthma status. It asks questions relevant to all asthmatic subjects and uses a time frame that is easily recognisable to patients. From initial testing the Q score is reliable and valid when compare to existing HRQL questionnaires.

The Q score is not alone in its approach, indeed, it has a common theme evident in the work of Jones *et al*, (1992b), Jones *et al*, (1999), and the GRASSIC study (Osman *et al*, 1996). Such systems emphasise their simplicity, commenting that other questionnaires are available but are too lengthy for use in everyday clinical practice (Rimington *et al,* 1997). These tools also stress that they are specific to asthma, quick and easy to use, yet ask questions that are relevant to the patient as an outcome

measure. Their scoring system can be used to audit outcome for single patients or a GP practice. At no time do such scores assess the process of care given, they simply reflect outcome.

In a recently held Royal College of Physicians (RCP, London) seminar a variety of tools in use nationally for assessing asthma were examined (Pearson and Bucknall, 1999). The seminar presented a diversity of tools relating to patient focused morbidity including the Q score. There was a consensus of agreement at the end of the seminar to which the Q score was able to concur. The main elements of a patient focused morbidity tool were summarised in the subsequent report following the RCP seminar. The Q score was able to concur with the following points raised:-

- The tool should be useful for adult asthma patients (age 16 and over)
- The tool should be asthma specific
- Is appropriate for all asthma patients irrespective of severity
- Questions used within the tool are specific to asthma symptoms
- The tool asks questions relating to night-time disturbance, daytime wheeze and affect on activities of daily living
- The questions are asked at every visit to GP practice
- The tool is capable of being recorded at any asthma intervention in primary or secondary care

The Q score is applicable to adult asthma patients. The seminar discussed the inclusion of paediatric assessment but as the guidelines for management are different, an inclusive tool seemed inappropriate. Questions included in the Q score are specifically

related to asthma patients and their symptoms. The Q score provides basic information that can indicate which patients may require further assessment and is envisaged as a simplistic outcome measure as opposed to a diagnostic tool. Questions relating to asthma symptoms are common to all patients regardless of their severity. Any asthma patient regardless of the severity of their disease and level of treatment step can experience wheeze, nights waking from sleep and disturbances in activities of daily living. The comments from the seminar came out strongly in favour of recording information at every contact. The information gathered from the Q score is quick and simple to obtain and record making it ideal to transfer to a simple computer based record system.

The Q score did not fulfil all recommendations of the seminar. The RCP report did recommend the use of a minimum of three questions with the possibility of expansion if a positive response was initially given. While the yes/no response allows no room for error, it lacks sensitivity. Jones *et al*, 1992a commented that when the morbidity index was piloted many centres concluded simple yes/no responses were as time consuming as could be allowed. Yet the Tayside Asthma Management Initiative report a simple scoring system expanded from the yes/no response is achievable and collectable and have reported their results (Hoskins *et al*, 1998).

The Q score does not fulfil the recommendation for yes/no scoring as the scores achieved relate to days of the week and do not allow for expansion. However, the core three questions recommended in the RCP report are incorporated in the Q score despite the lack of opportunity for expansion. Also included in the Q score is a question relating to the use of βagonist inhalers, this was felt to be more accurately recorded if prescription files

were accessed rather than to rely on patient reporting.

However, the core areas addressed by the RCP seminar were incorporated into the Q score. The Q score is asthma specific and gives an indication of outcome for the patient and would therefore seem to be a useful and worthwhile tool for further research. Jones *et al*, 1999 comment on the need for a simple asthma outcome measure which can be used in any clinical setting, "Patients will have better understanding of the goals of treatment if professionals agree on the on these and work towards achieving then in a coherent manner." The Q score will be assessed in the primary health care setting over a two-year period.

## 3.4 Discussion - The Characteristics of an Asthma Population

The characteristics of the population used in this study and the relationships within the data are described in section 3.4.1. The results reported and conclusions drawn are highly dependent on the population used. The intention was to study a stable asthmatic population over the two-year period. It was therefore necessary to establish that the subjects presented are representative of a typical population which can be found in any primary health care setting. Section 3.4.2. sets out the argument to support this study cohort as representative of a typical primary care based asthma population.

### *3.4.1 The Diagnosis of Asthma for the Study Population*

A protocol deliberately designed to study a typical group of adult asthmatics to be found in primary care was used (see section 2.2). Subjects selected for this study all came from the practice asthma register, a primary health care physician was in most cases responsible for the diagnosis of asthma thus the subject was placed on the practice register. The GP diagnosis for asthma was accepted, as all practices stated they adhered to BTS Guidelines

(Thorax, 1993) for the diagnosis and management of asthma. BTS Guidelines insist correct diagnosis is essential. In addition a requirement that all subject participating in the study should in the preceding six months have collected two or more scripts for βagonist or inhaled steroids was included. Thus the GP had diagnosed asthma and the patient had deemed it worthwhile to collect repeat scripts (see 2.2.4). If subjects who do not have asthma are treated as such with an increasing variety of medications including systemic steroids they will be exposed to risk of steroid use with little gain. Any presentation of asthma like symptoms requires close examination to ensure correct diagnosis. The diagnosis of asthma is commonly made by establishing the episodic nature of the disease with its associated variability in airways obstruction (NAEP, 1997).

When assessing subjects a detailed history noted the following items:-

- Presenting symptoms, which may include wheeze, cough, dyspnoea, chest tightness and disturbed sleep.
- Past respiratory symptoms such as repeated upper and lower respiratory tract infections.
- Trigger factors, including exposure to cold air, exercise, allergen or infection.
- Pattern of symptoms, often nocturnal or episodic.
- There may also be a familial history of asthma, eczema or hay fever.

As asthma is an episodic condition, physical examination may appear normal when the subject is symptom free and symptoms vary from subject to subject. It is a recommendation of guidelines that subjects who may have asthma have their PEF monitored to

ascertain any variation in PEF. Guidelines state subjects should record the best of three attempts first thing in the morning and last thing at night noting these over a two-week period. A variation in PEF of 15% or more is diagnostic of asthma. At the initial assessment subjects were included into the study if they fulfilled the inclusion criteria. It was the intention of the study to review GP asthma diagnosis by asking all subjects with a PFM to record PF over a two-week period as per BTS guidelines thus ensuring the credibility of the population used. Despite 63% (72/114) of the population stating they had received a PFM as part of their self management plan in order to monitor their asthma, of the subjects asked to record PF readings only 17/72 subjects returned their monitoring forms. This additional diagnostic test for asthma was therefore abandoned at an early stage and the GP diagnosis of asthma was unchallenged unless there was clear evidence from their practice records that elements for exclusion existed.

Many internationally published guidelines comment on the sporadic nature of symptoms associated with the diagnosis of asthma (Woolcock *et al*, (1989), from Australia and New Zealand, Hargreaves *et al,* (1990), from Canada, Thorax, (1997) for UK and NAEP, (1997) for the USA). All subjects were repeatedly asked to comment on their asthma morbidity in the AQLQ and Q score questionnaires at each intervention thus assessing their symptoms at that particular moment in time. It is accepted that responses will be dependant upon the subjects fluctuating asthma status but as this study took place over a two year period this should have assisted in avoiding problems associated with such short term exacerbation.

If published guidelines were adhered to as stated by all GP practices then all subjects were correctly placed on the asthma register making them suitable for inclusion in the study. Following the implementation of the NAEP guidelines in the

USA, primary care physicians were asked to comment on their adherence to nationally published guidelines (Legorreta *et al*, 1998, Picken *et al,* 1998). Of the cohort surveyed by these authors a positive response to the guidelines was given but local interpretation ensured the minimum use of PF meters for the assessment of all asthma subjects. Picken and colleagues suggested this may be due to clinicians not feeling all guidelines are pertinent to their patients and practice. This may account for the lack of compliance with guidelines by some patients, a direct result of the influence exerted by some practitioners on their patients.

When the dissemination of UK guidelines were assessed by Partridge *et al,* (1998) the number of GP and practice nurses responding positively to guidelines was high (82% and 79% respectively). Many practitioners agreed guidelines affected their approach to asthma management but the adherence to guidelines and the recommendation for the use of PF meters to record the variable nature of asthma was not recorded. It would seem that the cohort of asthma subjects in this study have been equipped with the tools to monitor their asthma (63% were supplied with PF meters) few (15%) complied with the use when requested. Observational studies such as this may therefore be useful in assessing the impact of national guidelines on local practice and more importantly the clinicians own interpretation and implementation.

Published guidelines also acknowledge the problem of a definitive diagnosis for asthma as an obstructive but reversible disorder that excludes any confusion with COPD especially when associated with smoking. (Thorax, 1997). The exclusion criteria

used in this study, (age below 60 years, smoking history less than 20 pack years), was an attempt to exclude all potential COPD subjects from the cohort thus ensuring a pure asthma population.

### *3.4.2 The Study Population Make-up and Stability*

This study hoped to secure a stable asthmatic population that could easily be followed over the two-year period (see Table 1). Although subject selection used a stratified sampling method there were only (2/114) of subjects who required hospital admission in excess of 24 hours over the follow up period, with one death and one subject leaving the area. The population is reflective of many GP asthma populations found within the UK with the majority of subjects (70%) in BTS Guidelines treatment step groups 1-2 (Horn and Cochrane, 1989). Subjects requiring increased therapy as per steps 3-5 had significantly ($p<0.001$) higher morbidity scores and depression ($p<0.05$) scores than subjects requiring less medication (see Table 6a and b). This observation was also noted by Horn and Cochrane (1989) who saw an increase in morbidity in subjects in higher treatment steps in a community based study though their study was completed prior to the publication of national guidelines for the management of asthma.

The cohort for this current study consisted of more females than males (72/42). Most studies relating to adult asthma exhibit a female bias (Pearson *et al*, 1995). This anomaly may be due to the recruitment methods employed in this study. As many subjects as possible were encouraged to attend their GP practice for assessment and opening hours were restricted from 9.00 am to 6.00 pm. Horne and Cochranes 1989 study did have access to evening appointments, which may have accounted for their almost equal gender population (157F: 155M). Access to practice facilities for this study were restricted for days and times, as no

practice could give access 9.00 am to 6.00 pm Monday to Friday and no access was given for weekends. This study was therefore limited to sessions, morning or afternoon on a variety of days and for many subjects working full time this proved impossible. Those willing to participate but unable to attend the practice were offered a home visit though not all agreed to this. Such difficulties in recruiting subjects are well documented, Horne and Cochrane comment "it is impossible to obtain 100% sample". Many published studies comment on asthma in general practice using small numbers eg, a cohort of 67 subjects being 0.5% of the total practice population. For this study a cohort of 114 subject from four practices would appear representative of such recruitment problems.

### *3.4.3 Compliance in the Use of Asthma Medication within the Population*

In order to take part in the study all subjects had to have been using a prophylactic inhaler for six months prior to entry or in the past six months received two or more prescriptions for a βagonist inhaler. All subjects complied with this requirement patient information was confirmed by computer prescription records.

Compliance according to Sackett and Snow (1979) may be defined as the extent to which a person's behaviour coincides with medical advice given (in the case of this study the ability of the subject to take inhaled medication as prescribed). Subject lack of compliance with medication uptake is well documented (Horn *et al*, 1990, Rand *et al*, 1992, Apter *et al*, 1998) with failure to adhere to prescribed medication occurring in up to 50% of subjects (Rand *et al*, 1992). Good compliance with medication characteristically take over 80% of prescribed therapy. Those taking 80-70% are deemed adequate compliers while subjects taking 50% or less are termed poor compliers (Sackett and Snow,

1979). Eighty three percent of the population in this study was prescribed inhaled steroids at the outset (see Table 1). At interview some subjects commented to the researcher a reluctance to comply with inhaled steroids.

Such anecdotal evidence has previously been noted (Yeung *et al*, 1994, van der Palen *et al*, 1997) and this cohort proved no exception in this case. When subjects were asked to confirm their prescription uptake many subjects freely commented on their personal reluctance to comply with recommended dose and frequency especially of inhaled corticosteroids. In general subjects preferred to use their βagonist inhaler more than prescribed (this data was not recorded). Anecdotal evidence was similar to that cited by Bosley *et al,* (1994) who demonstrated that many asthmatic subjects do not take their prescribed amount of inhaled medication. Subjects may not use their inhaled steroids regularly as they do not give immediate relief of symptoms or fear of associated side effects. Mayo *et al*, (1990) and Osman *et al* (1993) also reported their asthma subjects exhibited steroid "phobia".

Bosley and colleagues concluded that asthmatic subjects, no matter how distressing their symptoms, were no more likely to adhere to prescription regimens than subjects exhibiting little morbidity did.

Supposed steroid "phobia" is not the only reported cause of non-compliance. If subjects are not informed of how, when and why to use their inhaled medication, non-compliance is inevitable (Cochrane, 1996). Subjects taking regular inhaled steroids may subsequently improve, their asthma symptoms may decrease and they therefore discontinue treatment. Knowledge of inhaled medication is an important element of the patient's self-

management plan. Non-compliance would appear from the literature to be well reported, therefore practitioners must be aware that many of their patients with poor symptom control may well be non-compliant but it may not be the only confounding factor. Other elements affecting morbidity may well require due attention rather than simply altering asthma medication.

Compliance was not formally monitored with inhaled medication, but by merely noting actual prescription uptake in comparison to expected uptake. It was not expected that behaviour in relation to the use of inhaled medication had been affected by participation in this study. The monitoring of subject compliance is notoriously fraught with difficulties and beyond the scope and resources of this study. It has been previously reported (Mahwhinney *et al*, 1991, Rand *et al,* 1992, Yeung *et al*, 1994) when subjects are aware of compliance monitoring their behaviour with medication use can alter dramatically. Subjects are known to empty canisters immediately prior to clinic appointments and to discharge canisters at irregular intervals in an attempt to feign compliance with prescription medication (Bosley *et al*, 1994).

The anecdotal use of inhaled βagonist as opposed to inhaled corticosteroid is not a new phenomenon as previous studies monitoring compliance have reported similar difficulties. The use of quick acting βagonist for short term relief of symptoms is highly effective, however, the safety and efficacy of short acting therapy for long term use has been reassessed (Taylor *et al*, 1996). Long term regular use of quick acting βagonists is currently thought to affect morbidity and in some cases mortality. Subjects relying upon regular use of quick acting βagonists can develop worsening lung function, which remains masked until challenged by allergens resulting in inflammatory changes. These subjects are unable to further bronchodilate their airways thus

they are unable to respond to further bronchodilator therapy. Taylor *et al* refers to this as "agonist addiction". Long term abuse of βagonists may result in tachyphylaxis (Taylor *et al*, 1996) although this subject remains highly debated. The need for bronchodilator therapy should be reduced and preferably used only as required (Dickinson *et al,* 1998). BTS guidelines treatment step state that if subjects require quick acting βagonists more than once daily (step 1) inhaled anti-inflammatory therapy should be added to their treatment regimen (step 2). It would seem that despite published guidelines and the risks attached to βagonist abuse, many of our cohort of asthma subjects would prefer this course of action to regular inhaled steroid therapy. This would appear reflective of a typical asthma population.

### *3.4.4 The Use of Self-management Plans within the Population*

British asthma guidelines published in 1990 (BMJ, 1990) included in the recommendation "guided self-management plans". This shift in emphasis had begun in an attempt to empower patients to take control of their asthma and such a strategy involved a new partnership of patient and physician/nurse. Recommendations included written information to be given to all patients notifying them of such symptoms that would indicate their asthma was worsening and what specific treatment regimen to adopt. The updated guidelines in 1993 (Thorax, 1993) noted the change from the original stating "there is now considerable evidence of the benefit from patient education and the issuing of self-management plans". The 1997 revision also advocated the use of PFM as part of a patients self management plan (Thorax, 1997).

Some of the subjects in this study were assessed prior to the publication (Feb 1997) of the revised guidelines. All subjects were asked if they had a plan, given to them by their GP practice

to cope with worsening asthma symptoms and did they have a PFM. Sixty-three percent of subjects said they did have a self-management plan. Further details of self-management plans were not requested from subjects participating in the present study. The introduction and advocacy of self-management plans for asthma patients was thought to improve knowledge and reduce morbidity and in some cases mortality, (Hilton *et al*, 1986, Cochrane, 1993, Hoskins *et al*, 1996). Hoskins and co-workers did note that the adoption of self-management plans required an enthusiastic approach to care. In more recent publications (Neville, 1998), the importance of asthma management plans improving patient knowledge and reducing morbidity is supported. Neville comments that all asthma patients may not need or require self-management plans but patients who want to take an active part in their management would benefit from a structured approach to care.

The use of PFM as part of a structured self management plan had been advised in guidelines but Neville (1998) and Turner *et al*, (1998) amongst others question the use of routine PFM as part of a plan for many asthmatics (though poor perceivers and brittle asthmatics should use PFM). It has been previously documented that few subjects who have been prescribed PFM actually use them as part of their own monitoring process (Garrett *et al*, 1994). Subjects in this study who were issued with PFM also stated they were in receipt of self-management plans. It must therefore remain speculative how many of the cohort who do not use their PFM did not adhere to their self management plans, a common problem in any asthma population.

### *3.4.5 The Relationship of Morbidity to Subjective and Objective Markers of Asthma*

The physiological response to stimuli in asthma is one of

inflammation and bronchoconstriction resulting in expiratory wheeze, cough and dyspnoea all symptoms of asthma. According to Moxham and Costello (1997), bronchial 'hyper-reactivity' appears to be the key to the asthmatic reaction. Following exposure to a trigger the airways of the subject may (or may not) react immediately or over a period. This exposure can result in airways narrowing reducing normal levels of spirometry and PEF, such symptoms can be acute or occur over a short period and may eventually become a chronic feature of the disease. The extent to which the subject is affected will depend upon the exposure time and the extent of the response. It has been acknowledged for some time that subjects with asthma will have poorer lung function than non-asthmatic subjects when matched for age and gender (Peat *et al*, 1987). Associated with airway narrowing are the symptoms of cough and wheeze due to the hyper-responsive nature of the disease and dyspnoea that is often worse at night. Fletcher *et al,* (1976) in their classic publication noted the abnormal rate of decline in lung function in subjects with obstructive disease and this rate of decline is reflective of many asthma patients over their lifetime. The inter relationship between symptom reporting and objective measures of asthma (lung function and PEF) were explored along with subjective measures (psychological status and asthma severity) within the population (see section 3.2.2 and Table 2).

Symptom reporting along with PEF monitoring forms part of asthma management as per BTS guidelines (Thorax, 1997). The Q score asks subjects to comment on their symptoms of asthma, wheeze, nights waking and the occurrence of symptoms that disturb daily routines. The AQLQ symptom score similarly asks subjects' the extent to which symptoms interfere with daily life and which symptoms are the most distressing. In this study subjects who reported increased symptoms as measured by Q

score or AQLQ symptom score also recorded poor lung function and reduced PEF (see Figures 6 and 7). These subjects exhibit increased symptoms of asthma with consequentially poorer spirometry yet, they were receiving more treatment for their asthma symptoms (see Figures 8 and 9). The relationship within the study population of worsening symptoms, poorer lung function and increased asthma severity (increased treatment step) provides some face validity and is in keeping with other work (Horn *et al,* 1990 and Rand *et al*, 1992).

The relationship of poorer lung function to increased symptoms has previously been noted (Horn *et al*, 1990). This study attempted to study a cohort of subjects when they were relatively stable (ie, a GP based population as opposed to a hospital outpatient based population). These patients had a mean $FEV_1$ of 74% predicted and PEF of 76% predicted which might be suggestive of an element of fixed airway obstruction or a lack of compliance with prescribed medication. The question remains as to whether the poor lung function exhibited in this cohort was due to chronic disease or was due to their airways no longer respond to therapy despite patient compliance. Were the subjects non-compliant with their medication thus giving the impression of poor lung function as medication to improve airways calibre has simply not been administered?.

Connolly *et al,* (1994) have shown that best lung function obtainable decreases with increased treatment step. The cohort in the present study may (as previously noted) already exhibit an element of obstruction associated with longstanding respiratory disease or may choose not to comply with their prescribed dose of medication (see section 3.4.3). This may have resulted in poor lung function with increased morbidity.

Current literature does acknowledge the influence of psychological status on asthma symptoms (Dales *et al*, 1989, Yellowness and Kalucy, 1990, Janson *et al*, 1994, Bosley *et al*, 1995, Bosley *et al*, 1996). In this cohort depression significantly correlated with symptom scores (both $p<0.01$) and with measures of asthma severity ($p<0.05$) (see Figures 10, 11 and 12). Binary logistic regression was used to assess the influence of psychological status on reported symptoms after controlling for lung function and asthma severity (see Table 3). Whether symptoms were assessed by Q score or AQLQ symptom score depression was the best predictor of symptom level. While asthma remains high in media interest, can this be reflected towards the patient increasing their awareness for symptoms and thus raising their associated psychological status?

On the other hand, in this current study are we simply seeing subjects with increased severity of asthma depressed due to long-term illness?

### *3.4.6 Socio-economic Influence on the Population*

The mortality and morbidity of a large number of diseases can be linked to poverty and social deprivation (Smith *et al*, 1994, Eachus *et al*, 1996). Poor socio-economic status may contribute to the aetiology and subsequent management of asthma but in the UK asthma may not always be associated with reduced social status. However, it has been documented that smoking, exposure to high pollution levels, obesity and large family size are characteristics that can be associated with poverty, an element of social deprivation (Rona, 2000). According to Nsouli (1999), "poverty is the single most important risk factor for asthma hospitalisation" and in the West Midlands recent studies by Watson and co-workers have reported the association between increased admissions for asthma from areas with high deprivation

scores (Watson *et al*, 1995 and Watson and Lewis, 1995).

The cohort for this study was recruited from four GP practices, two inner city practices and two suburban practices (see Table 4a and b). To assess the different socio-economic influences in the different settings, Jarman scores were used as an estimate of deprivation. Jarman scores estimate community wide deprivation, noting weighted values for elderly people living alone, single parent families, number of children under five, social class and numbers unemployed etc within the locality based on census information. Jarman scores for each practice were based on the last public census of 1991. Poverty may be measured in several ways and although other scores are available that measure deprivation, the four practices used in this study was situated in differing Health Authorities and thus Jarman scores were the only deprivation score available for all practices.

The two groups were in differing socio-economic states, the inner city cohort was drawn from an area with increased levels of deprivation (high Jarman scores +18.7 and +13.45) while our suburban cohort had lower Jarman scores, (-19.58 and –18.27). In the study group, 75% of the inner city subjects were not working or unskilled whereas only 30% of suburban subjects where in the same situation. The assessment of social class is linked to poverty and deprivation (Rona, 2000) as the Jarman scores illustrate by using lower social class as one of the markers associated with increased deprivation.

Objective measures of asthma (spirometry and PEF) did not reveal any significant differences in the two social groups (see Table 4a and b). When looking at morbidity, despite the lack of significant differences between groups, inner city subjects always reported higher symptom scores at each treatment step than suburban subjects (see Figures 13, 14 and 15). Juniper (1998)

commented that symptom reporting was independent of objective measures of asthma. Such reporting can be linked to the subjects' personal perception of their symptoms and may be reflective of their immediate environment and personal circumstances. Some of the inner city subjects increased morbidity may be as a direct result of poor housing and the area of habitation as well as their personal situation as opposed to deteriorating lung function. In the 1995 Health Survey for England (Prescott-Clarke and Primatesta, 1997) wheeze and breathless (known symptoms of asthma) were unrelated to social class but nights waking (a question contained within the Q score and AQLQ score) reporting was highest in unskilled subjects. Although the 1995 survey did not differentiate between types of obstructive disease, in the present study nights waking was reported in 35% of inner city subjects as opposed to 17% in suburban mirroring the association of higher nights waking noted by more unskilled subjects in the 1995 survey.

Rona (2000) comments on the relationship of smoking to asthma noting increased smoking activity can be associated with poverty. The inner city subjects included in this study smoked significantly more ($p<0.01$) than their suburban counter parts. This could in some cases account for increased symptoms as inner city subjects reported increased symptoms for asthma at all levels of treatment step.

Recent publications have begun to investigate the connection between social deprivation and asthma commenting upon morbidity and mortality. Burr *et al*, (1997) looked at social deprivation and asthma using Townsend scores as a measure of deprivation. From Burrs survey taken in South Wales they agreed with a West Midland based study (Watson *et al*, 1995 and Watson and Lewis, 1995) that there was a strong association between

deprivation and increased morbidity associated with hospital admissions for asthma. Although Burrs *et al* surveyed children Watson (Watson *et al*, 1995 and Watson and Lewis, 1995) reviewed all age groups, illustrating the association can occur in all age groups. The inner city cohort presented in this study would seem to reflect current published work linking deprivation to increased morbidity.

Subjects residing in the inner city area are exposed to more pollutants. Not only is traffic in close proximity to many houses but some heavy industry remains close to the city centre where these subjects reside. Other areas of deprivation are situated near local industrial complexes situated close to motorway access routes. All must be considered as contributing to pollutants that this sub set of the population is exposed to on a daily basis. The reduced health status of such subjects may be connected to their increased smoking habit, exposure to increased pollution or poor housing which are all known factors allied to increased respiratory symptoms. This may go some way to account for the increase in morbidity reported by subjects in this study who reside in inner city areas.

### *3.4.7 Psychological Status and its Affect upon the Population*

Psychological status was explored using the HAD scale noting anxiety and depression levels of all subjects at the start of the study. Although 73% of the cohort exhibited no significant psychological symptoms when assessed at outset, there were some subjects with significant anxiety and depression (see section 3.2.4, Table 5a and b). Although asthma is not considered as a "psychological disease" the patients psyche can influence its outcome (Centanni *et al*, 2000). Subjects with anxiety and depressions scores over the threshold of eight on the HAD scale were said to exhibit signs of that phenomenon. Subject residing in

inner city areas exhibited significant depression ($p<0.01$) and anxiety ($p<0.001$). Such psychological symptoms can heighten morbidity and increasing therapy may well be the clinicians response. However, increased therapy will go little way to solving the subjects psychological problems. If a reduction in symptoms is not achieved the clinician might be wise to explore psychological influences as opposed to increasing medication further (Rimington *et al*, 2001)

The relationship between psychological and respiratory symptoms has been previously documented (Dales *et al*, 1989, Yellowness and Kalucy, 1990, Janson *et al*, 1994, Bosley *et al*, 1995, Bosley *et al*, 1996). Subjects from the European Commission's Respiratory Health Survey demonstrated an association between respiratory symptoms and psychological status although asthma subjects were no more anxious or depressed than any other subjects with respiratory symptoms (Jansen *et al*, 1994). A large Canadian study surveying the general health of a population noted that even healthy subjects were more likely to report respiratory symptoms such as cough, wheeze or dyspnoea if they also had an abnormal psychological status associated with increased anxiety, depression, anger or cognitive disturbances (Dales *et al*, 1989). Dales and co-workers commented that an increased anxiety state might well lead to subjects being more aware of their respiratory symptoms or their anxiety state heightened such symptoms to the subject. When assessing baseline data for the cohort as a whole (see section 3.2.2), anxiety and depression as measured by the HAD scale aligned to symptom scores more so than objective measures of asthma (spirometry and PEF) (see Figures 10.11 and 12). Subjects who were more anxious and/or depressed complained about their asthma symptoms (cough, wheeze and dyspnoea) more so than the subjects with reduced psychological status.

Yet Bosley *et al*, 1995 state that subjects with psychological problems can deny or disregard their asthma symptoms leading to difficulties in the management of their condition and the effective reduction of their morbidity. These subjects may desire to be, "in control" of their asthma equating a visit to the GP surgery as "loosing control" and subsequently deny symptom severity (Janson-Bjerklie *et al*, 1992). Bosley *et al*, (1995) also noted that psychological issues coexist with social problems. Subjects used in their study were recruited from four GP practices in inner city Southeast London.

Yellowness and Kalucy, 1990 also note that increased levels of anxiety can lead to denial of respiratory symptoms. Both Yellowness and Kalucy (1990) and Bosley *et al,* (1996) suppose that reasons for increased levels of anxiety are often multifactorial. If a trigger is elicited that causes increased levels of anxiety, panic can result which in turn may lead to hyperventilation and subsequent asthma. Subjects with increased panic and anxiety levels are also associated with increased uptake of care (Jansen *et al,* 1994). This study cohort reflect these findings, inner city subjects were from areas with high deprivation scores and subjects from such areas were more anxious and depressed ($p<0.001$ and $p<0.01$ respectively) and also reported higher symptoms levels than their suburban counter parts. These inner city subjects would not appear to be in denial of their symptoms but were reporting increased symptoms despite no significant reduction in objective measures of asthma. Thirty percent (22/74) of inner city subjects recorded HAD anxiety scores less than eight while 65% (48/74) had depression score less then eight whereas suburban subjects reported fewer psychological symptoms (anxiety scores lees than eight in 26/40, 65% depression scores less than eight in 35/40, 88%). The

increase in uptake of care in this study cohort as assessed by frequency of visits to the GP practice will be assessed over the two year follow up period.

Psychological issues are important factors to consider in the management of asthma and do contribute to the patient's overall experience of their disease affecting how they might cope with the variable nature of symptoms (Jansen *et al*, 1994). Published guidelines recommend patients receive self-management plans for the control of their asthma symptoms (Thorax, 1997), yet subjects with increased psychological symptoms may not comply with care plans (Bosley, *et al* 1995). Such disregard by subjects to self-management plans is a common feature of chronic disease in general. This is not related solely to subjects with respiratory symptoms. It has been documented that information and education do not necessarily alter behaviour (Cochrane, 1996). Subjects in this current study all attend GP practices that manage patients according to published asthma guidelines. Subjects may very well be in receipt of self-management plans for their asthma but if they have poor psychological status may not feel able to comply with instructions or, may simply deny their asthma morbidity requires any alteration in their current management regimen.

Indeed, as illustrated by this cohort no significant differences were found for spirometry, PEF or morbidity, yet 35% of the depressed subjects were receiving higher doses of treatment (as opposed to only 26% of non-depressed subjects) without an appropriate drop in symptom recording (see Tables 5a and b). Subjects with mild psychological problems such as anxiety and/or depression can therefore provide a challenge when their asthma management is being considered (Bosley *et al*, 1996).

The now widespread use of asthma guidelines in day to day

management has lead to the empowerment of patients in the management of their disease process (see section 1.3.2). Many subjects who exhibit psychological symptoms may feel increased levels of anxiety and stress associated with the added responsibility of implementing their self-management plans (Hyland *et al*, 1995). This increase in "bother" as termed by Hyland and colleagues may actually attribute to increased anxiety and depression in some asthma subjects that could add to the already heavy burden of these inner city subjects. This may in some part account for the increase in symptom reporting by the depressed inner city subjects who cannot cope with the added stress imposed by self management plans.

Awareness by the clinician of psychological factors and the influences that they can exert upon the asthma patient may play an important role in the management of asthma. When assessing patients, the reporting of their asthma symptoms is an important part of the consultation process. Symptom reporting in terms of increased morbidity (as associated with the inner city subjects) or, in terms of denial (as reported by Bosley *et al*, 1995) may be in response to psychological factors more so than to asthma status itself and is therefore worthy of consideration.

### *3.4.8 Asthma Severity as per BTS Guidelines Treatment Step*

Subjects in the study were divided into two sub-groups by their BTS Guidelines Treatment Step (Thorax, 1997) (see Tables 6a and b). Subjects requiring minimal medication were from steps one to two, these subjects had mild asthma symptoms while subjects requiring a variety of inhaled and oral medication were found in treatment steps three to five (moderate to severe asthma symptoms). Almost three-quarters of the cohort were found to be in treatment steps one to two. In a primary care based cohort this was expected (Horne and Cockrane, 1989). Subjects requiring

more medication were more depressed ($p<0.05$) than subjects in lower treatment groups and had significantly increased morbidity scores when assessed by Q score ($p<0.001$) and by AQLQ symptom score ($p<0.01$) but less so (see Table 6a and b). Subjects with long-standing disease are known to have increases psychological status more so than subjects with mild disease and the prospect of a life time consuming a variety of medication may well lead to increased stress (Yellowness and Kalucy 1990). The interaction between increasing medication for long standing asthma and psychological factors can result in differing outcomes. These subjects develop a variety of coping strategies for their level of disease severity (Moran 1994).

Published guidelines followed on from a variety of reports recording asthma deaths, most noticeably following the report from the British Thoracic Association in 1982. Prior to the publication of asthma guidelines many studies reported increased asthma deaths, guidelines sought to address this anomaly. Subsequent guidelines emphasised a structured approach to medical management relying in part upon symptom reporting by patients. With the publication and implementation of guidelines mortality rates in the UK are reported to have fallen (Bucknall *et al,* 1999). Although mortality rates are said to have fallen subsequent audits concerning asthma deaths report a core of subjects for whom under reporting of symptoms resulting in under treatment may have been a contributory factor to death (Sommerville *et al*, 1995, Burr *et al*, 1999).

The minimising of symptoms is a goal of asthma management and this relies to a certain extent on symptom reporting by patients. Published guidelines recommend a combination of therapy to ensure minimal or no symptoms (steps one to two). As treatment steps increase, (three to five) the aim is to achieve least possible

symptoms with therapy. Studies examining asthma deaths comment repeatedly on the probability of under treatment of asthma symptoms as a contributory factor to asthma death (Wareham *et al*, 1993, Janson-Bjerklie *et al*, 1992). It is thought some asthma patients may be poor perceivers of symptoms thus failing to recognise any deterioration in their asthma status (Bucknall *et al*, 1999, Burr *et al*, 1999, Sommerville *et al*, 1995, Wareham *et al*, 1993). Several papers have already noted psychological factors either attributed to the patient or associated with their immediate family can lead to difficulties in the management of symptoms and in the symptom reporting by patients. The East Anglia study (Wareham *et al* 1993) demonstrated seventy one percent of their asthma deaths had associated psychological problems that were thought to influence the patients demise.

Thirty percent of this study cohort had increased markers of severity (BTS guidelines treatment step three to five). This sub-group could therefore not be considered as poor perceivers of symptoms. Yet, within that sub-group, some subjects with mild depression may be being over prescribed asthma medication in response to reported symptom increase. Although no significant differences in objective measures of lung function were evident between the two groups morbidity scores were significantly different (Q score $p<0.001$, AQLQ symptom score $p<0.01$). Subjects with increased markers of severity not only complained more about their symptoms but they were more depressed ($p<0.05$), though no more anxious than subjects with decreased markers. Current literature would suggest that within the sub-group with reduced markers of severity, there could exist some cohort members who could be poor perceivers of their morbidity. Indeed many patients find the burden of their own asthma management too stressful and choose simply to ignore it (Bucknall *et al*, 1999).

BTS guidelines treatment step gives the clinician an indication as to the severity of asthma status. The treatment step onto which the patient is placed and subsequently managed is dependent upon two variables, PEF and symptom reporting. Although PEF monitoring is desirable it is not always made readily available by patients and it would seem that symptom reporting alone can be subject to many influences. The relationship of asthma severity, lung function, morbidity and psychological factors appears complex and it would seem for many of this study cohort inextricably linked.

### *3.4.9 Summary*

The aim of this study is to follow a cohort of known adult asthmatic subjects from differing primary health care settings over a two-year period. An important issue at outset was to try to ensure a true diagnosis of asthma for subjects included in the study. All GP Practices gave assurances that patients were assessed for asthma as per BTS Guidelines (BMJ, 1990, Thorax, 1993 and 1997). Diagnosis is based upon the variable nature of the airways as assessed by PEF monitoring. This study attempted to record PEF over an initial two-week period but the subject response rate was too poor to be of use to validate any previous diagnosis. The diagnosis of asthma by the GP was not challenged in this study. Subjects were excluded who may have had a diagnosis (give by GP) of COPD by disregarding smokers and any subject over sixty years of age. In doing this it was hoped to secure a pure asthma population to follow over the two-year period.

The population would appear typical of that found in any primary health care setting with the majority of subjects requiring minimal medication. Published guidelines for the management of asthma relies upon symptom reporting and PEF monitoring by the patient in order to keep symptoms to a minimum. Many patients are given asthma self-management plans along with their prescribed medication; it would appear that this study cohort report the same problems associated with medication and self-management compliance as others have previously noted. The population in this study would therefore appear to be representative of any given asthma population within any inner city and suburban primary health care setting.

This study set out to examine the relationship of symptoms,

(which may be considered as subjective markers of asthma) to objective markers such as spirometry and PEF. The investigation also wished to observe the inter relationship with the psychological status of the patient in their differing primary health care settings. Increased level of symptoms whether measured by AQLQ symptom score or Q score did correlate to poorer lung function and reduced PEF. Symptoms also correlated to BTS guidelines treatment step, thus subjects requiring more medication recorded higher levels of symptoms indicating poor control. Increased HAD scores also correlated to levels of morbidity but not to spirometry or PEF. It was interesting to note that logistic regression analysis revealed HAD scores were closely linked to symptom scores after allowing for lung function and severity. Health status was poorer, while morbidity and psychological status were higher for inner city subjects compared with a suburban sub-group while little difference was observed in objective measures of asthma.

The cohort presented in this investigation is representative of any given asthma population but this study found that morbidity can be more closely linked to psychological status rather than objective markers of asthma.

Asthma guidelines suggest that changing levels of symptoms should be used to monitor the effectiveness of treatment along side PEF. The compliance of patients to PEF monitoring remains unreliable and not always available to the clinician. Hence, the prescribing clinician may be left with symptom reporting alone upon which to base treatment. The baseline data discussed would suggest that reported symptoms may be misleading and unreliable because they may reflect non-asthma factors that cannot be expected to respond to changes in asthma therapy.

# CHAPTER 4

# Subjects reviewed at year one and year two recall

## 4.1 The Data

The aim of this study was to observe and follow a cohort of adult asthma subjects managed within the primary health care setting over a two-year period. This chapter contains data collected from ninety-five subjects from the original cohort who agreed to attend for review at twelve months (see Table 7) and data collected from ninety subjects who attended for review at twenty-four months (see Table 13). There were twenty-four subjects who withdrew from the study, their baseline data can be found in Appendix XII. Seventy-nine subjects were assessed at baseline, twelve and twenty-four months and their data can be reviewed in Appendix XIII.

The relationship of objective measures of asthma, health status, psychological status, prescribed asthma medication and asthma severity within the whole group were explored using the Spearman rank order correlation coefficient test for non-parametric data (see Table 8). These data were explored from baseline to twelve months and baseline to twenty-four months (as described in section 2.5).

Data were examined for differences (quasi-experimental design) from baseline to twelve months and baseline to twenty-four months using paired t tests for parametric data or Wilcoxon sign ranks tests for non-parametric data for the whole cohort (as described in section 2.5).

Data from the sub-groups (inner city versus suburban subjects, low versus high asthma severity, depressed versus non-depressed subjects and medication altered or not, as stated in 2.5.1) were explored for differences using unpaired t tests for parametric data and Mann-Whitney U tests for non-parametric data.

All data used within this chapter was collected using the patient data set contained within Appendix IV and V. All participating subjects were asked to complete the AQLQ, Q score and HAD scale (see sections 2.4.1 and 2.4.2). Spirometry and PEF were also recorded.

All data collected at twelve months for the whole cohort and the sub-groups are contained within section 4.2 and all data collected at twenty-four months are contained within section 4.3. Twelve and twenty-four month data are discussed together in section 4.4.

## 4.2 Changes and Relationships within the Cohort of Subjects at Twelve Months

One hundred and thirteen subjects were contacted at twelve months, one subject died within the first twelve months of the study though not due to respiratory disease. Seven subjects withdrew at this stage and their baseline data is included in Appendix XII. Eleven subjects refused appointments, were unable to attend for review or did not attend despite repeated contact. They remained within the study cohort and were contacted again at twenty-four months.

### *4.2.1 Twelve Month Data for 95 Subjects*

Table 7 illustrates the baseline data set and the twelve months data set for ninety-five subjects who attended for review. Data is explored against baseline for difference in order to note any changes in values. The relationships between morbidity (as measured by AQLQ symptom score and Q score), psychological status, (as measured by HAD scores) $FEV_1$ and PEF are explored in order to assess if relationships established at baseline persist at twelve months.

**Table 7: Data from 95 subjects at baseline and at twelve**

**months**

| *Variable* | *Base Line N=95* | *%* | *Mean (SD)* | *12 months N=95* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age (Years) | | | 43 (12) | | | |
| Gender (Male) | 34 | 36 | | | | |
| Living in inner city | 57 | 60 | | | | |
| Current Smokers | 23 | 24 | | | | |
| Using ß agonist | 88 | 93 | | 84 | 88 | |
| Using inhaled steroids | 80 | 84 | | 80 | 84 | |
| Using oral steroids | 6 | 6 | | 11 | 12 | |
| Inhaled steroids increased at 12 months | | | | 18 | 19 | |
| BTS Guidelines treatment step (3-5) | 32 | 34 | | 48 | 51 | |
| PEF | | | 344L/min(131) | | | 327L/min(132) |
| $FEV_1$ | | | 2.18L (0.96) | | | 2.12L (0.89) |
| AQLQ | | | 4.66 (1.23) | | | 4.54 (1.18) |
| AQLQ symptom score | | | 4.55 (1.50) | | | 4.50 (1.43) |
| Q score | | | 2.93 (2.47) | | | 2.92 (2.53) |
| HAD Anxiety | | | 8.09 (4.50) | | | 7.83 (4.54) |
| HAD Depression | | | 5.28 (3.83) | | | 4.54 (3.46) |

As with the baseline cohort of one hundred and fourteen subjects, there were more women than men (61/95) attending for review at twelve months and just over half of the population (60%) were from the inner city area.

There was a slight drop in the use of ßagonist (93% to 88%) over the first twelve months while the percentage of subjects using inhaled steroids remained unchanged at 80% but there was an increase in the use of oral steroids (6% to 19% respectively). This is reflected in the significant increase ($p<0.001$) in the number of subjects in higher treatment steps at twelve months (34% versus 51%).

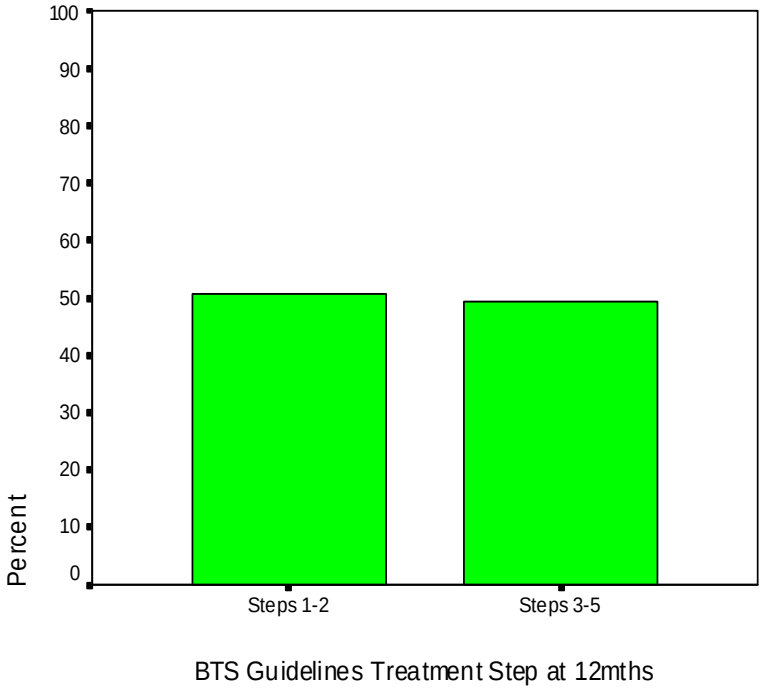
The population had remained stable over the twelve months with only 2% of subjects admitted to hospital for more than 24 hours for their asthma. Seventy-five percent (71/95) of the population

did not visit their GP for an exacerbation of their asthma and of those who did, 54% (13/24) received one or more courses of oral steroids. On their last visit to the GP practice prior to the twelve-month assessment, subjects were asked to give the reason for that visit. Forty-five percent reportedly did so because they required better control of their asthma morbidity, 22% wanted to check their medication whilst 14% complained specifically of sleep disturbance.

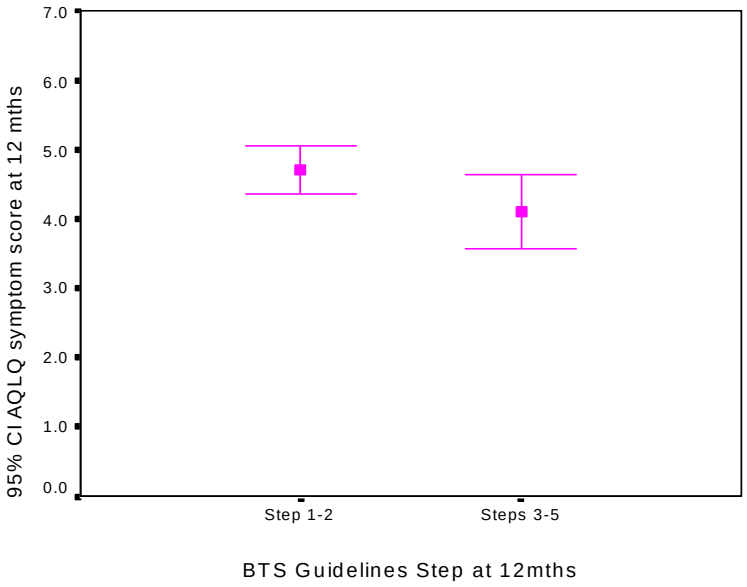
There were no significant changes in spirometry, PEF, morbidity, anxiety or depression at twelve months. However, there was a significant increase in the number of subjects in BTS treatment steps 3-5 ($p<0.001$, McNemar test) at twelve months (as shown in Figure 22b). Subjects in higher treatment steps also complained of more symptoms of asthma than did subjects in lower treatment steps (as shown in Figures 23a and b). The observation of higher Q scores and lower AQLQ symptom scores exhibited at baseline was repeated at twelve months.

■ **Figure 22a** Subjects in BTS Guidelines treatment steps 1-2 and 3-5 at baseline.

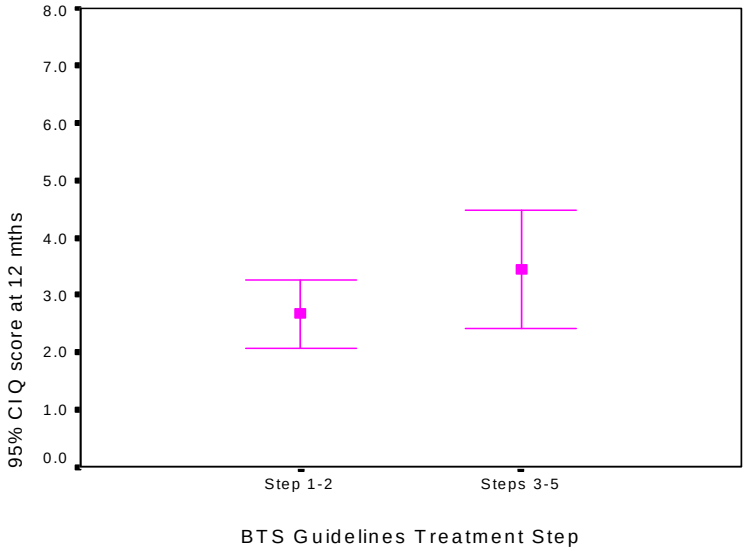

■ **Figure 22b** Subjects in BTS Guidelines treatment steps 1-2 and 3-5 at twelve month follow up ($p<0.001$).



■ **Figure 23a –** Mean AQLQ symptom score plotted against BTS Guidelines treatment step 1-2 and 3-5 at twelve months




■ **Figure 23b –** Mean Q score plotted against BTS Guidelines treatment step 1-2 and 3-5 at twelve months




*The Relationship of Quality of Life Measures to Lung Function and Psychological Status at Twelve Months*

Data examining the relationship of QoL measures to lung function and psychological status at baseline can be seen in Table 2. This was repeated at twelve months, data is shown in Table 8. At baseline symptoms scores (AQLQ symptom score and Q score)

were used as a measure of QoL, subjects spirometry ($FEV_1$) and PEF were also recorded as a test of lung function, anxiety and depression were noted to assess psychological status and BTS guidelines treatment step as a measure of severity.

*Cross sectional analysis of data collected at twelve months*

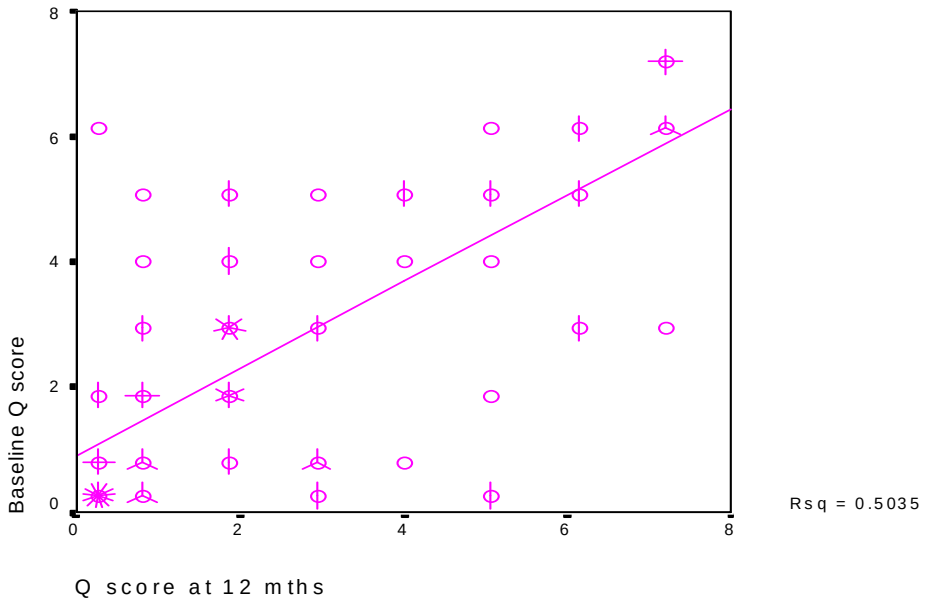
At twelve months symptoms of morbidity as measured by Q score and AQLQ symptom score correlate in a similar manner to baseline values (both $p<0.01$) (see Figure 24 and 25). Symptoms at twelve months also correlate to lung function ($FEV_1$ and PEF) (both $p<0.01$) (see Figures 26a and c and 27a and c) anxiety and depression again correlate in a similar manner to baseline (all $p<0.01$). Figures 26b and d and 27b and d show relationship of lung function and spirometry ($FEV_1$ and PEF) expressed as a percentage of predicted values to morbidity scores at twelve months. Anxiety weakly correlated to lung function ($p<0.05$) whereas the relationship with depression was stronger ($p<0.01$) at twelve months. At baseline the relationship of anxiety to $FEV_1$ and PEF was not significant while depression only had a weak relationship ($p<0.05$) with PEF. At baseline patients in higher treatment steps (BTS Guidelines steps 3-5) had increased depression and more symptoms. At twelve months these relationships were not significant.

**Table 8: Spearman's Rank Order Correlation Coefficients for 95 subjects at twelve months**

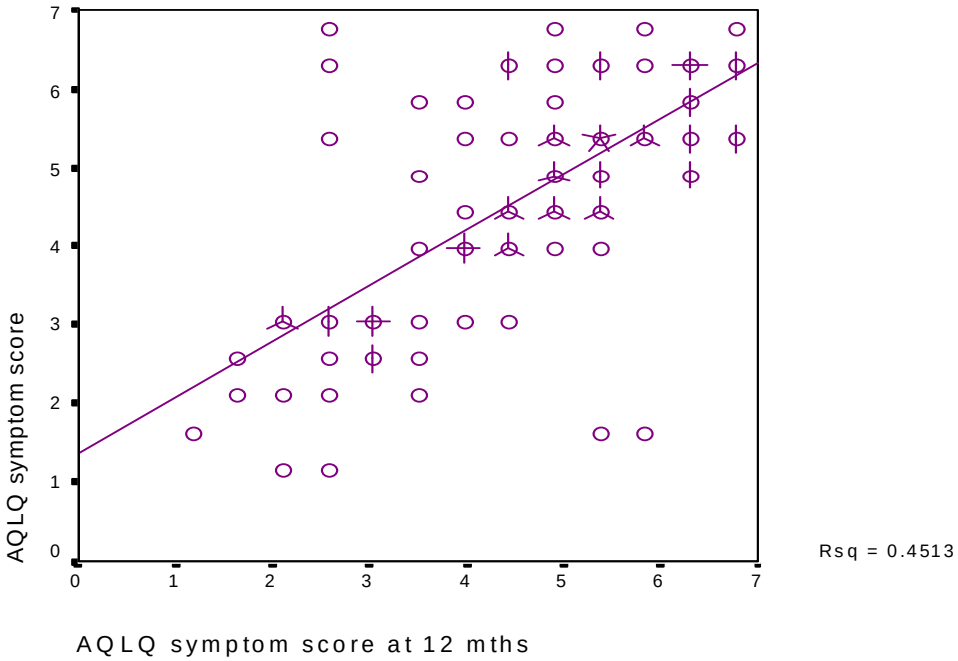
| | ***Q Score 12 months*** | ***AQLQ symptoms score 12 months*** | ***HAD Anxiety 12 months*** | ***HAD Depression 12 months*** | ***$FEV_1$ 12 months*** | ***PEF 12 months*** |
|---|---|---|---|---|---|---|
| ***Q Score 12 months*** | | -.825 | .495 | .526 | -.538 | .463 |
| ***AQLQ symptom score 12 months*** | -.825 | | -.527 | -.646 | .518 | -.450 |
| ***HAD Anxiety 12 months*** | .495 | -.527 | | .645 | -.252* | -.262* |
| ***HAD Depression 12 months*** | .526 | -.646 | .645 | | -.391 | -.415 |

All values were significant $p<0.01$ * significant $p<0.05$.

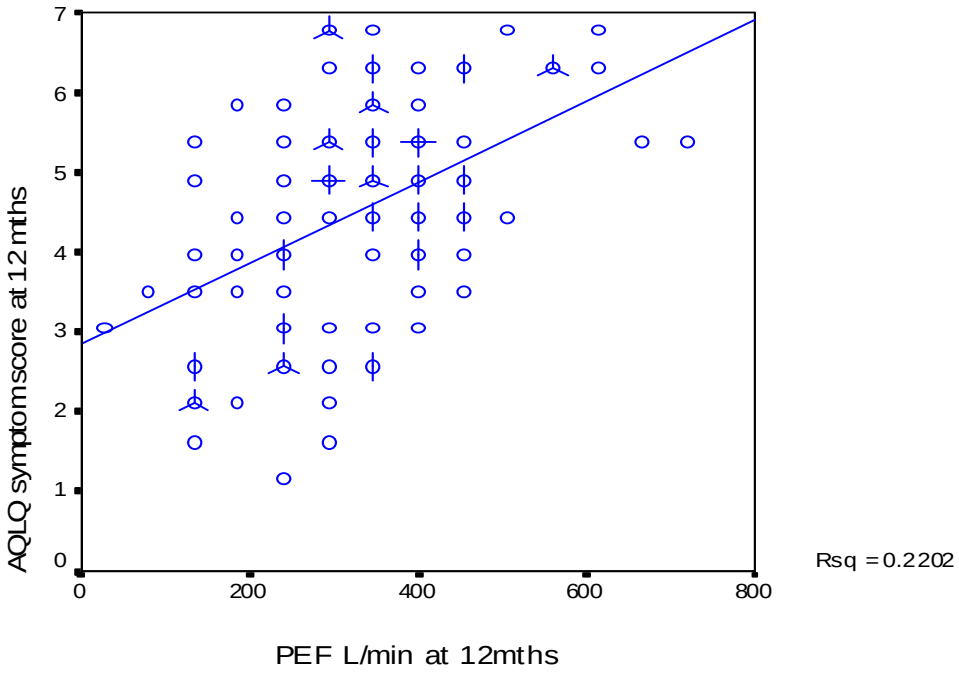
■ **Figure 24 –** Correlation of Q score at twelve months ($p<0.01$)



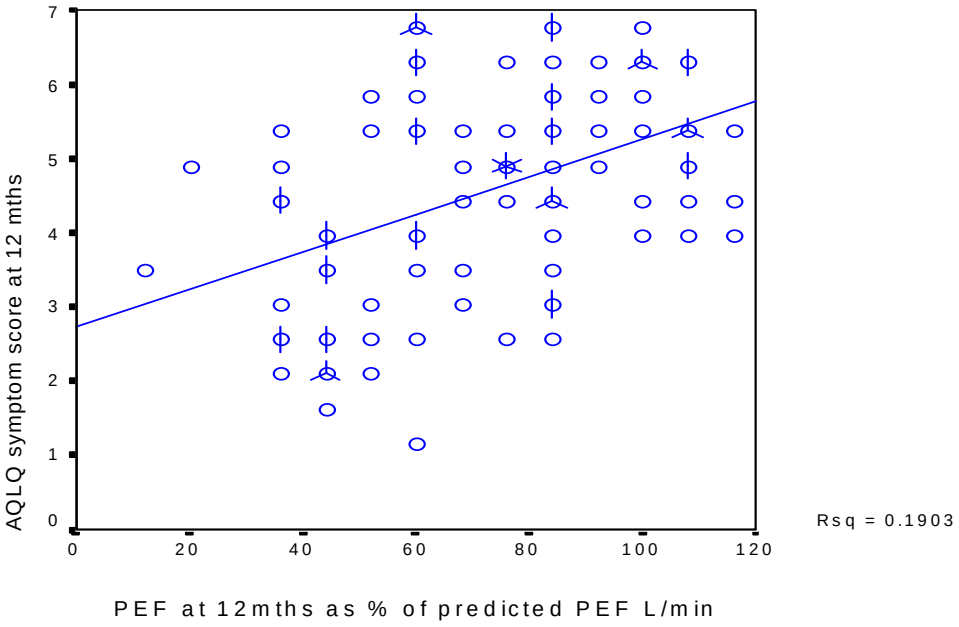

■ **Figure 25 –** Correlation of AQLQ symptom score at twelve months ($p<0.01$)



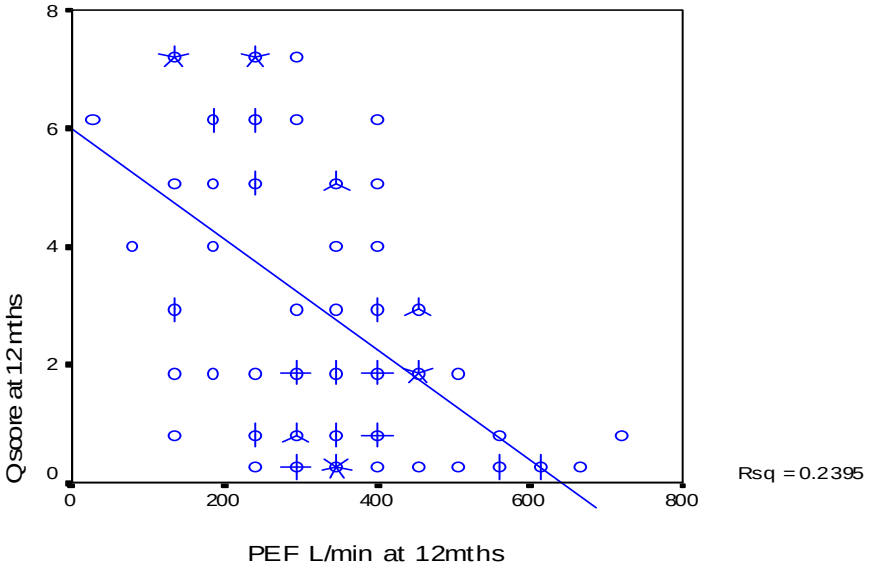
■ **Figure 26a** Correlation of PEF to morbidity as measured by AQLQ symptom score at twelve months (p<0.01).



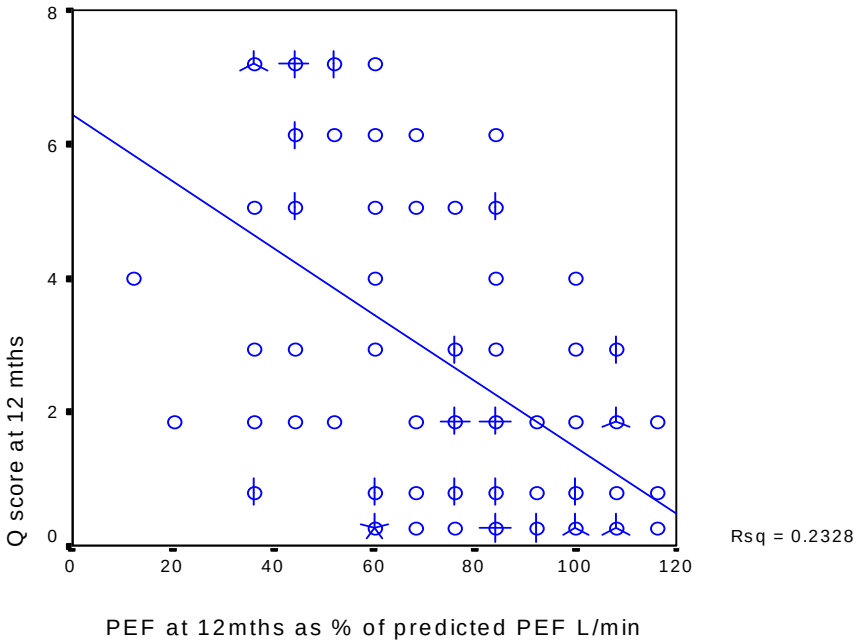

■ **Figure 26b -** Correlation of PEF at twelve months as a percentage of predicted PEF to morbidity as measured by AQLQ symptom score (p<0.01)



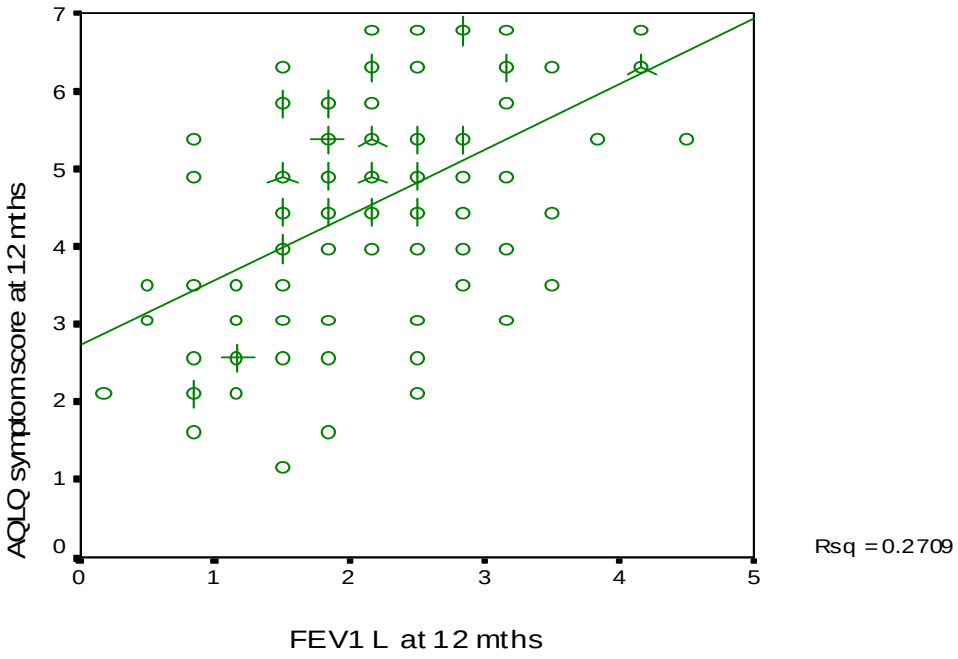
■ **Figure 26c** Inverse correlation of PEF to morbidity as measured by Q score at twelve months (p<0.01).



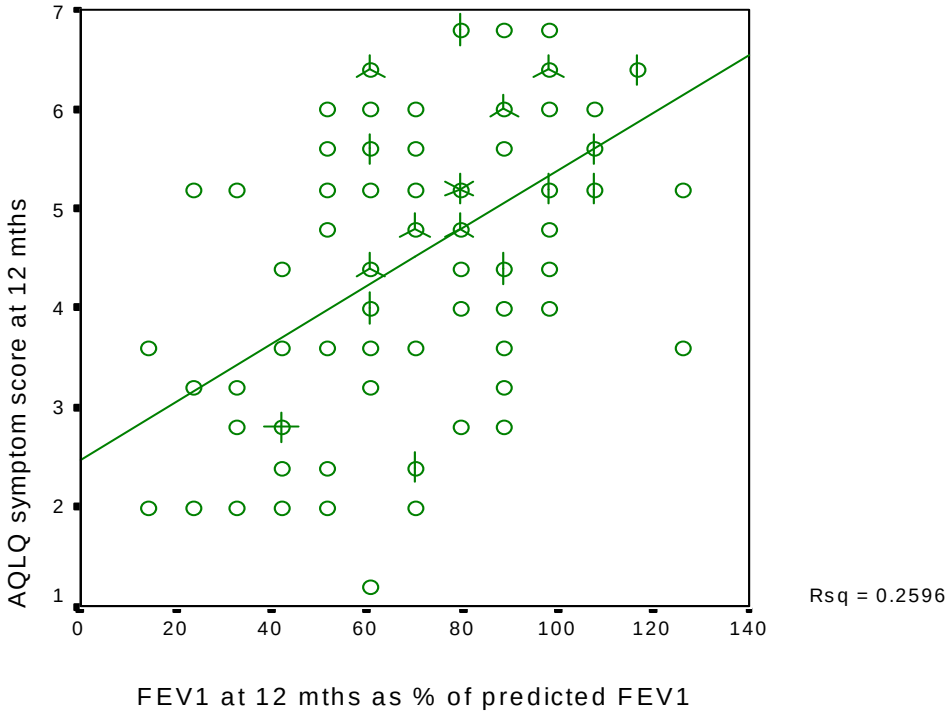

■ **Figure 26d -** correlation of PEF at twelve months as a percentage of predicted PEF to morbidity as measured by Q score (p<0.01)



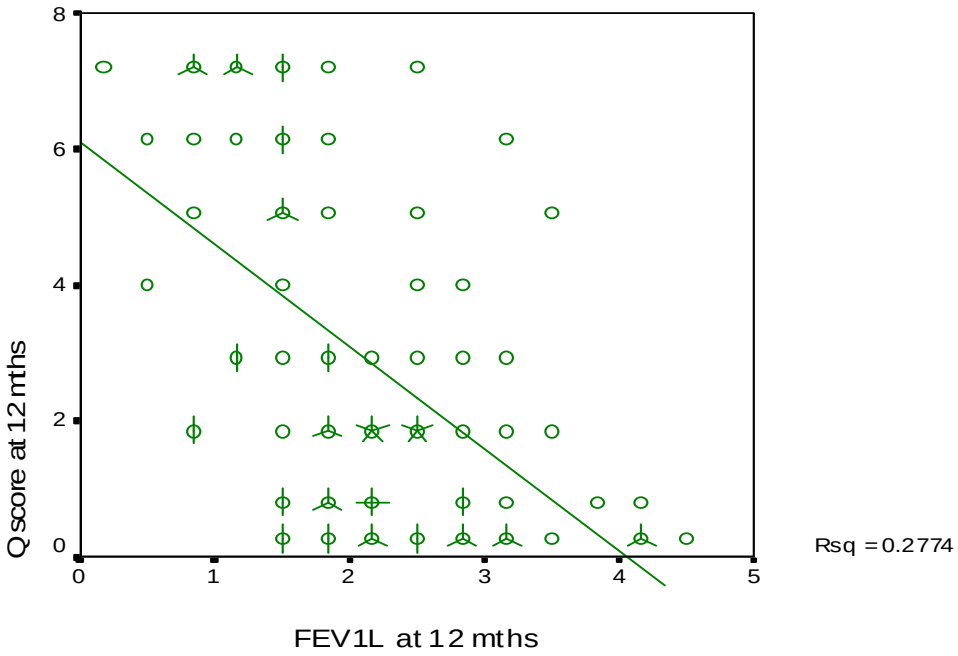
■ **Figure 27a** Correlation of $FEV_1$ to morbidity as measured AQLQ symptom score at twelve months ($p<0.01$).



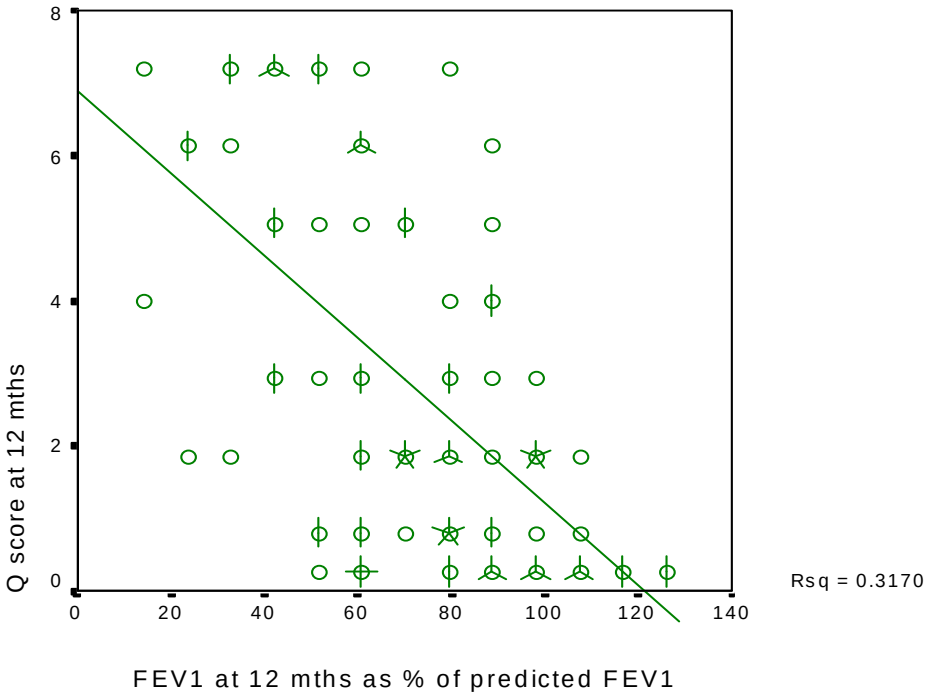

■ **Figure 27b** - Correlation of $FEV_1$ at twelve months as a percentage of predicted $FEV_1$ to morbidity as measured by AQLQ symptom score ($p<0.01$)



■ **Figure 27c** - Inverse correlation of $FEV_1$ to morbidity as measured by Q score at twelve months ($p<0.01$).




■ **Figure 27d** - Correlation of $FEV_1$ at twelve months as a percentage of predicted $FEV_1$ to morbidity as measured by Q Score ($p<0.01$)



### 4.2.2 *Changes at twelve-months - the population sub divided by place of residence*

The population was subdivided by their place of residence at baseline. Sixty-five percent (70/114) of subjects resided within the inner city area (see Table 4a and b). Similar proportions of groups, inner city and suburban residents attended for review at twelve months. Sixty-five percent of subjects resided in the inner city at baseline (74/114) with 60% (57/95) at twelve months. Thirty-five percent resided in the suburbs (40/114) at baseline and 40% (38/95) at twelve months. These data can be seen in Table 9a and b.

**Table 9a: Baseline Data and Twelve Months data for Inner City Subjects**

| *Variable* | *Base Line N=57* | *%* | *Mean (SD)* | *12 months N=57* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age (Years) | | | 41(12) | | | |
| Gender (Male) | 19 | 33 | | | | |
| Current smokers | 19 | 33 | | | | |
| Using ß agonist | 51 | 90 | | 49 | 86 | |
| Using inhaled steroids | 51 | 90 | | 50 | 88 | |
| Using oral steroids | 4 | 7 | | 9 | 16 | |
| Inhaled steroids increased at 12 months | | | | 12 | 21 | |
| BTS Guidelines treatment step (3-5) | 18 | 32 | | 26 | 46 | |
| PEF | | | 336L/min(140) | | | 315L/min(136) |
| $FEV_1$ | | | 2.13L(0.98) | | | 2.02L(0.92) |
| AQLQ | | | 4.34(1.29) | | | 4.37(1.18) |
| AQLQ symptom score | | | 4.13(1.52) | | | 4.16(1.49) |
| Q score | | | 3.43(2.73) | | | 3.64 (2.59) |
| HAD Anxiety | | | 9.44(4.36) | | | 8.64(4.50) |
| HAD Depression | | | 6.28(4.16) | | | 5.14(3.61) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 7 | 12 | |

**Table 9b: Baseline Data and Twelve Months data for Suburban Subjects**

| *Variable* | *Base Line N=38* | *%* | *Mean (SD)* | *12 months N=38* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age (Years) | | | 45 (12) | | | |
| Gender (Male) | 15 | 40 | | | | |
| Current smokers | 4 | 11 | | | | |
| Using ß agonist | 37 | 97 | | 35 | 92 | |
| Using inhaled steroids | 29 | 76 | | 30 | 79 | |
| Using oral steroids | 2 | 5 | | 2 | 5 | |
| Inhaled steroids increased at 12 months | | | | 6 | 16 | |
| BTS Guidelines treatment step (3-5) | 14 | 37 | | 22 | 58 | |
| PEF | | | 358L/min(117) | | | 344L/min(126) |
| $FEV_1$ | | | 2.26L(0.77) | | | 2.27L(0.82) |
| AQLQ | | | 5.14(1.25) | | | 4.80(1.14) |
| AQLQ symptom score | | | 5.19(1.25) | | | 5.01(1.17) |
| Q score | | | 2.18(1.79) | | | 1.84(2.03) |
| HAD Anxiety | | | 6.10(3.95) | | | 6.60(4.38) |
| HAD Depression | | | 3.81(2.74) | | | 3.65(3.06) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 4 | 11 | |

Fifty-seven (60%) subjects resided and attended GP practices within the inner city. Little increase occurred in the use of inhaled ßagonist or inhaled steroid but there was an increase in the use of oral steroids (7% versus 16%). Although no significant increase occurred in the number of subjects using inhaled steroids at twelve months 21% of subjects did have their dosage increased. This increase is reflected in the number of subjects moving to the higher treatment step (step 3-5) represents an increase of 14% ($p<0.01$).

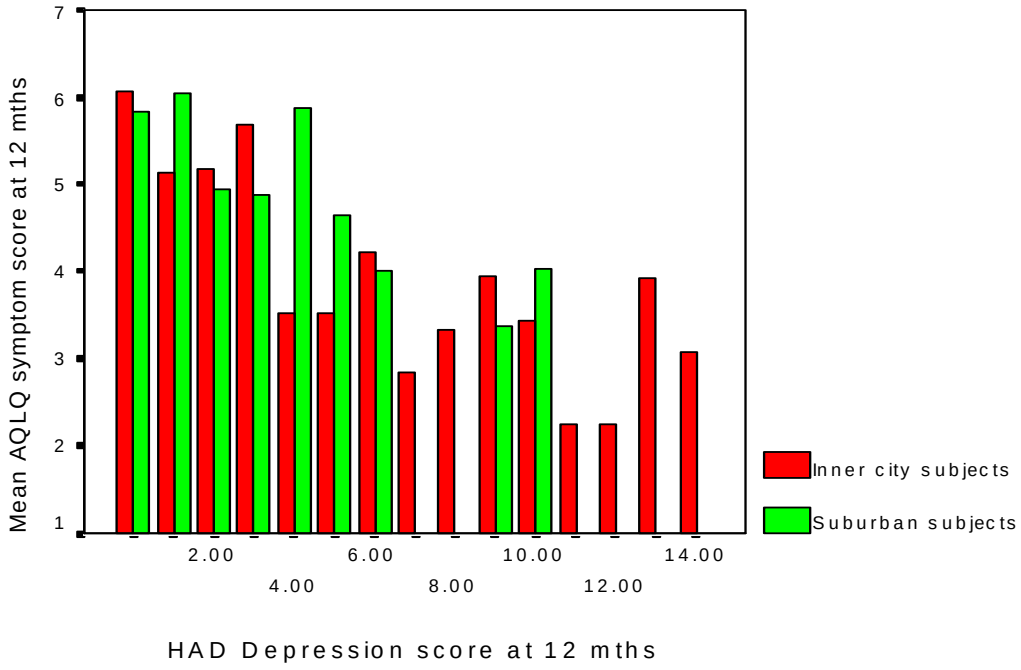
Thirty-eight (40%) subjects resided and attended GP practices within the suburbs. Inhaled medication used by suburban subjects remained almost the same at twelve months although 16% of subjects did have their inhaled steroids increased. This increase is reflected in the number of subjects moving to the higher treatment step (step 3-5) an increase of 21% ($p<0.01$).

At baseline there were no significant differences between groups for spirometry, PEF, morbidity or severity. Inner city subjects were however significantly more anxious ($p<0.001$) and depressed ($p<0.01$).

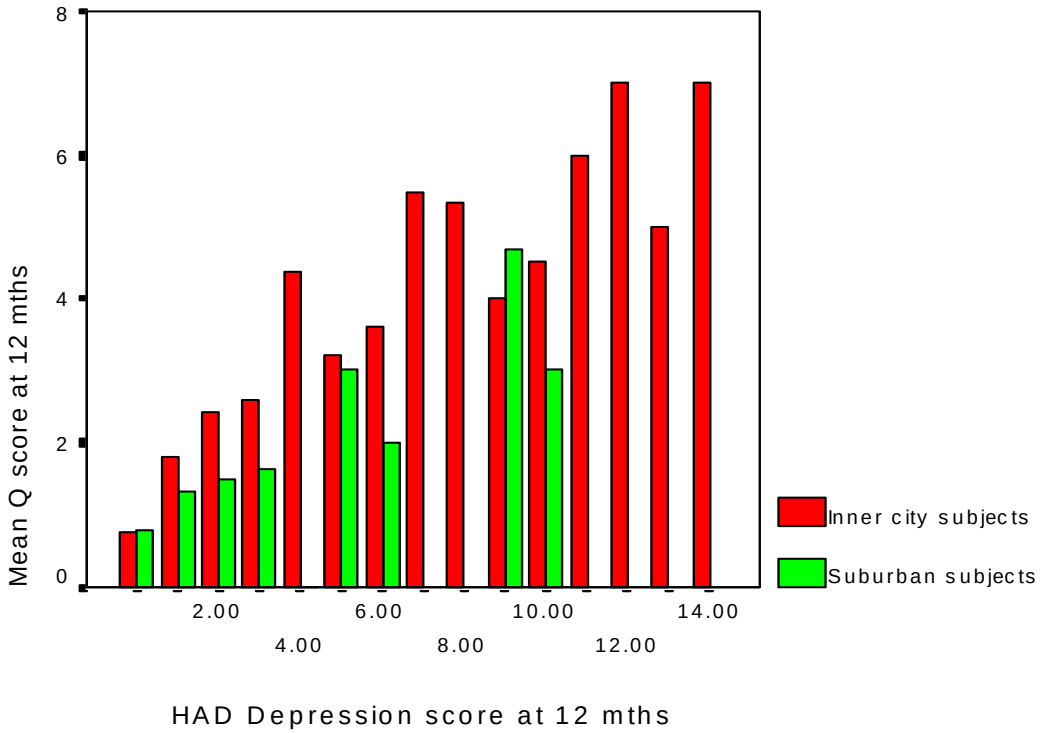
At twelve months the same relationship between groups for spirometry and PEF was maintained. Inner city subjects remained more depressed ($p<0.05$) but the relationship was weaker than at baseline and they were no longer more anxious than their suburban counter parts. Morbidity scores were however significantly higher in inner city subjects at twelve months (Q score, $p<0.001$ and AQLQ symptom score, $p<0.01$). Levels of treatment for inner city subjects at twelve months did increase more so than suburban with inner city subjects receiving more oral steroids (16% versus 5% and 21% versus 16% had inhaled steroid therapy increased).

Figures 28a and b illustrate inner city subjects were more depressed and reported more symptoms than suburban subjects. Increased Q scores are associated with increased depression scores while increased AQLQ symptom scores (improved QoL) were associated with reduced depression scores.

■ **Figure 28a** Bar chart of mean morbidity score as measured by AQLQ symptom score to HAD Depression for Inner City and Suburban subjects at twelve months.




■ **Figure 28b** Bar chart of mean morbidity score as measured by Q score to HAD Depression score for Inner City and Suburban subjects at twelve months.




*4.2.3 Changes at twelve-months - the population sub divided for*

*severity (BTS Guidelines treatment step 1-2 versus 3-5)*

Subject were sub-divided at baseline into two groups according to their asthma severity, BTS Guidelines treatment steps 1-2 and subjects who had more severe asthma requiring more therapy as found in BTS Guidelines treatment steps 3-5 (see Table 5a and b). At baseline 71% (80/114) of subjects were in BTS Guidelines treatment step 1-2 requiring low dose medication to control asthma morbidity. At twelve months sixty three subjects (63/80, 79%) from steps 1-2 attended for reassessment, 75% (47/63) of subjects remained in steps 1-2. There were 32/34 (94%) of the subjects in the higher treatment step attending for review at twelve months 31/34 (91%) remaining in steps 3-5. There were 80/114 (70%) subjects at baseline in BTS Guidelines treatment step 1-2, 63/80 (79%) attended for review at twelve months. There were 34/114 subjects at baseline in BTS Guidelines treatment step 3-5, 32/34 attended for review at twelve months. The data are shown in Table 10a and b.

**Table 10a: Baseline Data and Twelve months Data for subjects in BTS Guidelines treatment step 1-2**

| *Variable* | *Base Line N=63* | *%* | *Mean (SD)* | *12 months N=63* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 41 (12) | | | |
| Gender (male) | 20 | 32 | | | | |
| Current smokers | 16 | 25 | | | | |
| Living in inner city | 39 | 62 | | | | |
| Using ß agonist | 56 | 89 | | 53 | 84 | |
| Using inhaled steroids | 48 | 76 | | 48 | 76 | |
| Using oral steroids | 0 | | | 4 | 6 | |
| PEF | | | 349L/min(123) | | | 330L/min(129) |
| $FEV_1$ | | | 2.21L(0.85) | | | 2.13L(0.83) |
| AQLQ symptom score | | | 4.78(1.41) | | | 4.70(1.36) |
| Q score | | | 2.23(2.21) | | | 2.66(2.33) |
| HAD Anxiety | | | 7.96(4.51) | | | 7.68(4.65) |
| HAD Depression | | | 4.90(4.07) | | | 4.11(3.35) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 5 | 8 | |

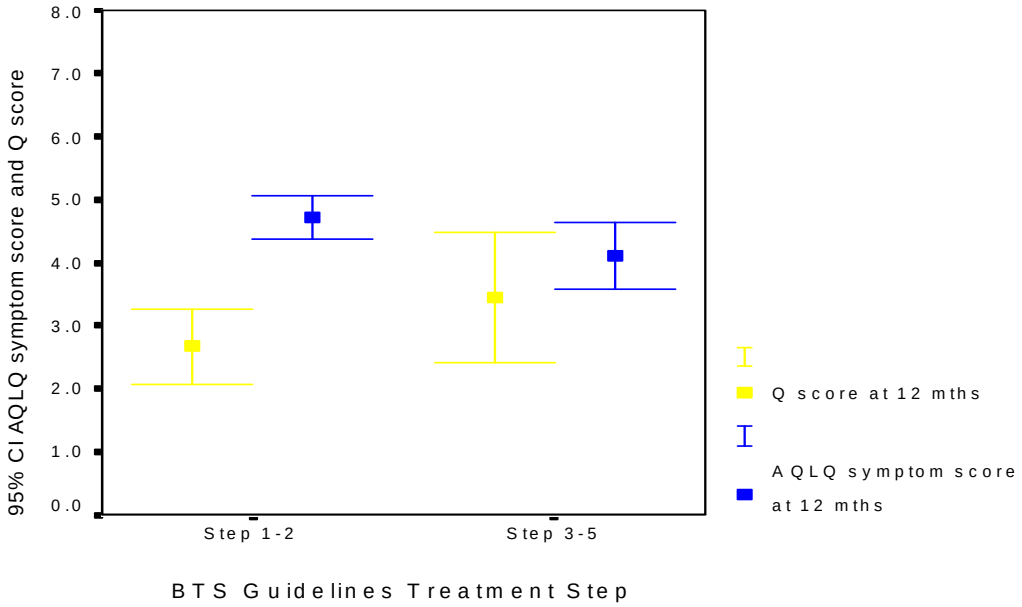
**Table 10b: Baseline Data and Twelve months Data for subjects in BTS Guidelines treatment step 3-5**

| *Variable* | *Base Line N=32* | *%* | *Mean (SD)* | *12 months N=32* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 46(10) | | | |
| Gender (male) | 14 | 44 | | | | |
| Current smokers | 7 | 22 | | | | |
| Living in inner city | 18 | 56 | | | | |
| Using ß agonist | 32 | 100 | | 31 | 97 | |
| Using inhaled steroids | 32 | 100 | | 32 | 100 | |
| Using oral steroids | 6 | 19 | | 7 | 22 | |
| PEF | | | 335L/min(149) | | | 320L/min(140) |
| $FEV_1$ | | | 2.13L(1.02) | | | 2.11L(1.00) |
| AQLQ symptom score | | | 4.10(1.59) | | | 4.10(1.49) |
| Q score | | | 4.31(2.40) | | | 3.43(2.86) |
| HAD Anxiety | | | 8.35(4.55) | | | 8.12(4.38) |
| HAD Depression | | | 6.06(3.22) | | | 5.40(3.57) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 6 | 19 | |

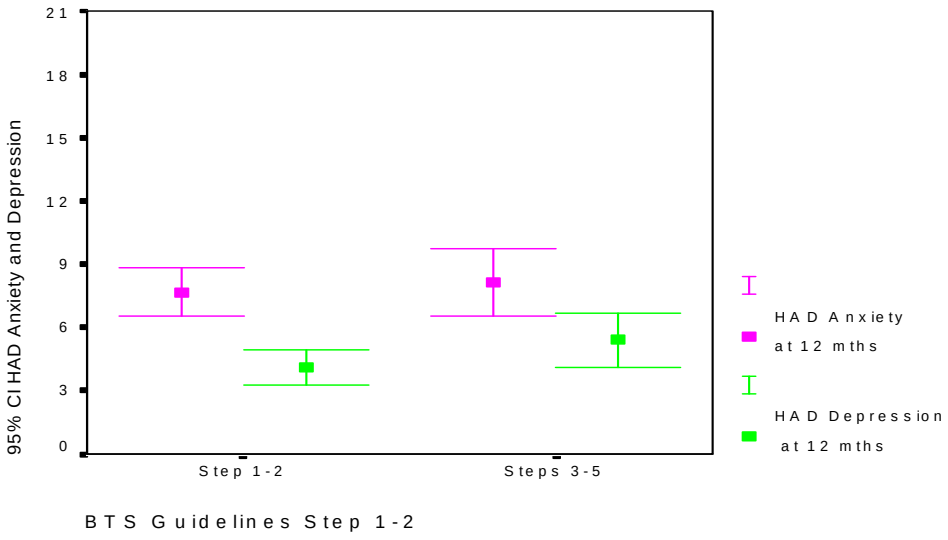
At baseline no differences between groups were observed for spirometry and PEF. This observation was repeated at twelve months. Subjects in higher treatment steps were significantly more depressed ($p<0.05$) and recorded more symptoms (Q score $p<0.001$, AQLQ symptoms score $p<0.01$) at baseline but this

observation was not repeated at twelve months. However, a trend of increased morbidity, anxiety and depression was evident at twelve months in the higher treatment steps (3-5). Which is illustrated in Figures 29 and 30.

■ **Figure 29 –** Mean AQLQ symptom score and Q score for BTS Guidelines treatment Steps 1-2 and 3-5 at twelve months.




■ **Figure 30** – Mean HAD Anxiety and Depression scores for BTS Guidelines treatment step 1-2 and 3-5 at twelve months.




*4.2.4 Change at Twelve Months – the population subdivided by initial Psychological Status*

The population was sub divided for depression at baseline (see Table 4a and b). Subjects with HAD depression scores of 7 or less were said to exhibit no sign of depression or anxiety while those with scores of 8 or greater were placed into the depressed group. The HAD scale delineates for borderline depression with scores of 8 or above. At baseline 83% (25/30) of depressed subjects lived in the inner city and more depressed subjects smoked (33% v 25%), although there was no significant difference for inhaled therapy more depressed subjects were prescribed oral steroids as part of treatment (6% versus 10%). Subjects in the depressed group at baseline were significantly more anxious and depressed (both $p<0.001$) but no significant differences were found between groups for morbidity. At baseline 30/113 (27%) subjects were depressed, at twelve months 26/30 (87%) depressed subjects attended for review, 15 subjects depressed at baseline remained so at twelve months. At baseline 80/113 (73%) subjects were not depressed, at twelve months 69/80 (86%) non-depressed subjects assessed at baseline attended for review, 64 subjects not depressed at baseline remained so at twelve months. These data are shown in Tables 11a and b.

## Table 11a: Baseline and Twelve Months data for Depressed subjects

| *Variable* | *Base Line N=26* | *%* | *Mean (SD)* | *12 months N=26* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 46 (9) | | | |
| Gender (male) | 10 | 39 | | | | |
| Current smokers | 9 | 35 | | | | |
| Living in inner city | 21 | 80 | | | | |
| Using ß agonist | 24 | 92 | | 23 | 89 | |
| Using inhaled steroids | 22 | 85 | | 22 | 85 | |
| Using oral steroids | 3 | 12 | | 3 | 12 | |
| Inhaled steroids increased at 12 months | | | | 4 | 15 | |
| BTS Guidelines treatment step (3-5) | 11 | 42 | | 15 | 58 | |
| PEF | | | 316L/min(147) | | | 301L/min(154) |
| $FEV_1$ | | | 2.12L(1.07) | | | 1.96L(1.05) |
| AQLQ symptom score | | | 3.72(1.55) | | | 3.86(1.58) |
| Q score | | | 4.30(2.54) | | | 4.03(2.69) |
| HAD Anxiety | | | 11.88(4.18) | | | 10.80(4.91) |
| HAD Depression | | | 10.23(2.65) | | | 7.65(3.65) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 7 | 27 | |

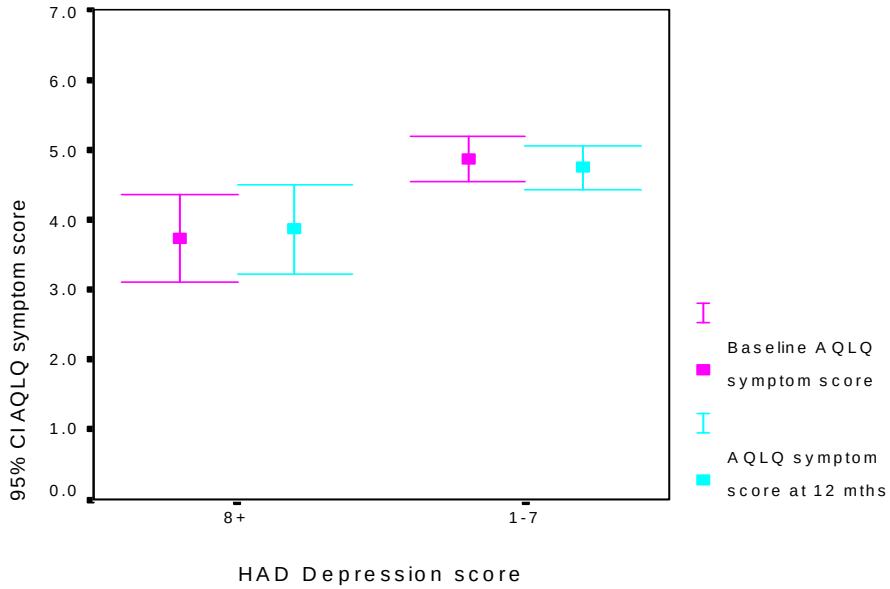
## Table 11b: Baseline and Twelve Months data for Non-Depressed subjects

| *Variable* | *Base Line N=69* | *%* | *Mean (SD)* | *12 months N=69* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 41(12) | | | |
| Gender (male) | 24 | 35 | | | | |
| Current smokers | 14 | 20 | | | | |
| Living in inner city | 36 | 52 | | | | |
| Using ß agonist | 64 | 93 | | 61 | 88 | |
| Using inhaled steroids | 58 | 84 | | 58 | 84 | |
| Using oral steroids | 3 | 4 | | 8 | 12 | |
| Inhaled steroids increased At 12 months | | | | 14 | 20 | |
| BTS Guidelines treatment step (3-5) | 21 | 30 | | 33 | 48 | |
| PEF | | | | | | |
| $FEV_1$ | | | 355L/min(124) | | | 337L/min(123) |
| AQLQ symptom score | | | 2.20L(0.84) | | | 2.18L(0.82) |
| Q score | | | 4.86(1.37) | | | 2.40(2.28) |
| HAD Anxiety | | | 2.42(2.25) | | | 2.40(2.28) |
| HAD Depression | | | 6.64(3.73) | | | 6.71(3.87) |
| Attends GP >1 | | | 3.39(2.17) | | | 3.37(2.57) |
| In 6 months | | | | 4 | 6 | |

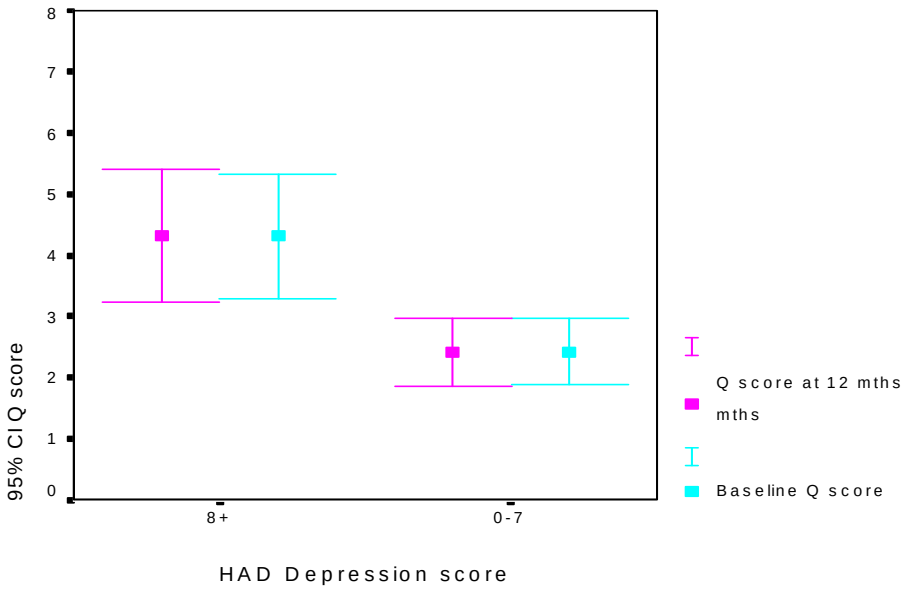
At twelve months 26/30 (87%) depressed subjects assessed at baseline attended for review while a similar proportion 69/80 (86%) of non-depressed subjects also attended. At twelve months depressed subjects had attended their GP practice more often (on more than two occasions 27% versus 6%). There was an increase in both groups into the higher BTS treatment step (3-5) more depressed subjects (58%) received more therapy at twelve months than non-depressed subjects (48%) though not significantly so. It should be noted that more subjects (20%) in the non-depressed group reported their inhaled steroids increased at twelve months than depressed subjects (15%) did.

The observation at baseline of depressed subjects recording significantly more depression and anxiety (both $p<0.001$) was repeated at twelve months. The trend of higher symptom reporting at baseline for the depressed subjects was significant at twelve months (Q score $p<0.01$, AQLQ symptom score $p<0.05$). Figure 31a and b illustrate higher symptom reporting in depressed subjects and Figure 32 illustrate that depressed subjects attended their GP practice more often than non-depressed subjects did.

■ **Figure 31a –** Mean AQLQ symptom score at baseline and twelve months for Depressed and Non-Depressed subjects.

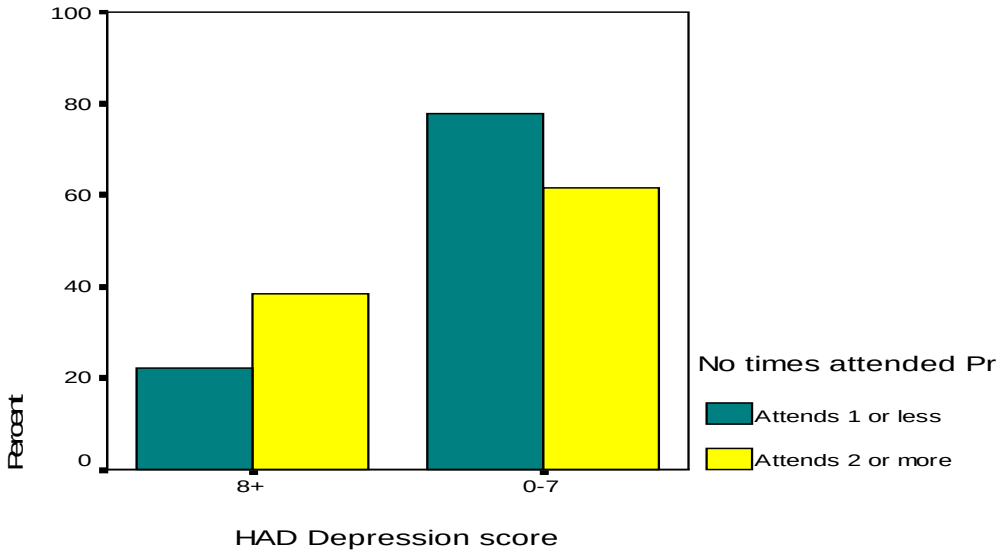



■ **Figure 31b** - Mean Q score at baseline and twelve months for Depressed and Non-Depressed subjects.




■ **Figure 32 –** Bar chart of Depressed and Non-Depressed subjects

who attended GP Practice once or less and twice or more over twelve months.




### 4.2.5 *Changes at twelve months – subjects who had Inhaled Steroid medication increased*

Subject prescriptions for inhaled asthma medication were reviewed at twelve months. The cohort was sub divided by subjects who had had their inhaled steroids prescription increased at the time of the twelve months assessment when compared to baseline prescription. Subjects were placed in the no change group if their inhaled steroid prescription remained as at baseline or their prescription altered in some other way from baseline (inhaled steroids reduced, other medication added or altered).

Eighteen subjects (18/95,19%) reported their inhaled steroids increased at twelve months resulting in sixteen subjects situated in the higher BTS treatment steps (3-5). Fourteen subjects (14/95, 15%) reported an alteration in their medication that did not involve an increase in inhaled cortico steroids. Such alterations included the addition of long acting βagonist, a change in βagonist, the addition of oral steroids, or the addition of other non-steroid medication eg, anticholinergic, theophyllines or cromoglycate. No subject had his or her inhaled steroids reduced at twelve months. While 63/95 (66%) reported no change in

inhaled steroid therapy. The data are shown in Tables 12a and b.

**Table 12a: Baseline Data and Twelve Months Data for Subjects with Inhaled Steroids Increased**

| *Variable* | *Base Line N = 18* | *%* | *Mean (SD)* | *12 months N=18* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 44(8) | | | |
| Gender (male) | 5 | 28 | | | | |
| Current smokers | 5 | 28 | | | | |
| Living in inner city | 12 | 67 | | | | |
| Using ß agonist | 17 | 94 | | 17 | 83 | |
| Using inhaled steroids | 17 | 91 | | 18 | 91 | |
| Using oral steroids | 2 | 11 | | 8 | 27 | |
| BTS Guidelines treatment step (3-5) | 5 | 28 | | 16 | 80 | |
| PEF | | | 316L/min(115) | | | 327L/min(98) |
| $FEV_1$ | | | 1.84L(0.70) | | | 1.94L(0.71) |
| AQLQ symptom score | | | 4.24(1.51) | | | 4.14(1.64) |
| Q score | | | 2.94(2.64) | | | 3.22(2.77) |
| HAD Anxiety | | | 8.17(4.20) | | | 8.94(5.42) |
| HAD Depression | | | 5.52(3.00) | | | 5.16(3.39) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 3 | 17 | |

**Table 12b: Baseline Data and Twelve Months Data for Subjects with Inhaled Steroids Reduced or No Change at Twelve Months**

| *Variable* | *Base Line N=77* | *%* | *Mean (SD)* | *12 months N=77* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 42(12) | | | |
| Gender (male) | 29 | 38 | | | | |
| Current smokers | 18 | 23 | | | | |
| Living in inner city | 45 | 58 | | | | |
| Using ß agonist | 71 | 92 | | 67 | 87 | |
| Using inhaled steroids | 63 | 82 | | 62 | 80 | |
| Using oral steroids | 4 | 5 | | 3 | 4 | |
| BTS Guidelines treatment step (3-5) | 27 | 35 | | 32 | 42 | |
| PEF | | | 350L/min(135) | | | 327L/min(139) |
| $FEV_1$ | | | 2.25L(0.93) | | | 2.16L(0.92) |
| AQLQ symptom score | | | 4.62(1.50) | | | 4.58(1.37) |
| Q score | | | 2.93(2.45) | | | 2.85(2.49) |
| HAD Anxiety | | | 8.07(4.59) | | | 7.57(4.31) |
| HAD Depression | | | 5.23(3.96) | | | 4.40(3.48) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 8 | 10 | |

An increase in subjects inhaled steroids at twelve months was not

linked to age, gender, smoking habit or place of residence. Subjects who had inhaled steroids increased did have poorer initial lung function but no difference in symptoms or psychological status was observed at baseline.

At twelve months subjects whose inhaled steroids were increased had improved their $FEV_1$ by 100mls but with no improvement in symptoms while subjects with no increase in inhaled steroids had dropped their $FEV_1$ by 90mls. No change in psychological status was observed between groups at twelve months.

## 4.3 Changes and Relationships within the Cohort of Subjects at Twenty-four Months

At twenty-four months one hundred and six subjects were left in the study. One subject had left the area without any forward address and fifteen subjects refused appointments, were unable to attend for review or did not attend despite repeated contact. Baseline data from twenty-four subjects who withdrew from the study can be found in Appendix XII. Ninety subjects attended for review at twenty-four months (90/114) 79% of the cohort. There were seventy-nine subjects who attended for review at baseline, twelve and twenty-four months. Their data can by viewed in Appendix XIII.

### *4.3.1 Twenty-four month data for 90 subjects*

Table 13 illustrates the baseline data set and twenty-four month data set for ninety subjects who attended for review. Data will be explored against baseline for differences in order to note any changes in values. The relationships between morbidity, (as measured by AQLQ symptom score and Q score) psychological status, (as measured by HAD scores) $FEV_1$ and PEF will be explored by Spearman rank order correlation coefficient in order to assess if relationships established at baseline persist at twenty-four months.

**Table 13: Data from 90 Subjects at Baseline and at Twenty-Four Months**

| *Variable* | *Base Line N=90* | *%* | *Mean (SD)* | *24 months N=90* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 43 (11) | | | |
| Gender(Male) | 35 | 39 | | | | |
| Living in inner city | 55 | 61 | | | | |
| Current smokers | 25 | 28 | | | | |
| Using β agonist | 83 | 92 | | 77 | 86 | |
| Using inhaled steroids | 75 | 83 | | 75 | 83 | |
| Using oral steroids | 7 | 8 | | 8 | 9 | |
| Inhaled steroids | | | | | | |
| Increased at 24 months | | | | 11 | 12 | |
| BTS Guidelines treatment step (3-5) | 28 | 31 | | 44 | 49 | |
| PEF | | | 357L/min(130) | | | 344L/min(127) |
| $FEV_1$ | | | 2.25L(0.89) | | | 2.37L(0.91) |
| AQLQ | | | 4.73(1.22) | | | 4.73(1.28) |
| AQLQ symptom score | | | 4.62(1.47) | | | 4.69(1.55) |
| Q score | | | 2.78(2.41) | | | 2.80(2.5) |
| HAD Anxiety | | | 7.93(4.22) | | | 7.81(4.93) |
| HAD Depression | | | 4.95(3.63) | | | 5.06(3.93) |

The observation at baseline and twelve months for the proportion of female subjects and subjects residing in inner city areas attending for review was repeated at twenty-four months. At twenty-four months 61%, (51/90) of subjects were female and 61% (55 /90) were from the inner city subgroup.

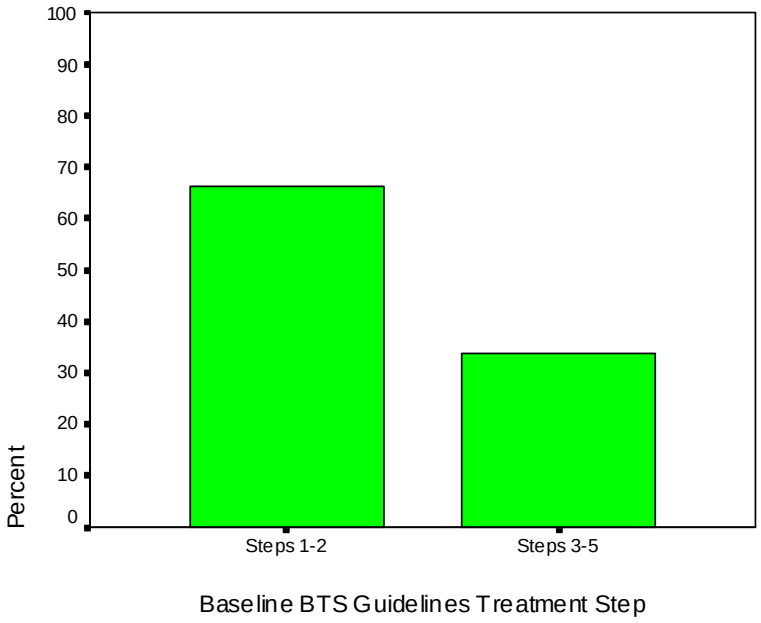
The decrease in the use of βagonist observed at twelve months from baseline was maintained at twenty-four months (93% at baseline, 88% at twelve months and 86% at twenty-four months). The use of inhaled steroids was maintained throughout the study period (83% at baseline, 84% at twelve months dropping 1% at twenty-four months). The use of oral steroids rose slightly from 7% at baseline to 12% at twelve months then down slightly to 9% at twenty-four months.

The stability of the population observed at twelve months was repeated at two years with only 2% of the cohort admitted to

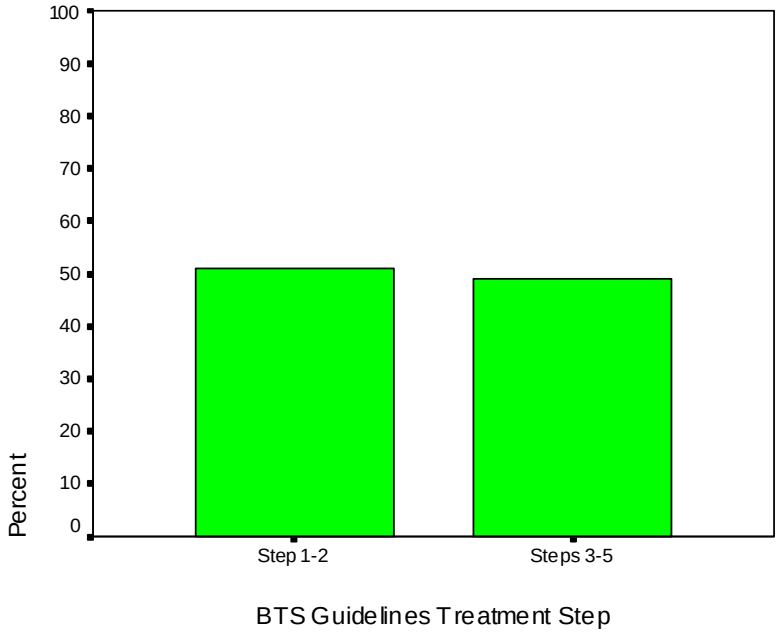
hospital in excess of 24 hours for exacerbation of their asthma. Similar observations occurred at two years for GP visits with 66% (59/90) of the population not visiting their GP for exacerbation of their asthma (75% at twelve months). Again similar observations were recorded for those who did attend their GP for exacerbation of their asthma at two years, 52% (16/31) received one or more courses of oral steroids with 54% (13/24) at twelve months. On their last visit to their GP for their asthma subjects were asked as to the purpose of their visit, 20% of subjects required better control of their asthma symptoms.

The group observations at twelve months were repeated at two years. Within the group of ninety subjects no significant differences were found at twenty-four months from baseline for PEF, $FEV_1$, AQLQ, AQLQ symptom score, Q score, HAD anxiety or depression. However, there was a significant increase in the number of subjects in BTS treatment steps 3-5 (31% versus 49%, $p<0.001$) from baseline to twenty-four months (McNemar test). Figure 33b illustrates this.

■ **Figure 33a -** Subjects in BTS Guidelines treatment steps (1-2 and 3-5) at baseline.




■ **Figure 33b -** Subjects in BTS Guidelines treatment steps (1-2 and 3-5) at twenty-four months follow up ($p<0.01$).



*and Psychological Status at twenty-four months.*

*Cross sectional changes*

The exploration of the cross sectional relationships of QoL measures to lung function and psychological status at baseline (see Table 2) was repeated at twelve months (see Table 8) and two years (see Table 14). At baseline symptom scores (AQLQ symptom score and Q score) were used as a measure of QoL, subjects spirometry ($FEV_1$) and PEF were also recorded as a test of lung function, anxiety and depression were noted to assess psychological status and BTS guidelines treatment step as a measure of severity.

The same observations recorded at baseline, twelve and twenty-four months for symptoms of morbidity, Q score and AQLQ symptom score correlated in the same manner (both $p<0.01$) (see Figures 34a and b). Symptoms correlated to lung function ($FEV_1$ and PEF) (both $p<0.01$) at baseline this observation was repeated throughout the two year study period (see Figures 35a and c) as did anxiety and depression (both $p<0.01$). Figures 35b and d show the relationship of recorded PEF expressed as a percentage of predicted values to morbidity scores at twenty-four months. Lung function ($FEV_1$) and PEF did not correlate to psychological status at two years. This was a different observation to baseline, depression weakly correlated to PEF while at twelve months anxiety ($p<0.05$) and depression ($p<0.01$) correlated to $FEV_1$ and PEF.

*Longitudinal changes*

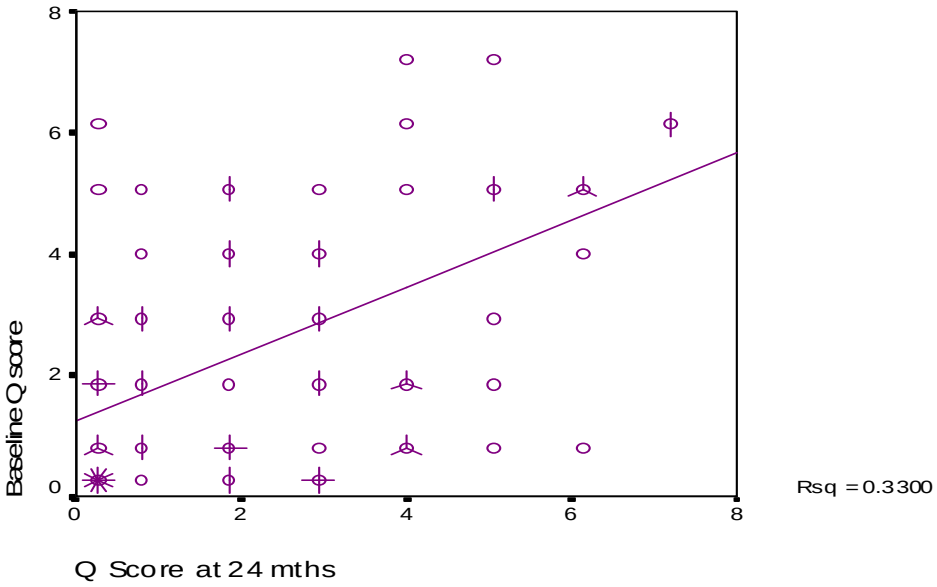
Within the group of ninety subjects reviewed there were no significant differences at twenty-four months from baseline for PEF, $FEV_1$, AQLQ, AQLQ symptom score, Q score, HAD anxiety or depression.

**Table 14: Spearman Rank Order Correlation Coefficients for 90 subjects at Twenty-four Months**

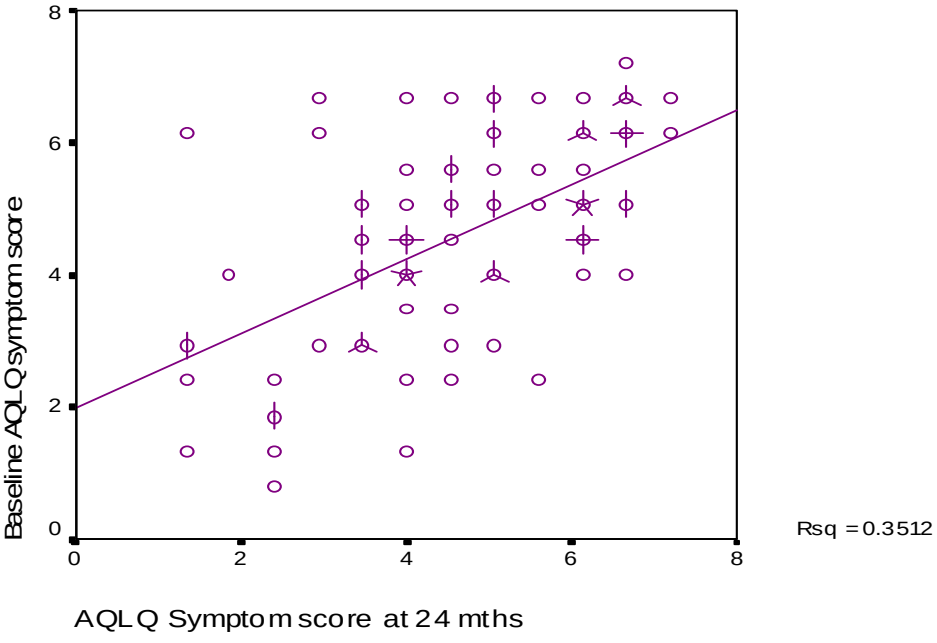
| | ***Q Score 24 months*** | ***AQLQ Symptom Score 24 months*** | ***HAD Anxiety 24 months*** | ***HAD Depression 24 months*** | ***$FEV_1$ 24 months*** | ***PEF 24 months*** |
|---|---|---|---|---|---|---|
| ***Q Score 24 months*** | | -.748 | .351 | .473 | -.469 | -.454 |
| ***AQLQ symptom score 24 months*** | -.748 | | -.400 | -.485 | .285 | .321 |
| ***HAD Anxiety 24 months*** | .351 | -.400 | | .719 | NS | NS |
| ***HAD Depression 24 months*** | .473 | -.485 | .719 | | NS | NS |
| ***$FEV_1$ 24 months*** | -.469 | -.469 | NS | NS | | |
| ***PEF 24 months*** | -.454 | .321 | NS | NS | | |

All values were significant $p<0.01$ NS not significant.

■ **Figure 34a** - Baseline Q score correlated to Q score at twenty-four months ($p<0.01$)

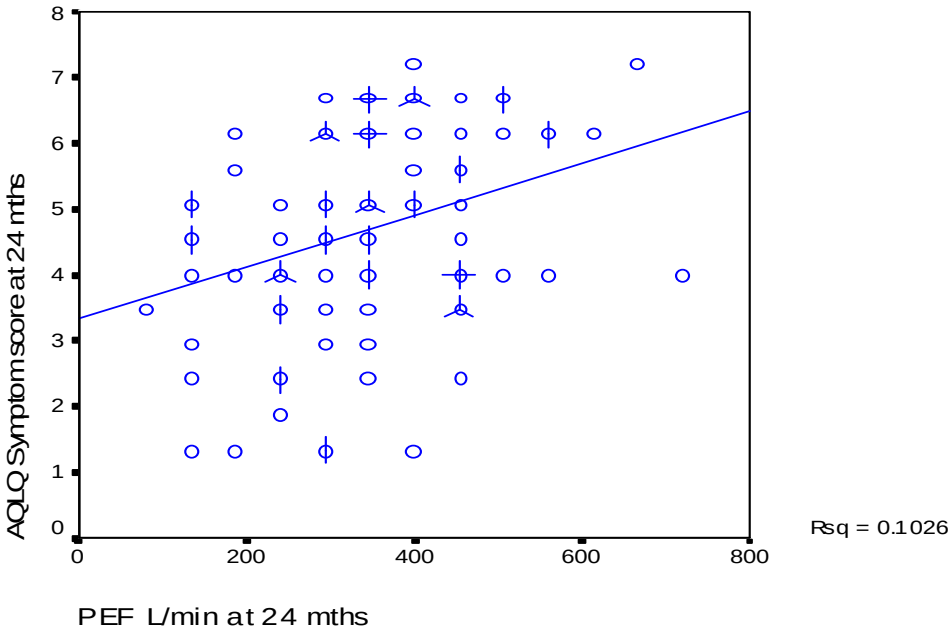



■ **Figure 34b** - Baseline AQLQ symptom score correlated to AQLQ symptom score at twenty-four months ($p<0.01$).

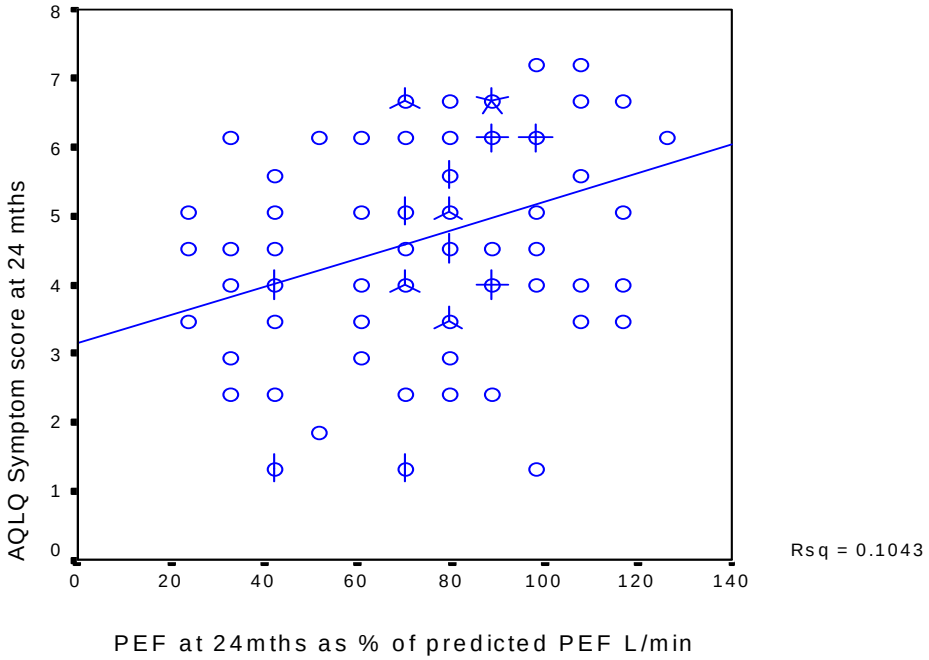



■ **Figure 35a** - Morbidity as measured by AQLQ symptom score correlated to poor lung function as measured by PEF at twenty-

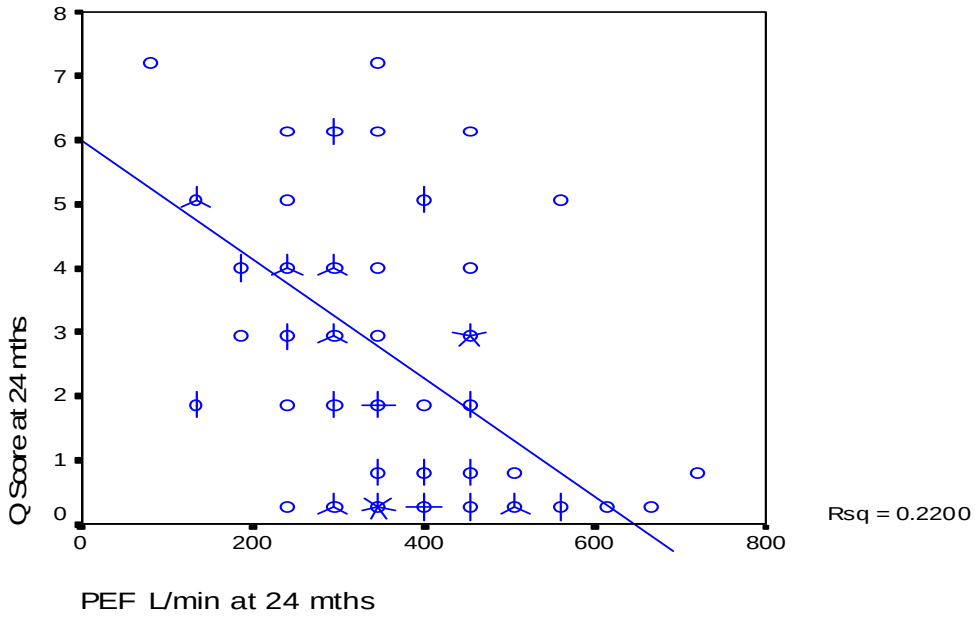
four months (p<0.01).



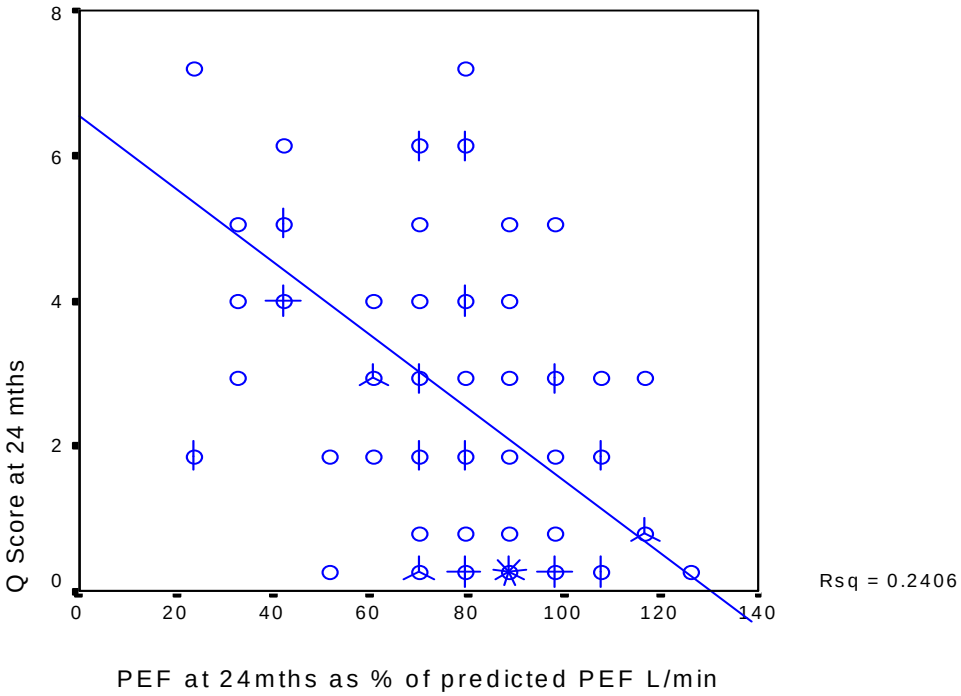

■ **Figure 35b** - Correlation of PEF at twenty four months as a percentage of predicted PEF to morbidity as measured by AQLQ symptom score (p<0.01)



■ **Figure 35c** Morbidity as measured by Q score correlated inversely to poor lung function as measured by PEF at twenty-four months ($p<0.01$).




■ **Figure 35d** - correlation of PEF at twenty four months as a percentage of predicted PEF to morbidity as measured by Q score ($p<0.01$)



### 4.3.2 *Changes at twenty-four months – the population sub divided by place of residence.*

The population was subdivided by their place of residence at baseline. Sixty-five percent (70/114) of subjects lived within the inner city area (see Table 4a and b). Similar proportions for groups' inner city and suburban residents attended for review at two years (inner city residents, 61%, 55/90) these data are shown in Table 15a and b. This was a repartition of the baseline and twelve months observation (see Table 9a and b).

**Table 15a: Baseline Data and Twenty-Four Month Data for Inner city subjects**

| *Variable* | *Base Line N=55* | *%* | *Mean (SD)* | *24 months N=55* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 41(12) | | | |
| Gender (male) | 21 | 38 | | | | |
| Smoking | 21 | 38 | | | | |
| Using ß agonist | 50 | 91 | | 48 | 87 | |
| Using inhaled steroids | 46 | 84 | | 46 | 84 | |
| Using oral steroids | 4 | 7 | | 7 | 13 | |
| Inhaled steroids increased at 24 months | | | | 8 | 15 | |
| BTS Guidelines treatment step (3-5) | 15 | 27 | | 24 | 44 | |
| PEF | | | 350L/min(137) | | | 333L/min(137) |
| $FEV_1$ | | | 2.2L(0.95) | | | 2.36L(0.97) |
| AQLQ | | | 4.47(1.35) | | | 4.42(1.36) |
| AQLQ symptom score | | | 4.25(1.52) | | | 4.29(1.62) |
| Q score | | | 3.25(2.67) | | | 3.27(2.67) |
| HAD Anxiety | | | 9.22(4.00) | | | 8.70(4.40) |
| HAD Depression | | | 5.83(3.97) | | | 5.69(3.98) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 11 | 20 | |

**Table 15b: Baseline Data and Twenty-Four Month Data for Suburban subjects**

| *Variable* | *Base Line N=35* | *%* | *Mean (SD)* | *24 months N=35* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 45(11) | | | |
| Gender (male) | 14 | 40 | | | | |
| Smoking | 4 | 11 | | | | |
| Using ß agonist | 33 | 94 | | 29 | 83 | |
| Using inhaled steroids | 29 | 3 | | 29 | 83 | |
| Using oral steroids | 3 | 9 | | 1 | 3 | |
| Inhaled steroids increased at 24 months | | | | 2 | 6 | |
| BTS Guidelines treatment step (3-5) | 13 | 37 | | 20 | 57 | |
| PEF | | | 369L/min(117) | | | 360L/min(110) |
| $FEV_1$ | | | 2.29L(0.78) | | | 2.38L(.80) |
| AQLQ | | | 5.14(0.88) | | | 5.21(.95) |
| AQLQ symptom score | | | 5.22(1.20) | | | 5.30(1.22) |
| Q score | | | 2.05(1.71) | | | 2.07(2.04) |
| HAD Anxiety | | | 5.94(3.81) | | | 6.40(5.42) |
| HAD Depression | | | 3.60(2.51) | | | 4.08(3.69) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 2 | 6 | |

Fifty-five (61%) subjects resided and attended GP practices within the inner city. Little change occurred in the usage of βagonist or inhaled steroids over the two-year period although there was an increase in the use of oral steroids (7% versus 13%). There was however, an increase in the number of subjects in the higher treatment group (BTS Guidelines treatment step 3-5) of 17% ($p<0.01$), this was a repeated observation from baseline to twelve months.

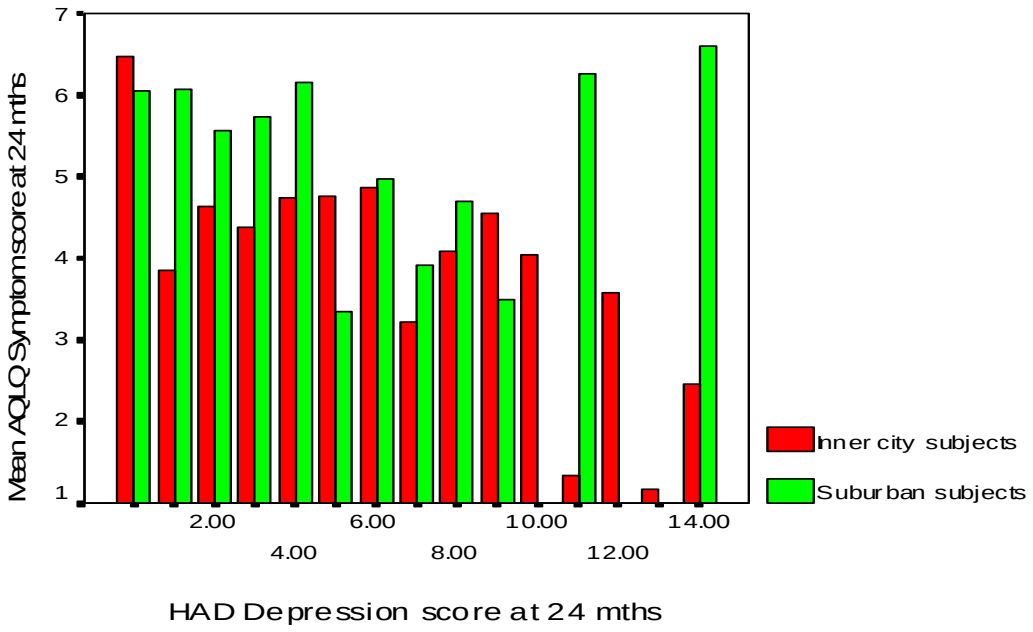
Thirty-five (39%) subjects resided and attended GP practices within the suburbs. There was little change in the use of medication over the two-year period in the suburban subjects. Although there was an increase in the dosage of inhaled steroids as noted by the 20% increase in the number of subjects in steps 3-5 ($p<0.01$), this was a repeated observation from baseline to twelve months.

The observation of no significant difference for lung function ($FEV_1$ and PEF) between groups at baseline was repeated at twelve and twenty-four months.

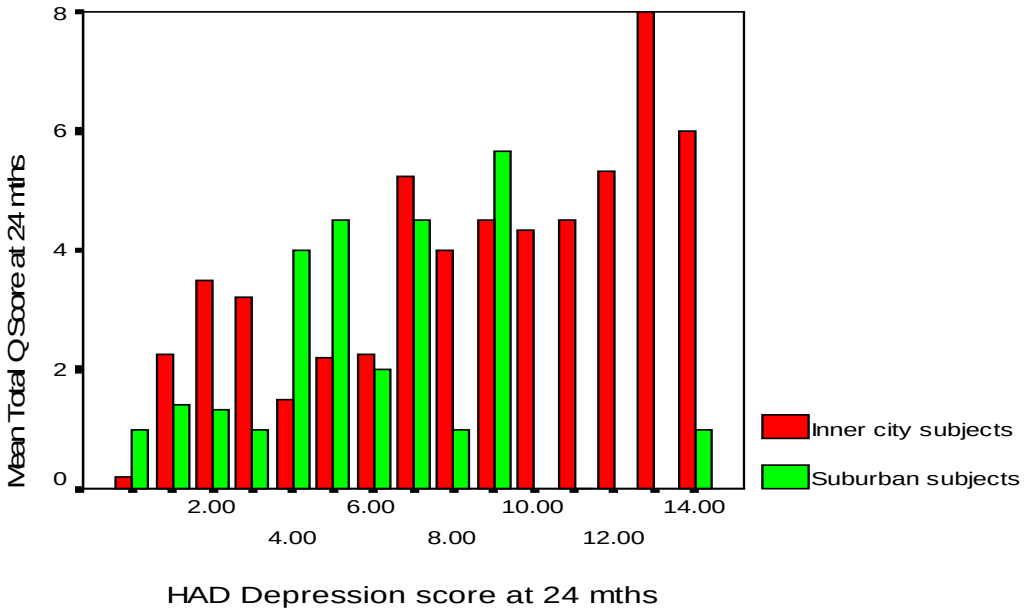
At baseline there were no significant differences between groups for morbidity scores. However, at twelve months morbidity score were significantly higher in inner city subjects. This observation was repeated at two years where morbidity as measured by Q score and AQLQ symptom score were significantly higher in inner city subjects ($p<0.05$ and $p<0.01$ respectively). Levels of treatment for inner city subjects did increase more so than suburban subjects at twelve months and this was repeated at two years. Inner city subjects received more oral steroids (13% versus 3%) and 15% versus 6% had their inhaled steroids increased.

The relationship of psychological status between groups changed over the two-year period. At baseline inner city subjects were significantly more anxious and depressed this was repeated at two years although the relationships were not as strong (anxiety $p<0.01$ and depression $p<0.05$). At twelve months inner city subjects remained depressed but no more anxious than their suburban counterparts. Figures 36a and b illustrate inner city subjects were more depressed and had increased morbidity levels when measured by AQLQ symptom score and Q score

■ **Figure 36a –** Mean AQLQ symptom scores and HAD Depression scores for inner city and suburban subjects at twenty-four months.




■ **Figure 36b** - Mean Q scores and HAD Depression scores for inner city and suburban subjects at twenty-four months.




*4.3.3 Changes at twenty-four months - the population sub divided for*

*severity (BTS Guidelines treatment step 1-2 versus 3-5)*

Subjects were sub divided at baseline into two groups according to asthma severity, BTS Guidelines treatment step 1-2 and 3-5 (see Table 6a and b). The majority of the subjects recruited to the study were in the lower treatment step of 1-2, 70% (80/114) at baseline. At twelve months 79% (63/80) attended for reassessment and 78% (62/80) at two years. A high percentage of subjects in treatment steps 3-5 attended for review at twelve months (94%, 32/34) this was repeated at two years with 82% (28/34) of subjects attending. At two-year follow up the majority of subjects (69%, 62/90) remained in the lower treatment group of BTS Guidelines treatment step 1-2.These data are shown in Table 16a and b.

**Table 16a:Baseline Data and Twenty-Four Month Data for subjects in BTS Guidelines treatment step 1-2**

| *Variable* | *Base Line N=62* | *%* | *Mean (SD)* | *24 months N=62* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 41(12) | | | |
| Gender (male) | 21 | 34 | | | | |
| Smoking | 19 | 31 | | | | |
| Inner city | 40 | 65 | | | | |
| Using ß agonist | 55 | 89 | | 50 | 81 | |
| Using inhaled steroids | 47 | 76 | | 47 | 76 | |
| Using oral steroids | 1 | 2 | | 1 | 2 | |
| PEF | | | 362L/min(117) | | | 343L/min(127) |
| $FEV_1$ | | | 2.30L(0.79) | | | 2.39L(0.87) |
| AQLQ symptom score | | | 4.80(1.40) | | | 4.88(1.48) |
| Q score | | | 2.19(2.09) | | | 2.62(2.45) |
| HAD Anxiety | | | 8.11(4.25) | | | 8.12(4.94) |
| HAD Depression | | | 4.50(3.68) | | | 4.61(3.93) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 6 | 10 | |

**Table 16b:Baseline Data and Twenty-Four Month Data for subjects in BTS Guidelines treatment step 3-5**

| *Variable* | *Base Line N=28* | *%* | *Mean (SD)* | *24 months N=28* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 47(10) | | | |
| Gender (male) | 14 | 50 | | | | |
| Smoking | 6 | 21 | | | | |
| Inner city | 15 | 54 | | | | |
| Using ß agonist | 28 | 10 | | 27 | 96 | |
| Using inhaled steroids | 28 | 0 | | 28 | 100 | |
| Using oral steroids | 6 | 0 | | 7 | 25 | |
| PEF | | | 344L/min(157) | | | 345L/min(129) |
| $FEV_1$ | | | 2.13L(1.08) | | | 2.32L(1.00) |
| AQLQ symptom score | | | 4.23(1.58) | | | 4.26(1.64) |
| Q score | | | 4.25(2.45) | | | 3.17(2.62) |
| HAD Anxiety | | | 7.51(4.20) | | | 7.10(4.91) |
| HAD Depression | | | 6.00(3.33) | | | 6.07(3.79) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 7 | 25 | |

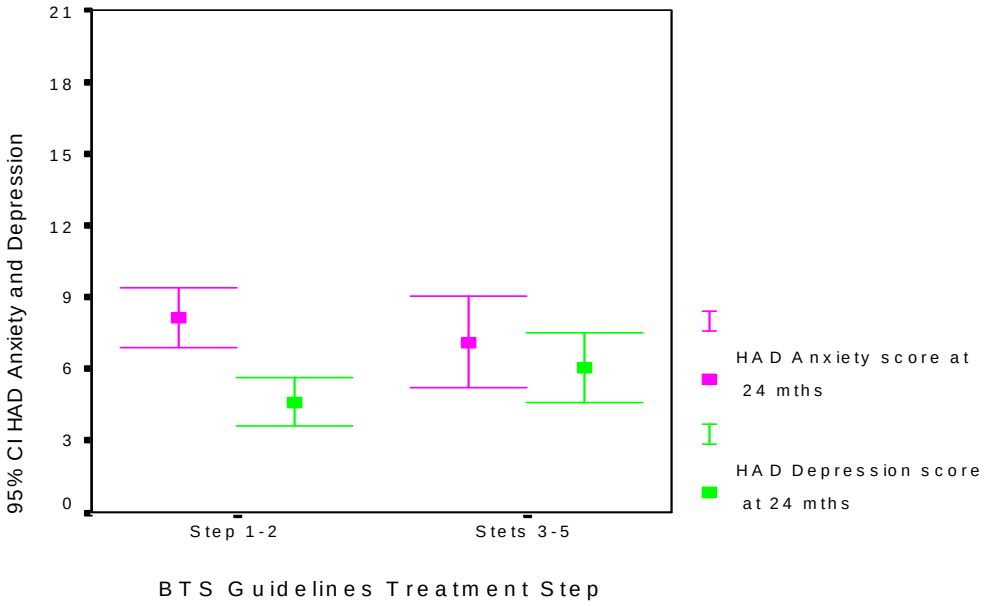
Sixty-nine percent (62/90) of subjects from baseline were in BTS Guidelines treatment step 1-2 requiring minimal medication to reduce asthma symptoms.

Thirty-one percent (28/90) of subjects from baseline were in BTS Guidelines treatment step 3-5 requiring moderate medication to minimise asthma symptoms. At twenty-four months all subjects (100%) within BTS Guidelines treatment step 3-5 had remained in the same step from baseline.

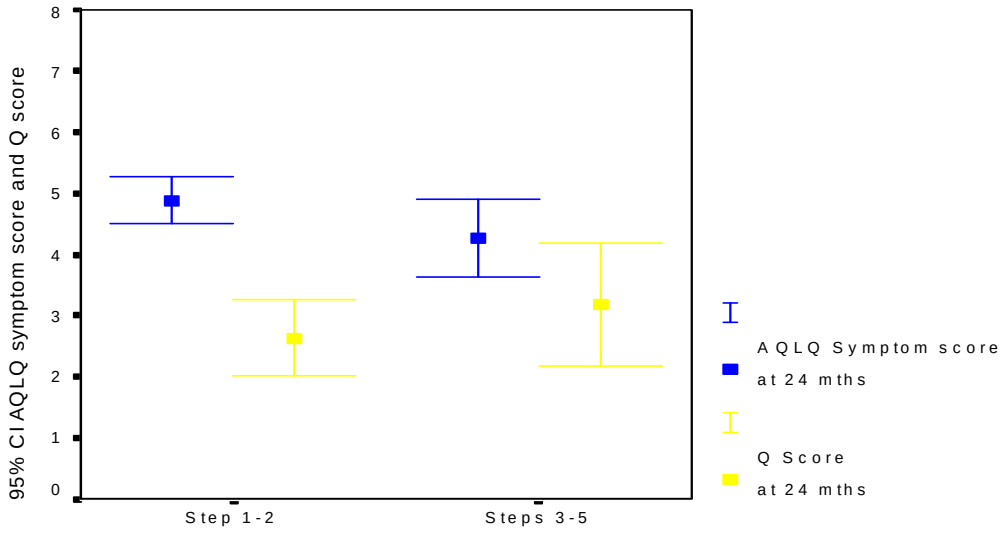
There were no significant differences between these groups at two years. However, the trend of increased morbidity associated with anxiety and depression in higher treatment steps noted at twelve months was repeated at two years. At twenty-four months subjects in high treatment steps also visited their GP practice more often (10% versus 25%) than their step 1-2 counter parts. Figures 37 and 38 illustrate subjects in high treatment step were more depressed and exhibited more symptoms of asthma than subjects in low treatment step. Figure 39 illustrates subjects in high treatment steps attended their GP practice more often than

other subjects did.

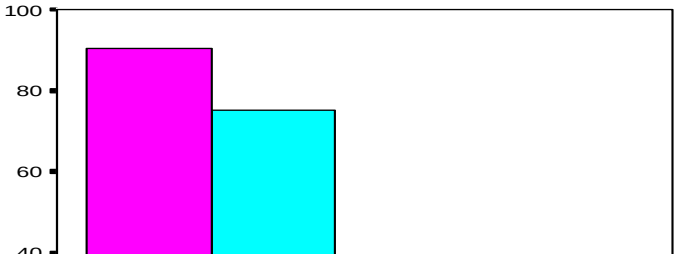
■ **Figure 37** - Mean HAD Anxiety and Depression scores for BTS Guidelines treatment steps 1-2 and 3-5 at twenty-four months.




■ **Figure 38 –** Mean AQLQ symptom score and Q score at twenty-four months for subjects in BTS Guidelines treatment steps 1-2 and 3-5.




■ **Figure 39** - Attendance at GP practice in last six months prior to twenty-four month review for subjects in BTS Guidelines treatment step 1-2 and 3-5.



### *4.3.4 Change at twenty-four months –the population subdivided by initial psychological status*

The population was subdivided for depression at baseline (see Table 5a and b). Subjects with HAD depression scores of 7 or less were said to exhibit no sign of depression or anxiety while those with scores of 8 or greater were placed in the depressed group. The proportion of depressed subjects was maintained throughout the two year study period with 27% (30/113) depressed at baseline, 27% (26/95) at twelve months and 24% (22/90) at two years. Three-quarters (76%, 83/113) of the cohort were not depressed at baseline. Leaving 24% (30/113) of subjects depressed, of those depressed subjects 86% (25/30) resided within the inner city and smoked (32% versus 27%) more than their non-depressed counterparts. Twenty-four percent (22/90) of subjects were classed as depressed at outset with HAD depression scores of 8 or more. At twenty-four months 14/22 (64%) subjects remained depressed. Seventy-six percent (68/90) of subjects were classed as non-depressed at outset with HAD depression scores below 8. At twenty-four months 58/68 (85%) subjects remained non-depressed. These data are shown in Table 17a and b.

**Table 17a: Baseline Data and Twenty-Four Months Data for Depressed subjects**

| *Variable* | *Base Line N=22* | *%* | *Mean (SD)* | *24 months N=22* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 48(8) | | | |
| Gender (male) | 8 | 36 | | | | |
| Smoking | 7 | 32 | | | | |
| Inner city | 19 | 86 | | | | |
| Using ß agonist | 19 | 86 | | 19 | 86 | |
| Using inhaled steroids | 20 | 91 | | 20 | 91 | |
| Using oral steroids | 3 | 14 | | 3 | 14 | |
| Inhaled steroids increased at 24 months | | | | 5 | 23 | |
| BTS Guidelines treatment step (3-5) | 9 | 41 | | 16 | 73 | |
| PEF | | | 318L/min(147) | | | 320L/min(139) |
| $FEV_1$ | | | 2.06L(.97) | | | 2.17L(0.98) |
| AQLQ symptom score | | | 3.73(1.52) | | | 3.85(1.80) |
| Q score | | | 4.13(2.47) | | | 4.09(2.89) |
| HAD Anxiety | | | 11.68(4.24) | | | 10.72(4.53) |
| HAD Depression | | | 10.04(2.21) | | | 8.59(3.41) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 5 | 23 | |

**Table 17b: Baseline Data and Twenty-Four Months Data for Non-Depressed subjects**

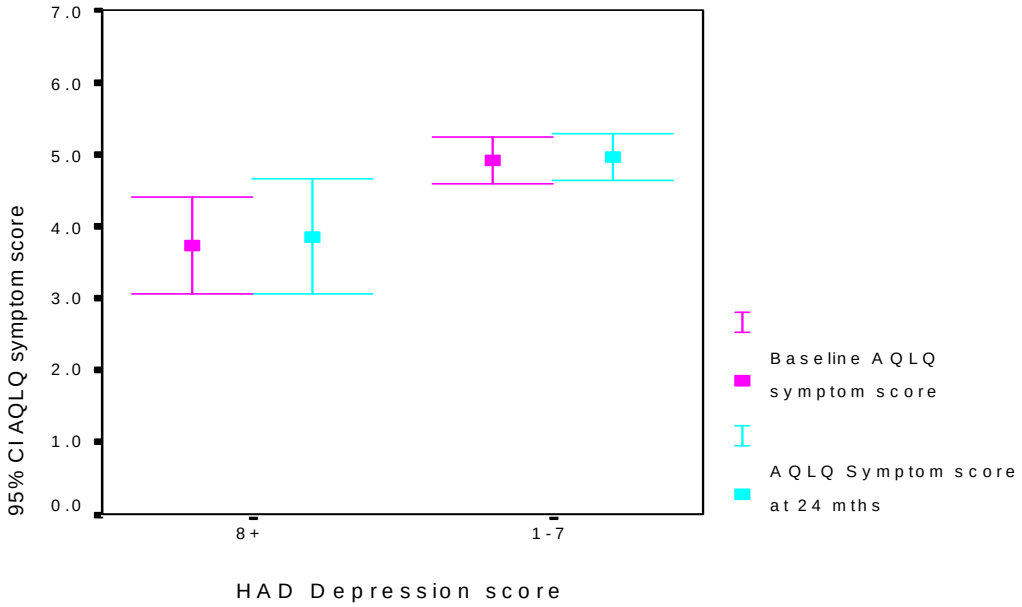
| *Variable* | *Base Line N=68* | *%* | *Mean (SD)* | *24 months N=68* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 41(12) | | | |
| Gender (male) | 27 | 40 | | | | |
| Smoking | 18 | 27 | | | | |
| Inner city | 36 | 53 | | | | |
| Using ß agonist | 64 | 94 | | 58 | 85 | |
| Using inhaled steroids | 55 | 81 | | 55 | 81 | |
| Using oral steroids | 4 | 6 | | 5 | 7 | |
| Inhaled steroids increased at 24 months | | | | | | |
| BTS Guidelines treatment step (3-5) | 19 | 28 | | 29 | 43 | |
| PEF | | | 369L/min(123) | | | 351L/min(123) |
| $FEV_1$ | | | 2.30L(0.86) | | | 2.43L(0.88) |
| AQLQ symptom score | | | 4.91(1.34) | | | 4.96(1.37) |
| Q score | | | 2.35(2.23) | | | 2.38(2.23) |
| HAD Anxiety | | | 6.70(3.44) | | | 6.86(4.70) |
| HAD Depression | | | 3.28(2.13) | | | 3.92(3.38) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 8 | 12 | |

There were more depressed subjects in the higher treatment step (3-5) at baseline and at twelve months this trend was maintained

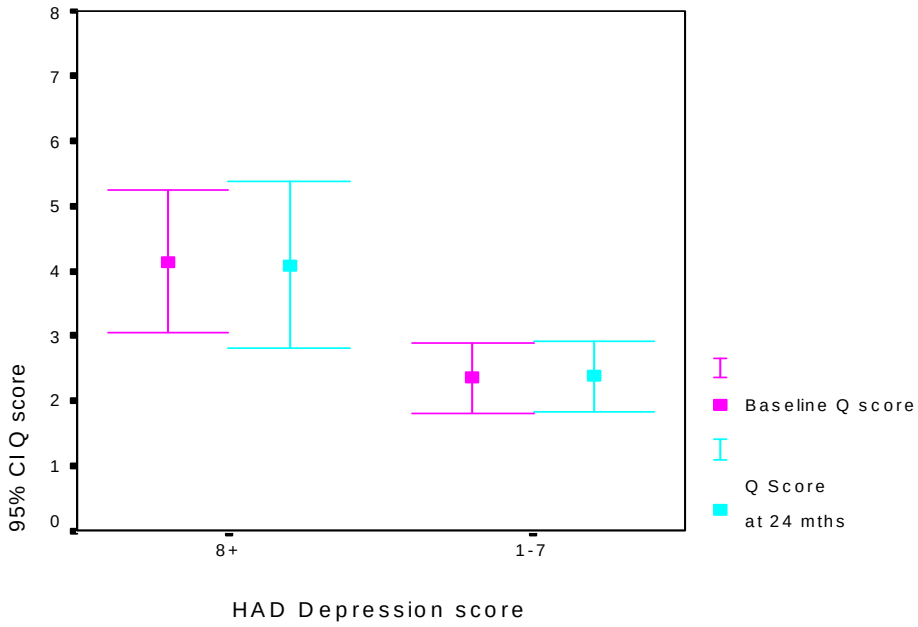
at twenty-four months (73% versus 43% at twenty-four months). At the two-year assessment the increase in the number of subjects from both groups into the higher treatment step observed at twelve months was maintained. Seventy-three percent of depressed subjects were in steps 3-5 by twenty-four months, increase in the number of subjects in the higher treatment group with 23% having their inhaled steroids increased. Subjects were said to have inhaled steroids increased at two years if their initial inhaled steroid therapy prescription was increased at the time of the two-year review. It should be noted that more subjects in the depressed group (23%) reported their inhaled steroids increased at twenty-four months than non-depressed subjects (7%) did. This is directly opposite to the twelve-month increase.

The initial and twelve-month observation that depressed subjects remained significantly more depressed and anxious was maintained at two years (both $p<0.001$). The twelve month observation regarding symptoms was also repeated at two years with depressed subjects reporting more symptoms of asthma (Q score $p<0.05$, AQLQ symptom score $p<0.01$) than their non-depressed counterparts. The observation at twelve months of depressed subjects attending their GP practice more often than a non-depressed subject was maintained at two years. Depressed subjects attended their GP practice on more than two occasions 23% versus 12% than non-depressed subjects (see Figures 40a and b and 41).

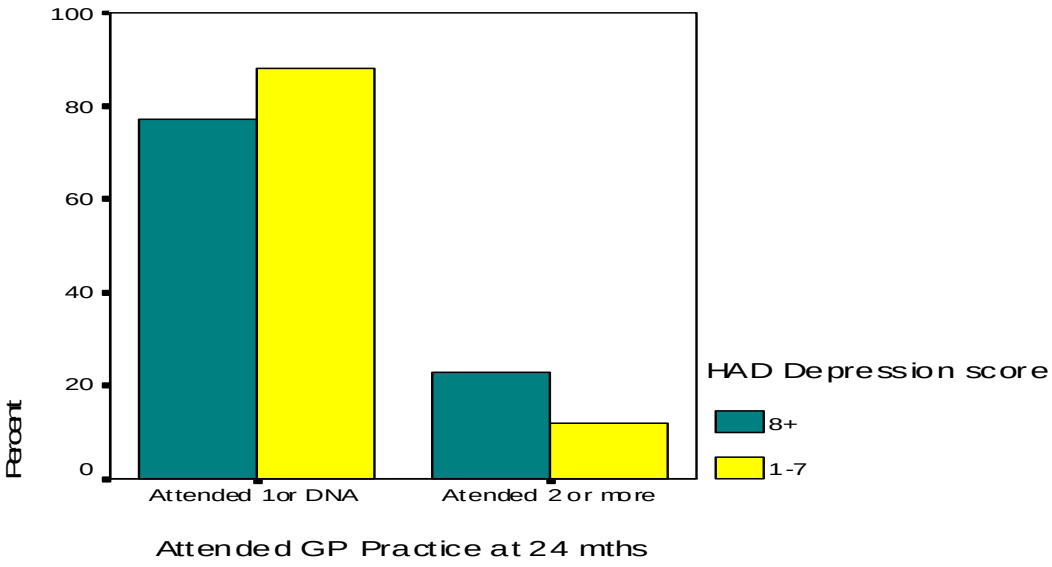
■ **Figures 40a –** Mean AQLQ symptom scores for depressed and non-depressed subjects at twenty-four months.




■ **Figure 40b** - Mean Q scores for depressed and non-depressed subjects at twenty-four months.



■ **Figure 41** - Attendance at GP practice in last six months prior to twenty-four month review for depressed and non-depressed subjects.




*4.3.5 Changes at twenty-four months – subjects with Inhaled Steroids medication increased*

Subject prescriptions for inhaled asthma medication were reviewed at twenty-four months. The cohort was sub divided by subjects who had their inhaled steroid prescription increased at the time of the two-year assessment ('increased treatment' group) when compared to baseline prescription. Subjects were placed into the 'no change' group if their inhaled steroid prescription remained as at baseline or their prescription altered in some other way from baseline (inhaled steroids reduced, other medication added or altered). Ten (11%) subjects recorded inhaled steroids increased at twenty-four months. Eighty (89%) subjects reported no change or a reduction in inhaled steroids at twenty-four months. These data are shown in Table 18a and b.

## Table 18a: Baseline Data and Twenty-Four Months Data for Subjects with Inhaled Steroids Increased

| *Variable* | *Base Line N=10* | *%* | *Mean (SD)* | *24 months N=10* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 43 (8) | | | |
| Gender (male) | 4 | 40 | | | | |
| Smoking | 3 | 30 | | | | |
| Inner city | 8 | 80 | | 10 | 100 | |
| Using ß agonist | 9 | 90 | | 10 | 100 | |
| Using inhaled steroids | 8 | 80 | | 10 | 100 | |
| Using oral steroids | 0 | 0 | | 3 | 30 | |
| BTS Guidelines treatment step (3-5) | 3 | 30 | | 10 | 100 | |
| PEF | | | 365L/min(118) | | | 323L/min(130) |
| $FEV_1$ | | | 2.46L(0.87) | | | 2.40L(0.91) |
| AQLQ symptom score | | | 4.02(2.02) | | | 4.15(1.59) |
| Q score | | | 3.60(2.95) | | | 4.10(2.99) |
| HAD Anxiety | | | 10.40(4.35) | | | 8.70(5.07) |
| HAD Depression | | | 6.70(4.00) | | | 6.56(4.64) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 4 | 40 | |

## Table 18b: Baseline Data and Twenty-Four Months Data for Subjects with no change or a reduction in inhaled steroids

| *Variable* | *Base Line N=80* | *%* | *Mean (SD)* | *24 months N=80* | *%* | *Mean (SD)* |
|---|---|---|---|---|---|---|
| Age | | | 43(12) | | | |
| Gender (male) | 31 | 39 | | | | |
| Smoking | 22 | 28 | | | | |
| Inner city | 47 | 59 | | | | |
| Using ß agonist | 74 | 93 | | 67 | 83 | |
| Using inhaled steroids | 67 | 83 | | 65 | 81 | |
| Using oral steroids | 7 | 9 | | 5 | 6 | |
| BTS Guidelines treatment step (3-5) | 25 | 31 | | 36 | 44 | |
| PEF | | | 356L/min(132) | | | 346L/min(0.91) |
| $FEV_1$ | | | 2.25L(0.90) | | | 2.35L(0.91) |
| AQLQ symptom score | | | 4.70(1.39) | | | 4.75(1.55) |
| Q score | | | 2.68(2.33) | | | 2.63(2.41) |
| HAD Anxiety | | | 7.62(4.13) | | | 7.70(4.93) |
| HAD Depression | | | 4.73(3.54) | | | 4.88(3.82) |
| Attends GP >1 | | | | | | |
| In 6 months | | | | 9 | 11 | |

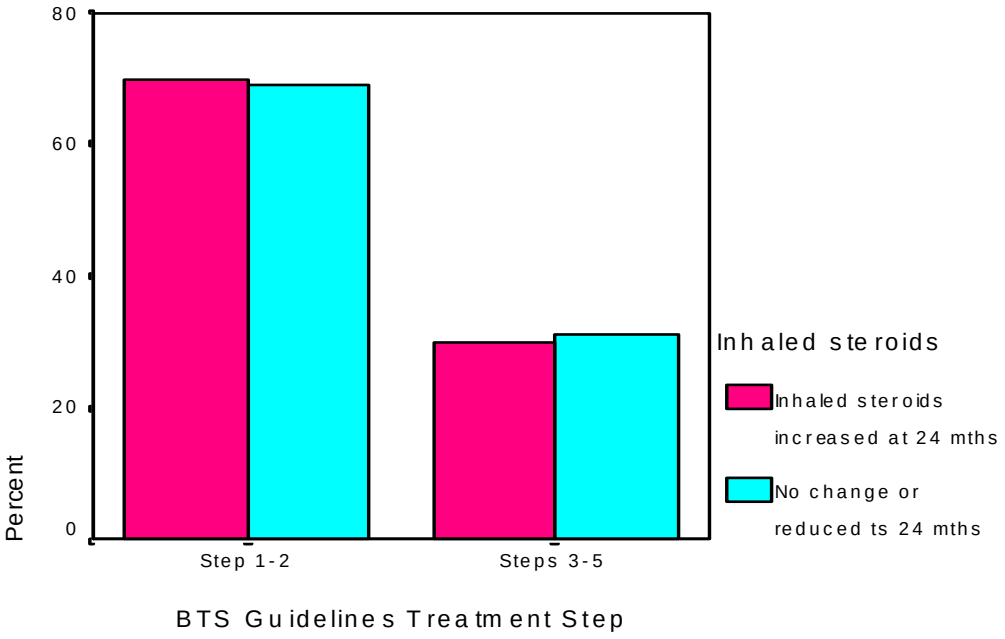
Ten subjects (10/90, 11%) reported their inhaled steroids increased at twenty-four months. Twelve percent (11/90) of subjects reported an alteration in their medication that did not involve an increase in their inhaled steroids. Such alterations included the addition of oral steroids, or the addition of other non-steroid medication eg, anticholinergic, theophylline or cromoglycate while one subject had their inhaled steroid stopped at two years. Sixty-nine subjects (69/90, 77%) recorded no change in inhaled steroids while. Overall seven subjects moved into the higher BTS treatment steps (3-5) over the two-year period. Figure 42 illustrates the limited increase in inhaled steroids in high and low treatment steps at two years.

Any increases in subjects inhaled steroids at two years were not linked to age, gender, smoking habit, or place of residence. At baseline the 'increased treatment' group did have slightly better PEF, but also had a slight increase in morbidity and psychological status. Figure 43a and b illustrate little change in morbidity despite any increase in inhaled steroids at two years.

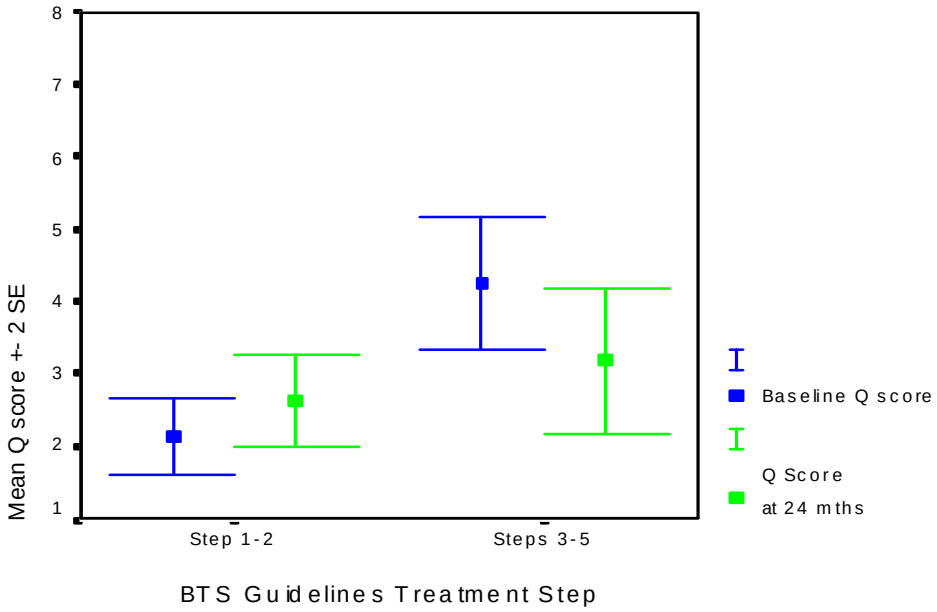
At two years there was deterioration in PEF for both groups but spirometry had increased slightly in the 'no change' group. The 'increased treatment' exhibited a slight increase in morbidity and psychological status. It should be noted that subjects whose inhaled medication was increased attended their GP practice more often (40% versus 11%) than other subjects.

■ **Figure 42 –** Bar chart of subjects in BTS Guidelines treatment

steps 1-2 and 3-5 with inhaled steroids increased, unchanged or reduced at twenty-four months



■ **Figures 43a –** Mean Q score for BTS Guidelines treatment steps 1-2 and 3-5 at baseline and twenty-four months.

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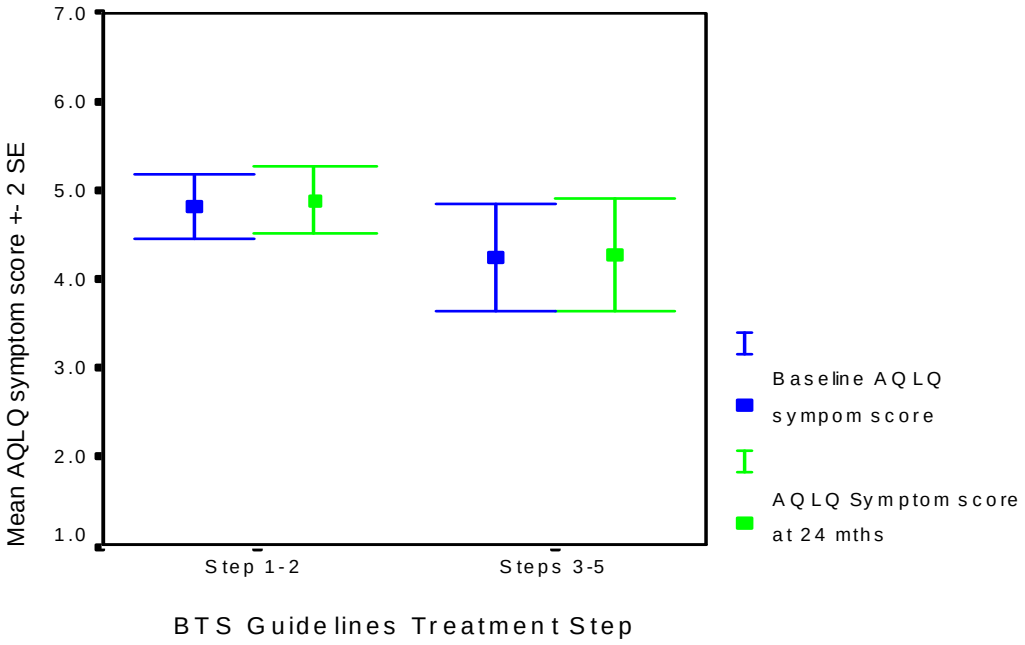
■ **Figures 43b –** Mean AQLQ symptom score for BTS Guidelines treatment steps 1-2 and 3-5 at baseline and twenty-four months



## 4.4 Discussion – Year One and Year Two Data

The aim of this study was to observe the management of a cohort of known asthmatic subjects in their own primary health care setting over a two-year period. The results of that observational process are examined in this section. Year one and year two data are dealt with together.

Objectives for the study were related to the observation of asthma management in primary care over the two-year period. Assessing subjects from differing socio-economic groups and exploring the relationship of morbidity to lung function, asthma severity, psychological status and increase in asthma medication.

*Overview of the two year study*

The majority of asthmatic subjects are routinely managed in primary care (Neville *et al*, 1999); the results presented in this thesis were obtained from adult subjects whose asthma management was under the control of their GP. The strength of this study lies in its observation of routine clinical practice in its natural setting over a two-year period. At no time throughout the study period was there any interference by the researcher into routine clinical practice. Data were gathered from subjects separate to GP assessment or review and were recorded and stored separate to GP data. Data gathered are therefore reflective of conventional GP care within the community and the same variables were gathered repeatedly over time. Subjects recruited for this study were ordinary adult asthmatics that could be recruited from any GP practice and are therefore by nature different from highly selected or trained subjects that are commonly used in clinical trails.

This study examined two groups of subjects from differing socio-economic backgrounds (inner city and suburban areas). Whilst differing socio-economic background can be objectively assessed by Jarman scores (Jarman, 1983) this study cannot differentiate between the health service providers. All GP practices professed to manage asthma patients

according to published BTS Asthma Guidelines (Thorax, 1993 and 1997) so the same therapies were available to all subjects.

One hundred and fourteen adult asthmatic subjects were recruited and had their treatment observed over a two-year period. Eighty three percent of subjects attended for review at one year while 79% attended for two-year review. Only one subject died and one subject moved away from the area during the study period. Although more female subjects and inner city residents were recruited to the study, the proportions attending from baseline to one and two-year recall remained constant (female subjects 63%, 64% and 61% respectively, inner city residents 65%, 60% and 61% respectively). Twenty-four subjects did not complete the study, their data can be found in Appendix XII. There were no significant differences at baseline between the subjects who withdrew from the study and those who continued in regard of their spirometry, PEF, asthma severity, psychological status or QoL.

Results obtained and conclusions drawn were based on a group of asthmatic patients that were randomly selected from their primary care base. The method of recruitment for this study was inclusive enough for conclusions to be applicable to other GP practices operating in similar circumstances. However, it should be noted difficulties were encountered when recruiting for suburban subjects. Within the cohort there would appear to be a recruitment bias towards subjects residing within the inner city (discussed in section 4.4.2). Subjects residing within the inner city had significantly increased psychological status at baseline ($p<0.001$ for HAD anxiety and $p<0.01$ for HAD depression) and this observation was present throughout the study period. At twelve months inner city subjects were more depressed ($p<0.05$) but not anxious while at two years they remained more depressed ($p<0.05$) and were again more anxious ($p<0.01$). Increased morbidity was also observed in this sub-group over the two years. At baseline no significant differences were noted but at twelve months morbidity scores were significantly increased (Q score

$p<0.001$ and AQLQ symptom score $p<0.01$) in the inner city sub-group and remained so at two years (Q score and AQLQ symptom score $p<0.05$ and $p<0.01$ respectively). However, there were no other significant differences between groups.

*Overview of results - Cross-sectional analysis*

The subjects were assessed at baseline and over the two year study period for interactions between spirometry and PEF, morbidity and overall QoL, psychological status, asthma severity and inhaled steroid increase. This is the first observational study assessing subjective and objective markers of asthma to be carried out over two years. Objective markers of asthma were recorded as spirometry, PEF and asthma severity, while subjective markers were considered as subject's HRQL including morbidity and psychological status (see Tables 1, 7 and 13 and 2, 8 and 14). The study explored the relationships between subjective and objective markers of asthma at baseline and over the two-year study period. Relationships were examined between subjects from differing socio-economic backgrounds, (see Tables 4a and b, 9a and b, 15a and b). Subjects with increased or reduced asthma severity (see Tables 6a and b, 10a and b, 16a and b). Differing psychological status (see Tables 5a and b, 11a and b, 17a and b) and from subjects with differing medication again over the two-year period (see Tables 12a and b and 18a and b). The inter-relationships of subjective and objective markers of asthma are discussed in section 4.4.1.

Poor lung function (spirometry and PEF) was associated with increased symptoms (AQLQ symptom score and Q score) and severity at baseline and observed throughout the study period (see Figures 6 and 7, 16 and 17, 26a and c and 27a and c and 35a and c). Recorded values for PEF and $FEV_1$ were both expressed as a percentage of the predicted values for each subject in order to control for age, height and gender (see Figures 6a and 7a, 16a and 17a, 26b and d and 27b and d and 35b and d).This did not improve the regression and findings must be due to other factors.

Depression was associated with these findings but the strength of the relationship varied throughout the study period (see Figures 10, 11 and 12, 31 a and b and 40a and b).

*Overview of results - Longitudinal analysis*

Differences between groups of subjects were also explored over time. The responses of subjects from different socio-economic backgrounds were sort (see Tables 4a and b, 9a and b and 15a and b). Results obtained at one and two year review indicate that there was little difference in objective markers of asthma (spirometry and PEF) between subjects residing in the inner city and their suburban counterparts. However, the initial observation of subjects from more deprived areas with increased morbidity did not diminish over time (see Figure 13 and 15). Observational data recorded over the two year period for subjects residing in inner city and suburban areas are discussed section 4.4.2.

In order to establish the cohort as representative of an asthma population the severity of subjects according to BTS treatment step was recorded at baseline (see Table 1). The majority of subjects recruited (70%) were in lower treatment steps and were reflective of a community based asthma population (Neville *et al,* 1999). Changes in asthma severity were observed over time in order to assess if reported changes in morbidity reflected severity. Subjects in higher treatment steps with more severe asthma reported more symptoms (see Figure 29 and 38) and were seen more often in the GP practice (see Figure 39). Thus subsequently received more treatment but reported no significant reduction in symptoms at one or two year review. The lack of improved outcome for subjects following an intervention by the GP practice is discussed in section 4.4.3.

Psychological status is not routinely assessed in asthmatics yet the influence the patients psyche can exert over their asthma has been

documented (Harrison, 1998). The initial observation of subjects with increased psychological scores reporting more asthma symptoms and visiting their GP practice more often than their non-depressed counterparts was repeated over the two year period (see Figures31a and b, 32, 40a and b and 41). It was noted that more subjects who were depressed came from inner city areas and this observation remained constant. It was unknown if subjects with increased psychological status were recognised and treated by the clinician but these subjects received more treatment for their asthma symptoms. Data gathered over the two-year study period for subjects with differing psychological status are discussed in section 4.4.4.

Current asthma management guidelines recommend increasing inhaled steroids to combat increased symptoms (Thorax, 1997). All GP practices recruited into the study operated using current guidelines. Any alteration in inhaled steroid medication was recorded at twelve and twenty-four months for all subjects against reported symptoms, anxiety and depression (see Tables 12a and b and 18a and b). If subjects were compliant then increasing inhaled anti-inflammatory medication would be expected to reduce symptoms and possibly alleviate anxiety and depression over time. Subjects with recorded increases in inhaled steroid medication did not note any significant reduction in symptoms, anxiety or depression following their treatment intervention. The lack of improved outcome for subjects following an intervention by the GP practice is discussed in section 4.4.5.

### *4.4.1 The relationship of Quality of Life measures to lung function and psychological status throughout the two-year study period.*

*Relationships at baseline*

The relationship of asthma QoL, especially morbidity in association with lung function and psychological status at baseline were explored (see Tables 2, 8 and 14). Objective markers of asthma ie, lung function are the markers most

commonly used by clinicians to assess for improvement or deterioration in asthma status. Alteration in these objective markers can lead to an increase or reduction in asthma medication. However, the patient may be unaware of any changes in lung function but may be receptive to small changes in symptoms. Does the health professional managing the patient assess symptoms in a similar manner to lung function? It has been previously documented (Juniper, 1998) that symptom reporting is subjective, subjects matched for lung function can report different symptom scores.

*The problems associated with symptom reporting*

In the overall cohort depression was the best predictor of symptoms (see section 3.4.7). This relationship might have important implications if the management of asthma is based upon symptom reporting alone. This study observed a sub-group of subjects at baseline (see Table 5a) who recorded increased morbidity and depression and also received more therapy (treatment steps 3-5). This could indicate there was a small group of subjects with mild depression who were receiving more medication in response to increased symptoms. The symptoms may be due to asthma but the reporting of the same symptoms may well differ between subjects (Juniper, 1998). If this hypothesis is correct then increasing asthma medication may therefore do little to alleviate asthma symptoms if they are associated with depression.

Asthma guidelines recommend the use of serial PEF monitoring. The experience of this study (see section 3.4.1) concludes that such data may not be readily available for the clinician at consultation and treatment may therefore be based on symptom reporting alone. Baseline data from this study reveals increased symptoms, depression and asthma therapy associated with

subjects residing in inner city areas (see Tables 4a and b, Figures 13, 14 and 15). Such symptom reporting in the inner city cohort may well be due to the stresses and strains of life under poor socio-economic conditions rather than any real increase in asthma symptoms. The implication of this finding is that little improvement can be expected if management is based upon symptom reporting accompanied by an increase in medication. Other possible causes for an increase in symptoms should be explored to ensure maximum improvement in these subjects. Does this observation reveal a sub-group of asthma patients in high treatment step (3-5) who are depressed by their long-term illness or does the increased awareness of symptoms result in depression? Therapy directed solely to asthma symptoms may not be always be appropriate, other factors such as increased psychological status may be worth considering (Rimington *et al*, 2001).

*Relationships over the two year period*

The population of asthmatics recruited for the study changed little during the two year period with only one subjects dying and one subject moving away from the area. Few subjects were admitted to hospital for more than twenty-four hours for exacerbation of their asthma symptoms over the two-year study period (2% at baseline, twelve and twenty-four months). As asthma is by nature a variable disease individual patients may well have attended the study assessment sessions when symptoms were increased. Any individual variations could be reduced by using group data thus diminishing the impact on the overall nature of the data.

It was to be expected there would be little significant change in symptom reporting by the more stable patients regardless of severity. A community-based population is by nature more stable that a hospital population requiring specialist care (Neville *et al*,

1999). However, there was a significant increase in the number of subjects into steps 3-5. The increased drug dosage may imply poor symptom control but it has been reported that symptom reporting can vary between subjects (Juniper, 1998). At the start of the study period there were 30% (34/114) of subjects in steps 3-5, this increased to 51% (48/95) at twelve months and 49% (44/90) at twenty-four months. If the increase in morbidity had been tackled by increased therapy then a reduction in symptom reporting should have been evident at the end of the two-year period. Poor control of symptoms persisted despite increased therapy. Also in the high treatment group (treatment steps 3-5) were subjects reporting increased psychological status (anxiety and depression) (see Figures 30 and 37). This increased psychological status would appear to be a problem not always associated with asthma and not necessarily recognised or tacked by a GP practice (Centanni *et al* 2000).

Objective markers of asthma (spirometry and PEF) along with morbidity and psychological status were assessed over the two-year period for differences. Table 7 illustrates twelve month data while Table 13 displays twenty-four month data. Morbidity scores changed little throughout the study period (see Figures 23a and b for twelve months and Figures 34a and b for twenty-four months). It is disappointing to note that morbidity did not decrease in line with increased therapy. Although both spirometry and PEF are known to decline with age (Cotes, 1993), there were no significant differences at twelve or twenty-four months. Lung function correlated to morbidity throughout the study period, as did anxiety and depression, patients with poor lung function complained of more asthma symptoms. Observations at baseline for lung function, morbidity and psychological status remained constant over time; patients did not deteriorate neither did they improve. However, severity of asthma did change over time. At

baseline and twenty-four months subjects with more severe asthma (steps 3-5) reported increased morbidity with poorer spirometry and PEF (see Figures 23a and b, 26a and b, 35a and b). Psychological scores responded in the same manner. The number of subjects in the higher treatment steps (3-5) increased significantly at twelve and twenty-four months (both $p<0.001$). It is however disappointing to note that in the cohort as a whole symptom reporting did not diminish in response to the increase in asthma treatment.

Guidelines for asthma management were reviewed in 1995 (Thorax, 1997) part way through this study. It would appear that the recommendations included within these and previously published guidelines (BMJ 1990 and Thorax 1993) to use the 'step wise approach' to care may have been adhered to by the GP practices. The number of subjects receiving inhaled asthma therapy rose over the two-year period (see sections 4.2.5 and 4.3.5).

The majority of subjects who visited their GP did so in order to achieve a reduction in their asthma morbidity. Some subjects did receive increased asthma medication as recommended by guidelines but all subjects did not record reduced asthma symptoms (see Tables 12a and 18a). The lack of a significant reduction in symptom reporting may be due to a variety of reasons. This may well have been due to a lack of structured care either by the GP practice or the patients themselves. Subjects may not have been asked to return to the GP practice following a suitable period in order to report their symptoms or subjects may not have bothered to report improvements to their GP or there may well have been a lack of compliance with prescribed medication. Poor compliance is a common feature for many patients receiving long term medication for chronic disease (Dales

*et al* 1989, Horn *et al*, 1990, Cochrane, 1993, Bosley *et al*, 1994, Yeung *et al*, 1994, Cochrane, 1996). Monitoring of symptoms is a crucial component of structured asthma care (Thorax 1997). A patient focused morbidity index such as the Q score (Rimington *et al*, 1997) or Jones score (Jones *et al*, 1992b) if used in the primary care setting could highlight subjects with increased medication and no subsequent reduction in morbidity.

Neville *et al*, (1997) in their UK study compared the management of acute asthma attacks by GPs in 1991/92 to 1992/93. Neville acknowledges the uptake of the invitation to participate in the study signals an interest in asthma so is not therefore representative of all UK GP practices. Similarly this study group mirrors that same interest and willingness to participate. Bearing in mind the first set of asthma guidelines were published in the UK in 1990 Neville and colleagues noted the gap between the management of acute attacks that occurred in GP practice and the recommendations for management that were given in the newly published guidelines. They did however comment on the increased use of inhaled steroids in the follow-up year (1992/93) as compared to the initial survey of 1991/92. UK asthma guidelines have been reviewed, published and distributed to all UK GP practices since 1990. GP practices participating in this study some three to four years later also reflect the same increase in the use of inhaled steroids following the 1995 review of asthma guidelines (published in 1997). As guidelines were reviewed and published part way through the study, has this re-enforced the goals of asthma management to participating practices? According to Hoskins *et al,* 1998, 2000 and Osman *et al*, 1996 GP practices could benefit from continued input and support with asthma management in addition to published guidelines

The publication of guidelines has brought about a change in the management of asthma in the primary care setting (Neville *et al*,

1997) but to maximise the desired outcome for patients publication of guidelines alone may not be enough. It has previously been documented that many practitioners freely interpret guidelines (Legorreta *et al,* 1998). Input by local specialist (be they consultant physician or GP with special interest) on a regular basis may be what is required to bring about consistency in the use and interpretation of guidelines. The difficulty remains not only in recruiting GP practices unwilling to participate but also in the amount of time required to achieve and maintain change. Some subjects in the present study did receive an increase in therapy, as a response to increased symptom reporting (see Tables 12a and b, 18a and b). What they may not have received or decided not to participate in was structured follow-up. Lack of structured care could lead to little improvement in outcome for patients. Could input by local specialist re-enforce guidelines or would audit of asthma management by individual GP practices highlight gaps in their implementation? Further study is required to answer such questions locally but others have already carried out further investigations.

The Tayside Asthma Management Initiative was set up with the aim of providing a regional led asthma management programme for use in primary care (Hoskins *et al,* 1998). The Tayside group wished to improve the management of asthma in primary care in order to reduce the number of acute asthma admissions, thus relieving pressure on acute services in their region and across Scotland (Hoskins *et al,* 2000). They offered to local practices a distance learning package related to asthma and detailed feedback regarding the asthma management of a number of selected cases. Subjects participating in the study were assessed by means of the Tayside Asthma Stamp which evaluates symptoms similar to the Q score but also records PEF, inhaler technique and compliance

with days lost from work. GP practices recruited to this study did not receive any additional support from local specialist or GPs with a special interest in asthma management assistance was available only by referral to specialist hospital clinic. Asthma management was based on a combination of clinical skills and their interpretation of published guidelines. The present study did not observe routine GP assessment of asthma patients so the role of PEF monitoring remains unclear in each practice, whether inhaler technique was checked on a regular basis or how accurately guidelines were implemented. The Tayside stamp incorporates elements of the Q score and elements of BTS Guidelines essential items for objective management. Such tools could easily have been incorporated into asthma care at GP practices used in this study ensuring appropriate questions for successful management were asked and answered at each intervention. Clinicians may well be unaware such simple tool are available and easy to use. The support of specialist input could assist with the introduction of such objective tools thus improving care for asthmatics in a similar manner to the Tayside project.

The GP practices participating in the current study may have exhibited some of the "enthusiast bias" reported in the Tayside initiative although no incentives were offered to take part in the current study. GP practices were however interested and keen to participate although their management of asthma patients may well adhere to published guidelines more so than practices that did not take part in the study. This phenomena has previously been reported by Neville *et al,* (1996) when the Tayside group carried out a study similar to their Tayside Asthma Management Initiative but recruiting GP practice's from across the UK. GP practice performance may well be improved if they receive structured feedback and support from specialist groups.

Other groups within the UK have looked at different ways to support GP practices in the management of asthma care following the publication of guidelines. Osman *et al* (1996) developed and studied a package of integrated care for asthmatics (GRASSIC, 1994). Recognising the vast majority of asthma patients were managed in primary care Osman *et al* and GRASSIC offered a service similar to the Tayside group. Difficult to manage patients could be referred to a specialist for feedback, the majority of stable patients continued to be managed by the practice. According to Osman *et al* this type of support can lead to better outcome for patients and a more cost-effective service for primary and secondary care. A package of integrated care has not been adopted by the local hospital and GP practices where the present study took place. Whether this approach could have improved the outcome for subjects with sustained symptoms remains speculative.

Inner city subjects who reported increased morbidity and depression persisting over the two-year study period despite increased inhaled steroids are a vulnerable group of patients who require identification and particular care (see Figures 28a and b, 36a and b). Specific patient sub-groups have been targeted, Dickinson *et al,* (1998) had implemented asthma guidelines in their practice but wanted to monitor closely patient's outcome. Subjects taking part in the study were assessed using the Jones morbidity index (somewhat similar to the Q score, (Jones *et al,* 1992b). Their medication was then reviewed in line with asthma guidelines and patients were monitored by use of the Jones index. Subject's asthma therapy was assessed and revised as necessary throughout the study period. At the end of the study subjects who had participated in the study all had inhaled steroids added to their therapy with symptom reporting decreased. This active input by interested health professionals again illustrates that

improvements can be made in line with guidelines but may rely on "enthusiast bias". If such a policy had been implemented would subjects in the present study with increased symptoms and depression have benefited from intervention rather than observation? Certainly using the Q score over the two-year period did highlight symptom reporting but this information was not available to the GP practice and therefore they were unable to act upon this information. Further follow up using the Q score by the GP practice for their information may well draw such patients to the attention of the health professional but remains speculative.

### *4.4.2 The Population by Place of Residence – Who Fairs Best, Inner City or Suburban Asthmatics?*

Recruitment bias for subjects from differing areas of residence has been acknowledged (see section 4.4) More subjects from inner city areas were recruited in this study (65%, see Table 1) although all practices approached were very willing for recruitment to take place. Recruitment to the study proved difficult (see section 2.2.5) subjects from suburban practices found it more difficult to attend the GP practice during working hours (see section 3.3.2). Sessions at the practice for study purpose finished before 6.00 pm and many subjects found it impossible to attend before then and were reluctant for the researcher to secure a home visit. Subjects from a suburban background reported to be in higher social classes (70% versus 24% groups I and II) and an unwillingness to allow the researcher to intrude into the home environment was evident. This sub-group may well have preferred more privacy with regard to their disease process than the inner city sub-group. This may well have influenced their poor recruitment to the study.

Little difference in objective markers of asthma (spirometry and PEF) was observed from outset to twelve and twenty-four

months, (see Tables 1, 7 and 13) a trend reflected in the study group as a whole. There was also a trend of increased medication and a subsequent rise in the number of subjects in higher treatment steps over the two-year period and again this was reflected in the cohort as a whole. Inner city subjects consistently reported significantly more symptoms and higher depression scores over the two-year period than suburban subjects, yet only at twenty-four months did they reportedly attend their GP twice as often as suburban subjects (20% versus 6%) (see Tables 9a and b, 15a and b). This would indicate suburban subjects were more self-reliant and coped better with their asthma symptoms than inner city subjects who were more dependent on health professionals for support.

Differences in socio-economic background based upon Jarman scores (Jarman, 1983) as used in this study rely upon the weighted values for percentages of the number of elderly persons living alone, children under five years, single parent families, social class V, unemployed overcrowding and ethnic minorities. A number of studies now suggest an association between increased reporting of morbidity and social deprivation (von Schlegell *et al,* 1999). Subjects living in areas of social deprivation may on account of the geographical location be exposed to higher levels of outdoor pollutants such as ozone and sulphur dioxide. While subjects indoor environment may be polluted by cigarette smoke, damp and overcrowding. This increased risk of exposure to trigger factors may go some way to account for some of the increased reporting of asthma symptoms (Hajat *et al*, 1999). This study did not seek information from subjects regarding their personal circumstances but inner city residents record more subjects in lower social classes, (95% of inner city residents in social class III, IV and V) and significantly ($p<0.01$) more inner city subjects smoked. This would go some way to re-enforce the

inner city population residing in areas of social deprivation according to Jarman scores.

In the UK asthma is not commonly associated with poverty (Rona, 2000) but there are many reports where asthma is associated with higher social class especially in children (Littlejohns and Macdonald, 1993). Do adults in higher social class prefer not to "bother" their GP practice with their own respiratory problems but are willing to report episodes and symptoms of their children, or are the suburban residents reluctant to attend their GP?. No significant difference was observed at twelve months with 11% suburban subjects attending GP on two or more occasions at twelve months versus 12% of inner city residents. At the two-year assessment suburban residents were somewhat more reluctant (6% versus 20%) than they had been previously. Respiratory disease can however be found more commonly in areas of socio-economic deprivation. Inner city subjects from this study attended their GP practice more often than their suburban counterparts. This phenomena has also been reported by the Lung and Asthma Agency, (2000). The Lung and Asthma Agency also note that these subjects come mainly from social class III, IV and V, 95% of the inner city sub-group were found to be in those social classes. Subjects from deprived areas are also known to attend Accident and Emergency Departments more often than other asthmatics of similar severity (Kolbe *et al*, 1997) yet over the two-year period only four subjects (all inner city residents) were admitted to hospital in excess of twenty-four hours. This would indicate a more stable population that that recruited by Kolbe *et al*. It may also appear that subjects from differing social classes respond differently to increases in morbidity. This observation may account for the number of inner city subjects attending the GP practice more often than suburban subjects.

Inner city subjects from the current study reported more asthma symptoms than their suburban counterparts (see tables 9a and b, 15a and b). Leidy and Coughlin (1998) comment that subjects from areas of socio-economic deprivation often reported more severe asthma and record lower educational standards. Inner city subjects also smoked more ($p<0.01$) and smoke inhalation is a well-documented trigger factor for increased morbidity (Martinez *et al*, 1992). Certainly in children increased morbidity is said to be higher in low socio-economic groups (Mielck *et al*, 1996). Education programmes for asthma usually involve guidance as to the benefits of smoking cessation alongside the recognition of triggers that increase symptoms and the reduction via self-management of such symptoms. Studies have previously examined the efficacy of education programmes for asthma subjects with low socio-economic status (Gibson *et al*, 1998). Although many of these studies related to poverty were carried out in the USA their finding may be applied to this cohort of inner city subjects. The majority of the inner city subjects were in social classes III, IV and V, which would indicate poorer educational standards. Subjects from areas of deprivation may have lower educational standards experiencing difficulty in the appreciation of the benefits of smoking cessation and the interpretation of guidelines for the management of asthma symptoms. This may go some way to account for the increased visits to the GP practice for the inner city subjects and the repeated observation of increased symptom reporting. These subjects may have been unable to successfully interpret self-management plans and appreciate the benefits of smoking cessation.

All GP practices participating in the study agreed that they followed current published guidelines for the management of asthma (Thorax, 1997). Current guidelines advocate the use of self-management plans for patients wishing to have an active role

in the management of their asthma. The results of this study would suggest that suburban subjects have risen to the challenge of self-management plans for asthma. GP practices in inner city areas – areas of social deprivation and poverty, may therefore need to spend more time educating their asthma sufferers if they wish to achieve a better outcome for their patients (Nsouli, 1999).

### *4.4.3 Asthma Severity – BTS Guidelines Treatment Step Group 1-2 versus 3-5.*

A community based asthmatic population was observed over a two-year period, the majority of subjects (80/114 at baseline, 63/95 at twelve months and 62/90 at twenty-four months) required little inhaled medication to control their asthma symptoms (BTS Guidelines treatment step 1-2). See Tables 6a and b, 10a and b, 16a and b. This spread of severity is an expected feature of a GP based asthma population (Neville *et al*, 1999). In Neville and colleagues 1999 study they wished to assess the proportion of adult asthmatics at each step of BTS Guidelines to provide a cost analysis of asthma prescribing in the UK. Over 17,000 adult asthma patients were recruited from GP practices across the UK. Almost half of the subjects recruited were in BTS Guidelines treatment step 1-2.

There was however a noticeable shift at twelve months that was maintained at twenty-four months of subjects moving into the higher treatment step (3-5)(see Tables 10b and 16b). Such an increase in therapy could possibly be associated with the publication and dissemination of the review of national guidelines for the management of asthma carried out in 1995 and published in 1997 (see section 4.4.1) (Neville *at al*, 1997). It is to be hoped that the publication, dissemination and repeated review of asthma guidelines within the UK has been recognised and acted upon by GPs resulting in the increase in prescribed asthma therapy for subjects over the two year study period.

Subjects in higher treatment steps 3-5 had greater morbidity and depression at twelve and twenty-four months than subjects with less severe asthma (see Figures 29, 30, 37 and 38). It might be expected that subjects with more severe symptoms of asthma, (cough, wheeze or dyspnoea) would require more therapy to reduce their symptoms, placing them in treatment steps 3-5. This could also go some way to account for patients in the higher treatment step visiting their GP more often (see Figure 39). If symptoms are troublesome this can lead to depression (Dales *et al*, 1989) and subjects in the higher treatment steps did record slightly higher depression scores than subjects with less severs asthma (HAD depression scores of 4.11.versus 5.90 at twelve months and 4.61 versus 6.07 at twenty-four months for steps 1-2 and 3-5 respectively).

Previous studies published before the production and dissemination of national guidelines (Horn and Cochrane, 1989) report the use of sub-optimal therapy when dealing with more severe asthma. Despite subjects with more severe asthma (treatment step 3-5) receiving more therapy, usually an increase in inhaled steroids or the addition of a long acting βagonist their symptom reporting did not reduce over the study period. Subjects were unable to stabilise symptoms adequately in order to reduce medication and move down into a lower treatment step. This phenomenon could be due to non-compliance but subjects with high morbidity scores require regular review (Jones, 1989). If the subjects with increased morbidity had received regular monitoring of symptoms or if offered, had participated in the review then morbidity may well have been reduced in a number of subjects thus a reduction in therapy and appropriate treatment step may also have been achieved.

Dickinson *et al*, (1997) used a GP based asthma population similar to the present study and is one of the few studies that notes and monitors changes in severity of asthma over time. Dickinson noted and targeted subjects with more severe symptoms of asthma (as measured by the Jones Morbidity Index, 1992b) by checking inhaler technique, altering medication as necessary and encouraging use of PFM as a means of monitoring airways hyper responsiveness. Subjects with higher morbidity scores who attended regular clinics over the twelve months period did report lower scores following practice intervention. It would appear that GP practices used in our study either did not offer regular review for subjects with increased symptoms or may have done so and subjects did not avail themselves of this service. In the present study the majority of subjects attended their GP on one (or less) occasions throughout the study period (75% at twelve months and 60% at twenty-four months). This study was unaware of any systems in place for objectively evaluating and recording symptoms at any GP practices used in this study. It would seem health care professionals remained unaware of persistently high symptoms, managing subjects only when they attended clinic.

Hoskins *et al*, (1997) commented that GP practices participating in an audit cycle combined with an asthma related distance learning package did at the end of the study period change their management of acute asthma attacks in accordance with published guidelines (see also section 4.4.1). Neville *et al*, (1996) also reported improvements in the overall management of asthma patients when GP practices participated in an audit cycle. Participating GPs in the Hoskins study were members of the General Practitioners in Asthma Group (GPIAG). This is a specialist interest group for the UK and was therefore representative of those practitioners who were interested in

improving their asthma management skills, a comment raised by the authors. The problem remains whether practice was altered due to the publication and dissemination of guidelines or the atypical GP population participating in asthma audit. If subjects are to benefit from guideline publication and dissemination and subsequent adherence to them (for the reduction of reported symptoms by patients) they should be supported by the GP with regular attempts to follow up and review patients. The GP practice may also benefit from specialist input by groups such as GPIAG and respiratory physicians. If the offer of review for the patient is perceived as unnecessary and the input from specialist for GPs viewed as unwelcome little progress can be made. Indeed published guidelines (Thorax, 1997) recommend that successful implementation is more likely with education of health professionals and patients alike accompanied by feedback from locally based asthma task forces.

GPs are at the forefront of asthma management but there continues to be a "missing link" between theoretical guidelines and practical implementation (Collins *et al*, 1998). It was unknown if GP practices used in this study participated in a regular audit cycle as suggested by Hoskins (*et al,* 1997). The researcher was unaware if any GP was a member of GPIAG or supported by a local asthma task force. Although the number of subjects in higher treatment steps (3-5) increased morbidity was not noticeably reduced (see Figures 22a and b, 3a and b, 29 and 38). Participating in an audit cycles may well have lead to the observation of long standing increased morbidity, once highlighted problem patients could be reviewed. Such actions would not address the problems of non-compliance but it appears GPs in this study were implementing published guidelines but without actively monitoring treatment as suggested.

### *4.4.4 Psychological Status – Why do Depressed Subjects Remain So?*

According to Zigmond and Snaith (1983) signs of depression may be exhibited by subjects if they have a HAD score at either the upper (11) or lower (8) end of the borderline range. This study chose to include those subjects with "borderline" anxiety and depression whose scores were of eight points or greater on the HAD scale. Subjects taking part in the study had three questionnaires to complete at the same time (AQLQ, Q score and HAD scale). The AQLQ asks the subjects to reflect on their asthma status over the past two weeks while the Q score asks them to reflect over the past week. The HAD scale also asks the subjects to reflect how they have felt over the past week so the psychological status of these asthma subjects closely mirrors morbidity.

Only a small proportion of the study cohort could be classed with borderline depression throughout the two year period (30/114 at outset, 15/22 remained depressed at twelve months while 14/22 remained depressed at twenty-four months) (see Tables 11a and b, 17a and b). What is note worthy is that these depressed subjects reported their asthma symptoms by attending their GP practice more often that their non-depressed counterparts (see Figure 43). The relationship of asthma to psychological status has a long history and was initially reported some years ago (Harrison, 1998 cites Osler from 1903). Since the introduction of inhaled steroids as first line management for symptoms the association of psychological status and the influence it can exert upon the asthmatic patient seems to have been forgotten. Yet only at the twenty-four month review did depressed subjects report their inhaled steroids increased more than non-depressed subjects (23% versus 7%). Current management relates to patients' symptoms rather than psyche but as recently as 2000 Centanni *et al* reaffirms the relationship of asthma morbidity to psychological status and

states that prior to therapy the clinician should consider the subjects' psychological status. Published guidelines (Thorax, 1997) do acknowledge the influence psychological factors can exert over symptoms and state that if asthma proves difficult to control then other factors should be investigated. If subjects are repeatedly reporting symptoms, as in the depressed subjects from this study health care professional may need to consider reviewing the subject's psychological status along with regular asthma management.

Harrison, (1998) postulated that within an asthmatic population as a whole there would appear to be a small sub-group of patients being either non-compliant with their medication, have very poorly controlled asthma (brittle asthma), suffer near fatal asthma attacks or patients who do actually die following an asthma attack. Superimposed upon this sub-set of an asthma population psychological influences can be found. The sub-group of depressed asthma patients in the current study who remained depressed throughout might well have exhibited any of the traits noted by Harrison (1998). However, only one subject died during the study period (though not due to asthma), subjects did not suffer near fatal asthma attacks nor were any subjects within the study cohort brittle asthmatics.

Problems with patient compliance have previously been noted in section 3.3.3. Some of the depressed subjects in this study may well have been non-compliant with their asthma therapy, resulting in poor symptom control. As previously stated by Dales *et al,* (1989) chronic symptoms can lead to depression. This circle of depression, non-compliance, increased morbidity and depression may go some way to account for some of the subjects who remain depressed. Such subjects can actively ignore warning signs of deteriorating asthma. Yet these subjects did visit their GP

practice complaining of increased morbidity, which may well have been assessed by the subject and GP as warranting further therapy. Indeed Bosley *et al*, (1995) noted that subjects with increased HAD scores were more likely to be non-compliant with asthma medication. Bosley comments that the reasons for asthmatic non-compliance can be complex but how patients feel about their disease can affect how they comply with therapy. Subjects who may be depressed may well perceive symptoms of asthma and report them but simply be too depressed to comply with treatment. Campbell *et al*, (1994) also thought that greater emphasis should be placed on psychological issues in subjects who were thought to be non-compliant. As psychological overlay has been largely ignored in recent years the health professional may no longer consider the role poor psychological status could play in symptom reporting. Treatment is not likely to be successful unless such influences are recognised and tackled as part of a structured management plan.

The majority of the depressed subjects were located in the inner city sub-group, (83%, 25/30) with 11/30 (37%) having depression scores of eleven or over, indicating significant depression (see Table 5a). Profound emotional stress related to poor housing and finances can be common and residents can be exposed to high pollutant levels which are known factors associated with deprivation (Jarman, 1983). Emotional stress and pollution are also associated with asthma morbidity. A previously reported strong association between asthma, depression and high Jarman scores in a similar inner city area to the ones used in this study was noted by Payne *et al*, (1993). Areas of high deprivation such as the inner cities can leave a patient exposed to pollution, poverty, over crowding and the stresses and strains of modern day living on a reduced income. The recording of continued depression by these inner city subjects (see Figures 28a and b, 36a

and b) over the two year study period could be due more to their area of residence rather than their asthma morbidity (Rimington *et al*, 2001). Indeed life events may exert an indirect effect on asthma morbidity if the subject has few psychological resources left to draw upon (De Araujo *et al*, 1973). Repeated visits to the GP reporting asthma symptoms that have not responded to increased medication may well suggest a need for attention other than for asthma.

### *4.4.5 Changes to Inhaled Asthma Medication over the Two-year Period – Increasing Inhaled Steroids Reduces Morbidity?*

Asthma guidelines have been the world-wide response to under diagnosis and under treatment of asthma. Published guidelines advise an increase in medication in response to symptom increase and PEF variability (Thorax, 1997). Horn *et al*, (1990) state that morbidity can be significantly reduced in asthma patients who receive high doses of inhaled steroids as in treatment steps 3-5 of BTS Guidelines. Guidelines actively encourage the monitoring of symptoms with corresponding adjustment to therapy. Recommended therapy by the BTS for increased symptom reporting is given by providing a "step wise approach" to management.

The subjects in the present study received an increase in medication including oral steroids, inhaled steroids and long acting βagonist as a response to increased symptom reporting (see tables 12a and b, 18a and b). Despite what was observed to be the adherence to guidelines by the GP practices participating in this study little was achieved as an improved outcome measure for these patients. There were eighteen subjects (18/95, 19%) who reported an increase in their inhaled steroid medication from baseline to twelve months and ten subjects (10/90, 11%) who reported inhaled steroids increased from baseline to twenty-four

months. Symptoms were not significantly reduced for these subjects when group data was explored. However Juniper *et al* (1997) notes that when using the AQLQ for group data statistically significant changes in QoL scores may not be detected. When using the AQLQ for individual subject a change of 0.5 in domain and overall AQLQ score may well denote what the patient would consider to be an improvement or a decline in their health status. This study analysed only group data and cannot therefore comment on individual cases. As the numbers for the sub-group 'inhaled steroids increased' remained small this may go some way to account for the lack of significant improvement from baseline. What is also important to note and as Juniper (1998) states symptom reporting is subjective. Patients can be matched for age, gender and lung function but when morbidity is assessed AQLQ scores may vary considerably, as patients perceive the same symptoms with differing severity.

The overall lack of improvement in symptoms may however be due to a variety of factors. Rona (2000) comments that subjects in lower socio-economic groups may well report symptoms of wheeze and remain under treated for such symptoms. This may be due to health care professionals considering other factors associated with low socio-economic status influencing subjects more so than symptoms associated purely with asthma (eg, cigarette smoke). Inner city residents smoked significantly more cigarettes ($p<0.01$) at baseline than suburban subjects did. Subjects in higher socio-economic groups may well report increased symptoms such as wheeze and receive appropriate therapy in response. Indeed some subjects may operate their own self-management plans and increase therapy immediately. Management of symptoms by health care professionals may therefore be influenced by the patient's socio-economic status.

It is well documented that subjects undervalue the influence that

anti-inflammatory therapy can have on their condition (Gottlieb *et al,* 1995). Inhaled steroids do not offer immediate relief of symptoms and may well be viewed as a poorer choice in the relief of symptoms in comparison to quick acting βagonists (Horn *et al*, 1990). Compliance with inhaled steroids would therefore appear to be more problematic than that of a βagonists (Bosley *et al*, 1994). The difficulties estimating patient compliance of inhaled medication has previously been discussed (see section 3.3.3). In many asthma studies less than half the study population at any one time are thought to be compliant with their medication (Yeung *et al* 1994). Also the severity of asthma seems to have little effect of rates of compliance, as subjects with severe asthma are just as likely to be non-compliant as those subjects with less severe symptoms. Subjects with their inhaled steroid increased may well have been advised to increase inhaled steroid intake but may have decided not to comply with recommendations resulting in little reduction in morbidity. Indeed poor compliance is a well-documented cause of persistent symptoms in asthma patients (Horn *et al,* 1990). Not only does poor compliance with therapy lead to poor symptom control but the overall cost of non-compliance with therapy leads to days lost from work (Costello, 1991).

Compliance can also be the result of poor knowledge of the disease process (Boulet, 1998). Subjects with poor standards of education can have difficulty understanding the concept of self-management and fail to grasp the different effects of their medication, (Bosley *et al*, 1994, Yeung *et al* 1994, Apter *et al*, 1998 and Boulet, 1998) though other studies relating to compliance had earlier refuted this (Hayes-Baulista, 1976). Clinicians looking after asthma patients should try to allay fears related to the use of inhaled steroids and need to question their patient carefully in order to assess if patients understand treatment

processes (Boulet, 1998). Poor compliance can be associated not only with poor educational standards but also with poor communication skills. Many patients have difficulty asking questions at consultation and this may result in the patient developing a lack of responsibility for the management of their disease being unable to respond to their own health needs. However, clinical time available for patient consultation is often limited and clinicians may not always ask the right questions nor seek to reassure patients (Keeley 1999). Such problems are more commonly associated with subjects from poor socio-economic background though not exclusively so (Cochrane, 1996).

### *4.4.6 Summary*

This study set out to observe the asthma management of a group of adult asthmatics over a two-year period. During the study period the researcher did not advise or comment on GP management during the follow up period. Asthma guidelines (BMJ 1990, Thorax 1993) were observed by all practices taking part in the study, although there was a lack of regular asthma specific clinics organised and managed by accredited asthma nurse available to the patients. Asthma guidelines were reviewed part way through the study, 1995 and published in 1997 (Thorax 1997).

Most subjects attended their GP on only one occasion during each of the twelve month periods (11/95, 12% of subjects attended more than once within the first twelve months while 11/90, 12% attended more than once in the second twelve month period). This is reflective of a community based asthma population. There was however, a significant increase in the number of asthmatic subjects in the higher treatment steps from baseline to twelve and twenty-four months (34% of subjects in BTS guideline treatment step at baseline, 51% at twelve months and 49% at twenty-four

months). This may well indicate that practices were adhering to guidelines by increasing inhaled therapy. However, there was within the study cohort a small population of subjects in high treatment steps (3-5) who required more therapy yet did not have an improved outcome following practice intervention. Also there remained a small group of subjects who were depressed at outset and remained depressed over the two-year period. Many of those depressed subjects came from the inner city sub-group (80% at twelve months and 86% at twenty-four months) who visited the GP practice more often, smoking more and reported more symptoms of asthma. These subjects who showed little improvement over the two-year study period in terms on symptoms or psychological status were not identified by the GP practice. The problems of patient compliance with treatment have already been discussed, subjects may have been advised to alter treatment and be in receipt of self-management plans but have not acted accordingly, resulting in poor outcome. If practices are not auditing their asthma management programmes then it is more likely that these subjects have been overlooked. Audit has been shown to improve clinical outcomes for patients (Bryce *et al*, 1995).

GP practices taking part in the study all had GPs with a specific interest in asthma though who was a member of the GPIAG was not established. All practices did not have an asthma nurse and none that had completed any post registration-training specific to the management of asthma. Asthma specific clinics were run at each GP practice though only one ran them on a regular basis all others were ad hoc. It was uncertain if asthma audit been completed or contemplated to assess how asthma guidelines were being implemented. There may therefore appear to be a lack of structure in the overall management of asthma patients within the primary care setting. With an absence of asthma dedicated staff

and none specific clinics, guidelines are administered but it is uncertain if assessment has been routinely carried out as to their efficacy. There may also appear to be poor symptom monitoring with health care professionals failing to ask the right questions. The Q score is a simple patient focused morbidity index that can be used by any member of the health care team. Using the Q score in the absence of any "gold standard" (as stated by Dickinson *et al*, 1997) might well have alerted clinicians to the evidence that increased therapy over the two-year period did not effectively reduce morbidity.

Some inner city subjects faced problems associated with their economic status. These subjects were more depressed, had poorer symptom control, smoked more, took more medication and visited their GP more often than others. This sub-group may well require sustained monitoring and input from health professionals if improvements in subjective markers of asthma are to be observed. Clear and consistent advice from all health care professionals involved asthma education and the development of good patient clinician relationship along with genuine two way communication could go some way to improving patient compliance with management (Dickinson *et al* 1998). Subjects who remained depressed reported symptoms of asthma that did not improve with therapy. Psychological status can exert a considerable influence on asthma symptoms, a small proportion of subjects may be receiving excess therapy when their reported symptoms are not caused by asthma alone (Rimington *et al*, 2001).

Extra input to GP practices by specialists in asthma may well be the answer to improve outcome for patients as proposed by the Tayside Asthma Management Initiative, its Scottish counterpart (Hoskins *et al* 1997, 1998, 2000) and the work by GRASSIC (1994). GP practices can audit asthma management and review

practice and most importantly ensure that they use questions such as those found in the Q score that are relevant to patients' asthma status.

## 4.5 Study Limitations

Problems associated with the recruitment of GP practices and subjects to the study must be acknowledged. GP practices participating in the study agreed they adhered to published guidelines for the management of asthma (BMJ, 1990, Thorax, 1993 and Thorax, 1997) but the researcher did not observe any health care professionals in consultation with individual patients. Therefore the accuracy of guideline interpretation has not been assessed. Legorreta *et al,* (1998) and Picken *et al*, (1998) both comment on the admission by clinicians as to differences in interpretation of guidelines at local level. How clinicians interpreted the "stepwise approach" to assist in the reduction of symptoms, the use of self-management plans and interpretation of PEF remains speculative.

It has already been stated (see section 3.3.1) that the diagnosis of asthma was taken from GP practice asthma registers. Verification of the diagnosis by the use of PFM and recording peak flow variability over a two-week period was attempted as stated in section 2.4.1. Unfortunately so few subjects returned peak flow diaries that is was impossible to use this data. The diagnosis of asthma from the GP was therefore accepted. Section 3.3.1 explores the diagnosis of asthma subjects used in this study. It must be must concluded that subjects participating in this two-year follow up study did have a true diagnosis of asthma but acknowledge some subjects may exhibit components of other respiratory disease. However, the subjects used for this study are reflective of a primary care based asthma population.

GP practices recruited to the study had an established interest in the management of respiratory disease and may therefore exhibit practice bias. All practices regularly referred patients to the local chest unit and

had participated in previous studies with the chest unit. This would indicate a willingness to participate in respiratory-based studies with a population of subjects who may previously also have been recruited. However, it must be stressed that no health professionals from any of the participating primary care settings took part in the selection of subjects for the inclusion into the study or in the collection of data.

More female subjects were recruited (63%) and more subjects came from inner city practices (65%) (see section 3.3.2). Moreover, the gender ratio is typical of a GP based asthma population (Neville *et al*, 1999). The original study aim was to recruit forty subjects from each of the four practices participating in the study (see section 2.2.5). Only one hundred and fourteen subjects were recruited and the reduced sample size is accepted. Due to a number of confounding factors (as stated in section 2.2.5) the population included fewer subjects from suburban practices. In order to prevent the bias towards an inner city population it may have been pertinent to have continued to recruit from the existing suburban practice or have included another suburban based GP practice into the study. However, time and resources were limiting factors in extending recruitment to ensure a larger sample or reduce inner city bias.

The study design was observational in nature used as "an appropriate technique for getting at 'real life' in the 'real world'" (Robson, 1993 pg.191). Therefore the study did not control for any factors; subjects were assessed on an annual basis independently from any asthma assessment carried out by the GP practices. This study did not report data to any participating practice until after the study was complete. The study process itself was therefore 'blind' to any treatment interventions by the clinician other than the recording of prescription up take by subjects. Observer bias was a possibility but all data using questionnaires was recorded without unnecessary assistance from the researcher taking part in the study. This problem could have been resolved by the use of 'blind' collection of data but resources were not available. Extraneous variables

were not control for. Subjects were assessed in different seasons of the year, on different days and at different time. Often subjects were reviewed in the GP practice but subsequently reviewed in their own home. Subjects on long term steroids may also be subject to mood swings (Costello, 1991) this was avoided in the present study by observing the population over a two year period.

## 4.6 Clinical Implications of the Study

The findings of this study relate to the validation of the Q score as a tool for monitoring patient symptoms and the management of asthma in primary care. The Q score was designed as a simple patient focused morbidity index and as such it is accepted that it is less complex and not as sensitive as the AQLQ. Nevertheless the Q score correlates to the AQLQ symptom score and is responsive to changes in the AQLQ symptom domain. In the absence of any "gold standard" for morbidity assessment the Q score would appear to be an acceptable outcome measure to use in any busy health care setting.

The Q score has been evaluated using a cohort of asthma subjects with varying degrees of severity as measured by BTS guidelines treatment step. The Q score reflects symptom activity at all levels of asthma severity. BTS guidelines recommend a "stepwise" approach to the management of symptoms. If therapy is increased as recommended by the "stepwise" approach and patients symptoms of asthma subsequently diminish a lower Q score should be achieved, regardless of the level of severity. The Q score will reflect any change in symptoms over a one-week period. The aim of current asthma management is to reduce patient symptoms to a minimum with minimum use of therapy. The Q score can be administered by any member of the health care team in order to assess current patient symptoms. If a high Q score is obtained this would indicate poor control of asthma symptoms and patients may therefore be invited to attend the GP practice for consultation in order to reduce

symptoms. Conversely, if a low Q score is observed this would indicate asthma symptoms were well-controlled at that point in time and therapy has been optimised. The Q score is not a diagnostic tool but a patient focused morbidity index and could therefore be used as single symptoms score for screening patients in the wider health care setting. For example NHS Direct could employ the Q score as a simple screening tool thus advising patients with high Q scores (increased symptoms) to seek early medical advice.

The Q score could be used as part of an ongoing asthma audit in any health care setting, either on a regular basis (annual or biannual) or when patients attend for any consultation. It can also be used to monitor change in therapy. Any increase or decrease in therapy may alter symptoms. The Q score can reflect changes in symptoms in response to alteration in therapy. The Q score could prove to be a simple evaluative tool in this area.

The Q score is a suitable tool for use with all adult asthma patients, the questions used being asthma specific. The Q score contains questions that the health practitioner should ask asthma patients at each consultation. Questions relating to nights waking, wheeze and interference with daily activities are incorporated into the Q score as the findings of the Royal College of Physicians recommend (Pearson and Bucknall, 1999). Using the Q score as an audit tool or to evaluate treatment change would not detract from valuable clinical contact time. Indeed, using the Q score at every contact would not adversely affect the consultation. Although the majority of asthma patients are managed in the primary care setting the Q score is an appropriate tool for use either there or in secondary care. It can ensure the clinician asks the patient the right questions every time (Keeley 1993).

Although it would appear asthma guidelines are adhered to in primary care as previously noted they are open to interpretation (Legorreta *et al,*

1998 and Picken *et al*, 1998). This study has drawn attention to the lack of routine monitoring in asthma management. As a regular procedure following an alteration in medication patients taking part in this study it is unknown if subjects were asked to attend for review. Any changes in subject morbidity should be assessed following an alteration in therapy. Poor monitoring can lead to subjects with increased symptoms over the two-year study period. Although problems with patient compliance to therapy have been noted subjects studied attend their GP practice only once or less in any twelve-month period nor where they supported by external experts in the field. Access to asthma specialists be they GPs, specialist physicians or other health professionals especially when dealing with problem patients has been shown to improve outcome for patients. Such action and support mechanisms should be incorporated into routine care in the primary setting.

This study observed a small sub-group who were depressed at outset and remained depressed over the two-year period. It remains unknown if the psychological status of these subjects was not noted and assessed by any member of the GP practice over the study period. These subjects complained of increased symptoms and visited their GP practice more often than others in the cohort. More of these subjects resided in inner city areas. These subjects may well have felt the stresses and strains of inner city life (reflected in social deprivation and poverty) giving rise to increased psychological status. Such subjects with a heightened psychological state may well be more aware of their asthma symptoms. It is well documented that symptom reporting is subjective (Juniper *et al*, 1998). Subjects with increased symptoms who do not respond to therapy may well have psychological problems that cannot be expected to respond to changes in asthma medication. If asthma subjects are monitored and reviewed as part of an audit cycle health care professionals may become aware of the influence of psychological status over morbidity.

## 4.7 Areas for Future Study

Other asthma specific questionnaires are available to assess morbidity but many are too long to be of practical use in the busy health care setting. The Q score was designed as a pragmatic instrument for use in every day asthma management and is by design less complex than other out come measures. The Q score was evaluated against a reliable and validated asthma specific QoL questionnaire (AQLQ) that uses four domains relating to asthma specific problems (activity limitation, emotional and environmental factors and symptoms). The symptom domain of the AQLQ was used to assess the sensitivity of the Q score over the two-year period. The Q score correlated to the AQLQ symptom domain throughout the assessment period. The Q score was only assessed with the AQLQ but as stated there are other asthma specific questionnaires available that also record symptoms. Further studies are advisable to assess the Q score against such tools eg, the Jones morbidity index (Jones *et al,* 1992b) and St George's short form questionnaire (White and Jones, 1997).

It is proposed and supported by the RCP (London) that data in relation to morbidity should be collected at each patient visit. While it is recognised that all asthma subjects do not visit their GP on a regular basis, certainly in the cohort in the present study 88% visited their GP only once or not even at all in a twelve-month period. Indeed, studies have shown that up to two thirds of patients with asthma fail to attend for review (Barritt and Staples, 1991, Gruffydd-Jones *et al,* 1999). Over five years the majority of subjects will probably have incurred at least one visit. Data collected at routine visits should be recorded separately to emergency visits, as symptom reporting will certainly be higher on such occasions. Data may also be recorded following postal or telephone contact and can be collected by any member of the health care team (Pearson and Bucknall, 1999). It is recommended that further studies use the Q score to collect data with regards to morbidity on each visit to the GP practice for all asthma subjects. This should form part of a regular asthma audit.

The GPIAG are in the process (personal communication) of conducting a randomised controlled trial comparing the clinical and cost effectiveness of telephone consultations with face to face consultations for the management of adult asthmatics in primary care. It is intended to recruit two hundred and twenty-five adult asthmatics from five GP practices within the UK. The study proposes to use the Q score and the AQLQ as part of their evaluation tools. All consenting patients will be sent postal questionnaires at baseline, patients will then be randomised to a face to face consultation or telephone consultation for their asthma. Twelve weeks following consultation subjects will be sent the two questionnaires (Q score and AQLQ) again. The study hopes to establish that telephone consultations can be as successful an intervention as face to face consultation, measured by a reduction in symptoms (Q score) and improvement in QoL (AQLQ).

It is the intention of the author to submit for publication further work from this thesis. The present study aimed to observe the management of asthma subjects in their own primary care environment over a two-year period. The author intends to comment on the observed management of the subjects in relation to published guidelines (Thorax, 1997) over that two-year period. As the GP practice is at the forefront of asthma management the implementation and interpretation of guidelines requires evaluation and deserves comment. The problem of compliance by adult asthma patients with the regular use of inhaled medication is well documented and has been addressed in 3.4.3. The author also intends to explore the relationship of compliance to social class. Data were collected from all subjects taking part in the study pertaining to their social class and asthma severity (as measured by BTS guidelines treatment step). Although compliance was not formally monitored actual prescription uptake by patients was noted over the two-year period and can be compared to medication prescribed. It is intended to examine how subjects from differing social classes comply with their prescribed asthma medication.

## 4.8 Conclusion

The aim of this study was to observe the management of a cohort of adult asthma patients in the primary care setting over a two-year period. Also to assess a newly devised patient focused morbidity index (Q score) for validity, reliability, sensitivity and specificity by comparison to an established asthma-based QoL questionnaire (AQLQ). This study accepts the hypothesis that the Q score is as reliable as the AQLQ symptom score when used to monitor symptoms as part of the management of asthma patients in primary care.

The Asthma Outcomes Seminar held at the RCP (London) in 1998 published their report the following year (Pearson and Bucknall, 1999). The aim of the seminar was to "investigate the feasibility of reaching a consensus across a national spectrum for a simple patient focused tool for measuring clinical outcome in chronic persistent asthma". The author was invited to present the baseline results of this current study and introduce the Q score at the seminar.

The main conclusions from the seminar were:-

- Outcome measures should be patient focused and based upon asthma related symptoms.
- The assessment tool should consist of three questions that are relevant to the clinician and the patient.
- The three questions should cover night-time disturbance, day-time symptoms and interference with daily activities.
- Each question should cover a short time span either a week or a month and have a response that can be quickly and easily recorded.

The Q score complies with the RCP seminar conclusions. It is a short patient focused morbidity index devised in consolation with a variety of

health care professionals. It is suitable for use with adult asthmatics of any severity. It asks questions that are important and relevant to the patient and is short enough to be used during any asthma intervention. The questions asked should routinely be asked but are often overlooked by patient and clinician. However, the Q score does contain four as opposed to three questions, the fourth question relates to the use of βagonist inhalers. The rationale for the inclusion of this question in the Q score was as a means of indicating the patient's asthma control. Thus the Q score must be envisaged as a reliable asthma specific tool that can be used quickly, simply and effectively for better patient management and outcome.

The study also set out to observe asthma management in primary care. Guidelines for the management of adult asthma have been published, disseminated and embraced by many GP practices with improved outcome for patients. The success of the guidelines following implementation may be attributed to the manner in which they were disseminated. Success can only be maintained by repeated educational activities focused on improving the health professionals' knowledge and understanding of the guidelines. Such activity needs to be carried out in conjunction with practice audit assessing the process of care.

The GP practice remains at the forefront of asthma care and should therefore be offering appropriate treatment and regular review of patient's asthma control. Altering medication as per BTS Guidelines can give the impression of treating asthma, but without short-term reassessment the same levels of morbidity can persist. Relying upon reported symptoms of asthma alone as a guide for any alteration in treatment may be misleading. The relationship between morbidity and non-asthma related factors can be complex. When assessing reported asthma symptoms psychological and socio-economic factors should always be considered by the health professional.

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# APPENDIX I

GP Practice Agreement

## ASTHMA OUTCOMES PROJECT – GP PRACTICE AGREEMENT

**Aims of the Study**
To follow cohorts of asthmatic patients from differing primary health care settings over a two-year period. To assess a newly devised short answer morbidity index relating to asthma for validity, reliability, sensitivity and specificity by comparison to an established asthma based quality of life questionnaire (Juniper *et al*, 1993).

**The Practice**
Subjects for the study will be recruited from four different practices within South Sefton area.

**The practice is asked to supply a list of asthma patients. This will require scrutiny by practice members for rogue patients.** (Reade Code (five characters) H33.)

Following that members of the project team will take over the collection of data, subjects suitable to take part in the study will be chosen randomly from the supplied list (maximum 40 patients per practice).

Suitable subjects will be aged **16 - 60 years**. They should have been receiving treatment for their asthma for the **past 6 months**. Such treatment may include **any prophylactic inhaler or 2 or more prescriptions for a Beta2agonist inhaler**.

Each subject must present evidence of asthma either at entry to the study or retrospectively.

It is anticipated project staff will initially require assistance from the Practice Manager and clerical staff in order to familiarise themselves with practice record keeping and administration. The practice is asked to supply project staff with accommodation to assess patients within the practice itself. A few patients may require home visits, project staff will be free to do so if required.

**Exclusion from the Study**
Subjects will be excluded from the study if they present with a smoking history of >20 pack years. If they have existing bronchiectasis, other lung pathology or cardiac disease.

Subjects will be free to exclude themselves from the study at any time.

**Method of Assessment**
Data will be collected for the cohort by members of the University of Salford. Such data will include the administration of various questionnaires monitoring the patients use of prescribed medication, PEF and noting any hospital admissions for asthma. This will take place over the 2-year period at **12 monthly intervals**.

**Copies of the full protocol are available from Lesley Rimington on request**.
This project has received approval from South Sefton Research Ethics Committee - 25.06.96.
Practice assistance with this project will be acknowledged.

# APPENDIX II

Patient Consent Form

**PATIENT INFORMED CONSENT**

## ASTHMA MANAGEMENT IN THE PRIMARY HEALTH CARE SETTING

Aintree Chest Centre along with your GP Practice proposes to follow up over **two years** a group of patients with asthma. Over that two year period we would monitor your asthma management by looking at your lung function (eg, peak flow readings), noting down your medication and asking you to complete one or two questionnaires at **regular 12 monthly intervals**. At the assessments three questionnaires will be used along with the lung function assessments and the medication identification. All information collected during this study will be dealt with in confidence and anonymously.

This study does not involve any tests, which are not normally undertaken by patients with asthma, and therefore there are no risks to me if I enter this study.

I understand that I am free to withdraw from this study at any time and this will in no way prejudice my subsequent treatment.

I hereby agree to take part in the study

Signed: Date:

I have explained the purpose and procedures of the study to the above named patient and have answered any questions that have arisen.

Investigators' signature: Date:

If at any time you have any questions relating to the study then please contact:

Dr MG Pearson, Aintree Chest Centre, Aintree Hospitals, Fazakerley, Liverpool.
Telephone: 0151 529 3857
or,
Lesley Rimington, Department of Rehabilitation, Faculty of Health Care and Social Work Studies, University of Salford.
Telephone: 0161 295 2418.

# APPENDIX III

British Thoracic Society Guidelines Treatment Step

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

NATIONAL **ASTHMA** CAMPAIGN
getting your breath back

BPA KINGS FUND

This Poster is funded by the National Asthma Campaign and re-printed from *Thorax* 1993 ; **48** Supplement SI-S24

# APPENDIX IV

Patient Data Sheet - Baseline

**ASTHMA MANAGEMENT IN THE PRIMARY HEALTH CARE SETTING**
**BASELINE PATIENT DATA SHEET**

| Patient No: |
|---|

Date of interview:

Practice: (circle)

N S W R Y

Patient Name:

Patient address/phone:

Date of birth: M/F

**Smoking history:**

| Yes | No |
|---|---|

Pack years

**Allergy:**

| Yes | No |
|---|---|

**Occupation**/previous occupation:

**Patient Medication** (list ALL - oral and inhaled):

| **DOSAGE**<br>(amount and how many times per day) | **MEDICATION**<br>(name) |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |

Self-management plan for asthma?

**Severity** (as per BTS Treatment Step):

In the past 6 months note:

| | |
|---|---|
| Number of hospital admissions (in excess of 24 hours) | |
| Number of exacerbations (visits to GP for deteriorating asthma) | |
| Number of oral steroid prescriptions | |
| Number of repeat prescriptions for INHALED steroids medication | |
| Number of repeat prescriptions for INHALED bronchodilators | |

**Spirometry**: Recorded

| | |
|---|---|
| PEF | |
| FEVI | |
| FVC | |

**Spirometry**: Predicted

| | |
|---|---|
| PEF | |
| FEVI | |
| FVC | |

## SHORT ANSWER QUESTIONNAIRE (Q SCORE)

**In the past week:**

(please circle)

1 On how many days have you wheezed or been breathless?

0-1 2-4 5-7

2 On now many nights have you been woken because of asthma?

0-1 2-4 5-7

3 On how many days has asthma prevented you doing your normal activities?

0-1 2-4 5-7

4 How many times are you using your **reliever** inhaler each day?

0-1 2-4 5+

SCORE

0 = left
1 = middle
2 = right column (total score out of 8)

0 = well controlled
8 = poor control

## PATIENT EXPECTATION OF TREATMENT

When you **last came to the GP practice (for your asthma)** what did you want to achieve from your visit?

a) I wanted my asthma to be better controlled

b) I wanted to check my medication

c) I wanted to discuss the side effects of my medication

d) I wanted to know what to avoid so my asthma would go away

e) I wanted to stop my sleep from being disturbed by my chest

f) Other ……..

……..

Write below the **first and second most important** things you expected to achieve following your visit to the GP practice.

**First** ……

**Second** ……

## PRACTICE QUESTIONNAIRE

**Name of GP Practice:**

**Date:**

1 Does the practice have a designated Asthma Nurse and/or GP?

Asthma Nurse

| Yes | No |
|---|---|

Designated Asthma GP

| Yes | No |
|---|---|

2 Does the practice have any specific asthma clinics?

| Yes | No |
|---|---|

If YES, how often are they run eg, weekly, fortnightly, monthly?

3 Does the practice follow the recommendations of the BTS Asthma guidelines (eg, prescribe PF metres regularly, issue self-management plans, ask patients to keep PFM charts, use inhaled steroids etc)?

| Yes | No |
|---|---|

# APPENDIX V

Twelve/Twenty Four Months Patient Data Sheet

**ASTHMA MANAGEMENT IN THE PRIMARY HEALTH CARE SETTING**
**TWELVE AND TWENTY FOUR MONTHS PATIENT DATA SHEET**

Patient No:

Date of interview:

Practice: (circle)

N S W R Y

Patient Name:

Patient address/phone:

Has the patient's medication changed since last seen in study?

| Yes | No |
|---|---|

If YES, what has changed?

**Patient Medication** (list ALL - oral and inhaled)

| **DOSAGE** (amount and how many times per day) | **MEDICATION** (name) |
|---|---|
| | |
| | |
| | |
| | |

**Severity** (as per BTS Treatment Step):

In the past 12 months note:

| | |
|---|---|
| Number of hospital admissions (in excess of 24 hours) | |
| Number of exacerbations (visits to GP for deteriorating asthma) | |
| Number of oral steroid prescriptions | |
| Number of repeat prescriptions for INHALED steroids medication | |
| Number of repeat prescriptions for INHALED bronchodilators | |

**Spirometry**: Recorded

| | |
|---|---|
| PEF | |
| FEVI | |
| FVC | |

**SHORT ANSWER QUESTIONNAIRE (Q SCORE )**

**In the past week:**

(please circle)

1 On how many days have you wheezed or been breathless?

0-1 2-4 5-7

2 On now many nights have you been woken because of asthma?

0-1 2-4 5-7

3 On how many days has asthma prevented you doing your normal activities?

0-1 2-4 5-7

4 How many times are you using your **reliever** inhaler each day?

0-1 2-4 5+

SCORE

0 = left
1 = middle
2 = right column (total score out of 8)

0 = well controlled
8 = poor control

## PATIENT EXPECTATION OF TREATMENT

When you **last came to the GP practice (for your asthma)** what did you want to achieve from your visit?

a) I wanted my asthma to be better controlled

b) I wanted to check my medication

c) I wanted to discuss the side effects of my medication

d) I wanted to know what to avoid so my asthma would go away

e) I wanted to stop my sleep from being disturbed by my chest

f) Other .....

.....

Write below the **first and second most important** things you expected to achieve following your visit to the GP practice.

**First** .....

**Second** .....

# APPENDIX VI

Asthma Quality of Life Questionnaire

**ASTHMA QUALITY OF LIFE QUESTIONNAIRE - (AQLQ)**
**(JUNIPER *ET AL*, 1993)**

Patient No:

Date: 0/12/24 months review

You should identify 5 activities that are limited by your asthma.
If more than 5 activities are identified then choose the 5 most important.
To ensure all possible activities are included use the following list as a prompt.

Bicycling
Dancing
Doing home maintenance
Doing housework
Gardening
Hurrying
Jogging, exercising or running
Laughing
Mopping or scrubbing the floor
Mowing the lawn
Playing with pets
Playing with children
Playing sports
Singing
Doing regular social activities
Having sexual intercourse
Talking
Running upstairs or uphill
Vacuuming
Visiting friends or relatives
Walking upstairs or uphill
Woodworking or carpentry
Carrying out your activities at work

When 5 activities have been identified please ask the patient to what extent they have been limited by each of the activities they have chosen. List the activities 1-5.

Then for each activity - please indicate how much you have been limited by your asthma in (insert activity) during the last two weeks by choosing one of the following options. (**Green card**)

| **Activity** | **Score** |
|---|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |

The remaining 27 questions are the same for all patients.

| | | |
|---|---|---|
| 6 | How much discomfort or distress have you felt over the last two weeks as a result of chest tightness? (**Red card)** | ❑ |
| 7 | In general, how often during the last two weeks have you felt concerned about having asthma? **(Blue card)** | ❑ |
| 8 | How often during the past two weeks did you feel short of breath as a result of your asthma? **(Blue card)** | ❑ |
| 9 | How often during the past two weeks did you experience asthma in your chest? **(Blue card)** | ❑ |
| 10 | How often during the past two weeks did you experience a wheeze in your chest? **(Blue card)** | ❑ |
| 11 | How often during the past two weeks did you feel you have to avoid a situation or environment because of cigarette smoke? **(Blue card)** | ❑ |
| 12 | How much discomfort or distress have you felt over the past two weeks as a result of coughing? **(Red card)** | ❑ |
| 13 | How often during the past two weeks did you feel frustrated as a result of your asthma? **(Blue card)** | ❑ |
| 14 | How often during the past two weeks did you experience a feeling of chest heaviness? | ❑ |
| 15 | How often during the past two weeks did you feel concerned about the need to take medication for your asthma? **(Blue card)** | ❑ |
| 16 | How often during the past two weeks did you feel the need to clear your throat? | ❑ |
| 17 | How often during the past two weeks did you experience asthma symptoms as a result of being exposed to dust? **(Blue card)** | ❑ |
| 18 | How often during the past two weeks did you experience difficulty breathing out as a result of your asthma? **(Blue card)** | ❑ |
| 19 | How often during the past two weeks did you feel you had to avoid a situation or environment because of dust? **(Blue card)** | ❑ |
| 20 | How often during the past two weeks did you wake up in the morning with asthma symptoms? **(Blue card)** | ❑ |
| 21 | How often during the past two weeks did you feel afraid of not having your asthma medication available? **(Blue card)** | ❑ |
| 22 | How often during the past two weeks were you bothered by heaving breathing? **(Blue card)** | ❑ |
| 23 | How often during the past two weeks did you experience asthma symptoms as a result of the weather or air pollution outside? **(Blue card)** | ❑ |

| | | |
|---|---|---|
| 24 | How often during the past two weeks have you been woken at night by your asthma? **(Blue card)** | ❑ |
| 25 | How often during the past two weeks have you had to avoid going outside because of the weather or air pollution? **(Blue card)** | ❑ |
| 26 | How often during the past two weeks did you experience asthma symptoms as a result of being exposed to strong smells or perfume? **(Blue card)** | ❑ |
| 27 | How often during the past two weeks did you feel afraid of getting out of breath? **(Blue card)** | ❑ |
| 28 | How often during the past two weeks did you feel you had to avoid a situation or environment because of strong smells or perfume? | ❑ |
| 29 | How often during the past two weeks has your asthma interfered with getting a good night's sleep? **(Blue card)** | ❑ |
| 30 | How often during the past two weeks have you had the feeling of fighting for air? **(Blue card)** | ❑ |
| 31 | Think of the overall range of activities that you would have liked to have done during the past two weeks? How much has your range of activities been limited by your asthma? **(Yellow card)** | ❑ |
| 32 | Overall, among all the activities that you have done during the past two weeks, how limited have you been by your asthma? **(Green card)** | ❑ |
| | | ❑ |

## HOW TO SCORE THE AQLQ QUESTIONNAIRE

### Domains

The items are grouped into 4 domains:-

1 Activity limitations
(Items 1-5, 11, 19, 25, 28, 31, 32)

2 Symptoms
(Items 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 29, 30)

3 Emotional function
(Items 7, 13, 15, 21, 27)

4 Exposure to environmental stimuli
(Items 9, 17, 23, 26)

### Scoring

Calculate the mean scores for the items within each domain for each subject.

The overall **QoL** score may be estimated from the mean score for all items.

## AQLQ RESPONSE OPTIONS

### Green Card

1 Totally limited, couldn't do activity at all
2 Extremely limited
3 Very limited
4 Moderate limitation
5 Some limitation
6 A little limitation
7 Not at all limited

### Red Card

1 A very great deal of discomfort or distress
2 A great deal of discomfort or distress
3 A good deal of discomfort or distress
4 A moderate amount of discomfort or distress
5 Little discomfort or distress
6 Very little discomfort or distress
7 No discomfort or distress

### Blue Card

1 All of the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little bit of the time
6 Hardly any of the time
7 None of the time

### Yellow Card

1 Severely limited - most activity not done
2 Very limited
3 Moderately limited - several activities not done
4 Slightly limited
5 Very slightly limited - very few activities not done
6 Hardly limited at all - have done all activities that I wanted to do
7 Not limited at all - have done all activities that I wanted to do

# APPENDIX VII

Hospital Anxiety and Depression Scale

**HOSPITAL ANXIETY AND DEPRESSION SCALE**
**(ZIGMOND AND SNAITH, 1983)**

Patient No:

Date: 0/12/24 months review

Doctors are aware that emotions play an important part in most illnesses. If we know about these feelings we will be able to help more.

This questionnaire is designed to help us know how you feel. Read each item and underline the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.

1a I feel tense or "wound up":
- most of the time
- a lot of the time
- from time to time, occasionally
- not at all

2d I still enjoy the things I used to enjoy:
- definitely as much
- not quite as much
- only a little
- hardly at all

3a I get a sort of frightened feeling as if something awful is about to happen:
- very definitely and quite badly
- yes, but not too badly
- a little, but it doesn't worry me
- not at all

4d I can laugh and see the funny side of things:
- as much as I always could
- not quite so much now
- definitely not so much now
- not at all

5a Worrying thoughts go through my mind:
- a great deal of the time
- a lot of the time
- from time to time but not too often
- only occasionally

6d I feel cheerful:
- not at all
- not often
- sometimes
- most of the time

7a I can sit as ease and feel relaxed:
- definitely
- usually
- not often
- not at all

8d I feel as if I am slowed down:
- nearly all the time
- very often
- sometimes
- not at all

9a I get a sort of frightened feeling like “butterflies” in the stomach:
- not at all
- occasionally
- quite often
- very often

10d I have lost interest in my appearance:
- definitely
- I don’t take so much care as I should
- I may not take quite as much care
- I take just as much care as ever

11a I feel restless as if I have to be on the move:
- very much indeed
- quite a lot
- not very much
- not at all

12d I look forward with enjoyment to things:
- as much as ever I did
- rather less than I used to
- definitely less than I used to
- hardly at all

13a I get sudden feelings of panic:
- very often indeed
- quite often
- not very often
- not at all

14d I enjoy a good book or radio or TV programme:
- often
- sometimes
- not often
- very seldom

## HOW TO SCORE THE HAD SCALE

The HAD scale scores for both depression and anxiety. The even numbers refer to depression (i.e., 2, 4, 6 ..) and the odd numbers to anxiety. The rating is based on a 4-point scale.

Score nos.: 1, 3, 5, 6, 8, 10, 11, 13 as

| | | |
|---|---|---|
| Top scores | - | 3 |
| Next scores | - | 2 |
| Next scores | - | 1 |
| Bottom scores | - | 0 |

Score nos.: 2, 4, 7, 9, 12, 14 as

| | | |
|---|---|---|
| Top scores | - | 0 |
| Next scores | - | 1 |
| Next scores | - | 2 |
| Bottom scores | - | 3 |

Anxiety score nos.: 1a, 3a, 5a, 7a, 9a, 11a, 13a

Depression score nos.: 2d, 4d, 6d, 8d, 10d, 12d, 14d

A score of 0 - 7 is indicative of no depression or anxiety.

A score of 8 - 10 indicated a possible or “borderline” depression or anxiety.

A score of 11 - 21 indicates probable significant depression or anxiety.

Remember, for the depression total score add up the scores for all the even questions.

For the anxiety total score add up the scores for all the odd questions.

# APPENDIX VIII

Letter to Patient Confirming Date/Time of Appointment

# APPENDIX IX

Peak Flow Chart

# APPENDIX X

Letter to Patient if Did Not Attend for Appointment

# APPENDIX XI

Local Ethical Approval

# APPENDIX XII

Base-line Data for Twenty-Four Subjects who did not complete the Study

The following table illustrates the baseline data for twenty-four subjects who did not complete the two-year study. Subjects withdrew of their own free will.

There were no significant differences at baseline between subjects who withdrew from the study and those who continued with the study for lung function, PEF, morbidity or psychological status.

| **Variable** | **N=24** | **%** | **Mean (SD)** |
|---|---|---|---|
| Age | | | 40(13) |
| Gender (male) | 7 | 29 | |
| Inner city subjects | 19 | 79 | |
| Still smoking | 6 | 25 | |
| Pack years | | | 2.7(5.8) |
| Using βagonist | 24 | 100 | |
| Using inhaled steroids | 19 | 79 | |
| Using oral steroids | 1 | 4 | |
| BTS Guidelines Treatment Step (3-5) | 6 | 25 | |
| PEF | | | 338L/min(110) |
| Predicted PEF | | | 449L/min(88) |
| $FEV_1$ | | | 2.15L(0.90) |
| Predicted $FEV_1$ | | | 2.97L(0.58) |
| FVC | | | 2.93L(0.93) |
| Predicted FVC | | | 3.74L(0.65) |
| $FEV_1$/FVC | | 72 | |
| AQLQ score | | | 4.80(1.27) |
| AQLQ Symptom score | | | 4.80(1.50) |
| Q score | | | 2.50(2.53) |
| HAD Anxiety | | | 9.66(4.49) |
| HAD Depression | | | 5.95(4.93) |

# APPENDIX XIII

Data for Seventy-Nine Subjects Assessed at Baseline, Twelve and Twenty-four Months

The following table illustrates data for seventy-nine subjects who participated in the study at baseline, twelve and twenty-four month. There were no significant differences between subjects who attend attended on all three occasions and those who did not.

| ***Variable*** | ***Baseline*** | | | ***12 months*** | | | ***24 months*** | | |
|---|---|---|---|---|---|---|---|---|---|
| | ***N=79*** | ***%*** | ***Mean(SD)*** | ***N=79*** | ***%*** | ***Mean(SD)*** | ***N=79*** | ***%*** | ***Mean(SD)*** |
| Age (years) | | | 43(11) | | | | | | |
| Gender (male) | 30 | 38 | | | | | | | |
| Inner city residents | 45 | 57 | | | | | | | |
| Current smokers | 19 | 24 | | | | | | | |
| Pack Years | | | 2.75(5.79) | | | | | | |
| Using βagonist | 73 | 92 | | 69 | 87 | | 68 | 68 | |
| Using Inhaled Steroids | 65 | 82 | | 68 | 86 | | 69 | 87 | |
| Using Oral Steroids | 6 | 8 | | 10 | 13 | | 7 | 9 | |
| BTS Guidelines Treatment Step (3-5) | 28 | 35 | | 39 | 49 | | 41 | 52 | |
| Inhaled Steroids increased | | | | 14 | 18 | | 8 | 10 | |
| PEF | | | 352L/min(135) | | | 331L/min(137) | | | 344L/min(128) |
| Predicted PEF | | | 463L/min(89) | | | | | | |
| $FEV_1$ | | | 2.20L(0.91) | | | 2.18L(0.90) | | | 2.35L(0.91) |
| Predicted $FEV_1$ | | | 2.98L(0.62) | | | | | | |
| FVC | | | 2.82L(0.98) | | | | | | |
| Predicted FVC | | | 3.79L(0.73) | | | | | | |
| $FEV_1$/FVC | | 77 | | | | | | | |
| AQLQ score | | | 4.65(1.24) | | | 4.35(1.39) | | | 4.71(1.31) |
| AQLQ Symptom score | | | 4.54(1.51) | | | 4.51(1.45) | | | 4.67(1.60) |
| Q score | | | 3.0(2.44) | | | 2.94(2.54) | | | 2.82(2.62) |
| HAD Anxiety | | | 7.73(4.27) | | | 7.82(4.56) | | | 7.51(4.85) |
| HAD Depression | | | 5.12(3.61) | | | 4.74(3.60) | | | 5.20(3.97) |

# APPENDIX XIV

Published Papers and Abstracts from Conference Presentations Associated with this Thesis

**http://thorax.bmj.com/cgi/content/abstract/56/4/266**

**http://www3.interscience.wiley.com/cgi-bin/fulltext/119423635/PDFSTART**

LD Rimington, D Furphy, R Nissen, A Patel, C White and MG Pearson (2000).

CHANGES IN DEPRESSION OVER TWO YEARS – A FOLLOW-UP STUDY OF ASTHMA PATIENTS IN PRIMARY CARE. *Am J Crit Care Med* **161**; 3: A315.

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Published asthma guidelines focus on the control and reduction of symptoms, they do not take into account psychological status. We studied 71 subjects (mean (SD)) age 42 (12) range 16-60, 27 males, $FEV_1$ 2.2L (0.95), $FEV_1$ predicted 3.0L (0.62) and PEF 352L/min (140) over two years from four health care practices, two inner city, two suburban. We recorded Juniper AQLQ and Q Score (Rimington *et al*, 1997), HAD Scale, UK Asthma Guidelines treatment step and inhaled medication at outset and at 24 months. 30% of patients recorded HAD depression scores of ≥8 denoting depression (10.14(±2.2) v 3.0(±2.0)). 90% of these subjects were from inner city GP practices. Depressed patients were of similar asthma severity (proportion of treatment step 3-5, 38% v 20%, mean $FEV_1$ 2.01L (±0.97) v 2.32L (±0.94) and PEF 313L/min (±149) v 369L/min (±134), inhaled steroids 91% v 80%). Over the two year period depressed patients visited their GP more often (on two occasions or more 24% v 18%) with no significant reduction in morbidity as measured by AQLQ and Q score. Anxiety and depression were slightly reduced but again not significantly so, 12.91 (±3.6) v 10.95 (±4.5) and 10.14 (±2.2) v 8.6 (±3.4) respectively. We have previously reported the relationship between morbidity and psychological status (Rimington *et al,* 1998) this follow-up data continues to support the rationale that using morbidity to monitor asthma may be misleading, psychological factors may influence reporting.

LD Rimington, D Furphy, R Nissen, A Patel, C White and MG Pearson (2000).

TWO YEAR FOLLOW-UP STUDY OF ASTHMA MANAGEMENT IN PRIMARY HEALTH CARE. *Am J Crit Care Med* **161**; 3: A319.

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Asthma remains a high profile disease with pressure to improve outcomes for patients (Neville and Higgins, 1999). We studied 71 subjects (mean (SD)) age 42 (12) range 16-60, 27 males, $FEV_1$ 2.2L (0.95), $FEV_1$ predicted 3.0L (0.62) and PEF 352L/min (140) over two years from four health care practices. We recorded Juniper AQLQ and Q Score (Rimington *et al*, 1997), HAD Scale, UK Asthma Guidelines treatment step and inhaled medication at outset and at 24 months. No specific advice was given to clinics regarding asthma management over the study period. 82% of subjects were taking inhaled steroids at 2 years, 14% had inhaled steroids increased while 63% had no change in inhaled steroids at the end of the study period. Subjects taking inhaled steroids v reduced or no steroids (82% v 18%) had no significant difference in morbidity as measured by AQLQ 4.3(1.6) v 4.8(1.1) or Q score 3.1(2.7) v 2.5(1.8) at two years. Subjects with increased inhaled steroids were slightly more depressed, HAD anxiety 8.4(4.7) v 7.0(4.7) and HAD depression 5.7(3.8) v 3.5(3.5) ($p<0.01$). 53% of subjects taking inhaled steroids were in BTS treatment step 3-5. Despite the increase in inhaled steroids, these subjects (14%) had no significant reduction in morbidity over 2 years, AQLQ 4.0(2.0) v 4.1(1.5), and Q Score 3.6(2.9) v 4.1 (2.9). In subjects with unchanged inhaled medication (68%), morbidity also remained unchanged. AQLQ 4.4(1.4) v 4.3(1.7), Q Score 3.1(2.5) v 2.9(2.7). Anxiety and depression did not change significantly in either group. Despite the publication of asthma guidelines, this observation of clinical practice reveals levels of persistent morbidity with no improvement in outcome for patients.

LD Rimington, A Fisk, S Hannah, G Midgeley, S Whitehall, I Ryland and MG Pearson (1999).

DOES CHANGE IN MEDICATION OVER 12 MONTHS AFFECT ANXIETY AND DEPRESSION IN ASTHMA PATIENTS IN PRIMARY CARE *ERJ* **14**; Suppl 30: 106.

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Emotional disorders are commonplace in patients exhibiting longstanding disability and depression can be associated with increasing morbidity. A random sample of 75 patients were studied (mean (SD)) age 42 (12) range 16-60 years, 26 male, $FEV_1$ 2.14L (0.97), $FEV_1$ 70% predicted. Subjects were assessed using Juniper AQLQ and Q Score (Rimington *et al*, ERJ 1997 ; 10:194) HAD Scale and UK Asthma Guidelines Treatment Step. Measurements were recorded before and after 12 months of routine care and no advice was given to the treating physician. Over 12 months 26 subjects had their inhaled medication increased (11 no increase in inhaled steroids) 49 did not. There were no other differences between the two groups. Change over 12 months in 49 subjects were Juniper Symptom score 4.4 (1.5) v 4.4 (1.4), Q Score 3.04 (2.6) v 3.3 (2.4), HAD Anxiety 8.9 (4.4) v 8.4 (4.4), HAD Depression5.2 (4.0) v 4.7 (3.6). In the 26 subjects, Juniper Symptom score 4.2 (1.45) v 4.2 (1.5), Q Score 3.4 (2.4) v 3.1 (2.5), HAD Anxiety 7.9 (4.7) v 7.6 (4.5), HAD Depression 6.2 (4.1) v 4.9 (2.9). Depression decreased (p=0.03) amongst those who's treatment increased. Over 12 months treatment symptoms remained unchanged in both groups. Depressed patients received more treatment without affecting asthma symptoms.

LD Rimington A Fisk S Hannah G Midgeley S Whitehall I Ryland and MG Pearson (1999).

AN AUDIT OF ASTHMA MANAGEMENT IN PRIMARY CARE. *ERJ* **14**; Suppl 30: 106.

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The impact of asthma specific clinics in Primary Health care is said to reduce morbidity. We assessed a random sample of patients from 4 GP Practices, (2 inner city, 2 suburban) claiming to adhere to BTS Treatment Guidelines and providing Nurse led asthma clinics although only 1 practice ran clinics on a regularly monthly basis. 75 patient attendance and prescribing records were examined over a 12-month period. Mean (SD) data, age 42 (12), range 16-60 years, 26 male $FEV_1$ 2.4L (0.97), $FEV_1$ 71% predicted, 81% were prescribed regular inhaled corticsteroids. We recorded Juniper AQLQ, Q Score (Rimington *et al*, ERJ 1997; 10:194) and BTS Treatment Step at outset and 12 months. 73% of patients did not attend asthma specific clinics over the 12-month period, 12% attended on 2 or more occasions. Non attenders had no change in symptoms over 12 months, Juniper symptoms scores 4.4 (1.5) v 4.5 (1.3), Q Score 2.9 (2.6) v 3.0 (2.4) despite 32% of subjects having inhaled medication increased. Clinic attenders had increased symptom scores ($p=0.042$) but no change over 12 months, Juniper symptom scores 3.4 (1.5) v 3.3 (1.4), Q Score 4.7 (1.7) v 5.3 (2.0) although 56% had their treatment increased. A minority of asthma patients with higher symptom scores used the formal asthma clinics though neither group had fewer symptoms at 12 months.

LDRimington A Fisk S Hannah G Midgeley D McKearney I Ryland and MG Pearson (1999)

THE RELATIONSHIP OF ANXIETY, DEPRESSION AND ASTHMA SYMPTOMS IN DIFFERING SOCIO ECONOMIC PRIMARY HEALTH CARE SETTINGS. *Am J Crit Care Med* **159;** 3: A654.

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The relationship between social deprivation and increased asthma morbidity is well-documented (Watson and Lewis, 1995). We studied 114 subjects (mean (SD)) age 42 (12) years (range 16-60), 42 male, $FEV_1$ 2.23L (0.89); $FEV_1$ predicted 3.00L (0.62), PEF 353L/min. (126) from 4 primary health care practices. Jarman scores (Jarman, 1983) were used as an index of community wide social deprivation. The 2 inner city practices had worse Jarman sores (more deprived) than the two suburban practices (+18.7 and +13.45 versus -19.58 and -18.27 respectively). Subjects were assessed using Juniper AQLQ and Q Score (Rimington *et al,* 1997) the HAD Scale and BTS Asthma Guidelines Treatment Step. Smoking was also recorded. Inner city patients were of similar asthma severity (proportion of treatment step 3-5, 26% vs. 29%, mean $FEV_1$ 2.2L vs. 2.3L and PEF 348 vs. 363L/min) as suburban patients but were more depressed (5.95 vs. 3.72 $p<0.05$) significantly more anxious (9.5vs 6.17, $p<0.001$) and were more likely to be current smokers (36% vs. 10% $p<0.001$). Within the whole group anxiety correlated strongly with lower AQLQ, higher Q Score and with increased treatment level (all $p<0.01$) and was the greatest difference between asthma patients in different socio economic areas. Some of the increased asthma morbidity in deprived areas may be manifestation of anxiety rather than of difference in disease.

LD Rimington A Fisk S Hannah G Midgeley I Ryland and MG Pearson (1999).

CHANGES IN TREATMENT AND MORBIDITY OF ASTHMA OVER ONE YEAR IN PRIMARY HEALTH CARE CLINICS *Am J Crit Care Med* **159**; 3: A759.

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Primary health care clinics should expect to decrease asthma symptoms over time (Jones *et al* 1992). We studied 75 subjects (mean (SD)) age 42(12) range 16-60 years, 26 male, $FEV_1$ 2.14L (0.97) PEF 338L/min (141) 81% were on regular inhaled corticsteroids. We recorded the Juniper AQLQ, Q Score (Rimington *et al*, 1997) the HAD Scale and UK Asthma Guidelines treatment step at out set and at 12 months. No specific advice was given to clinics regarding asthma management. Initial cross sectional data showed that Juniper AQLQ and Q Score correlated with worsening levels of $FEV_1$, PEF, increased treatment step (all $p<0.01$) and increased HAD scores for depression ($p<0.01$) (Rimington *et al*, 1998). 34% of patients had their treatment modified during the year. These patients had similar lung function, levels of treatment and age as those who's treatment was unchanged. There was a trend to a lower initial symptom level (AQLQ 17.2 Vs 18.5, Q Score 3.4 Vs 3.0) and an improvement over 12 months (AQLQ 17.7, Q Score 3.15) against no change in those with unaltered therapy (AQLQ 18.3, Q score 3.36) but none of these trends were statistically significant. Initial and 12 month AQLQ and Q scores remained closely correlated (both $p< 0.001$). The sub group with the highest Q Scores$\exists$4, 75%) were in treatment step 3-5 continued to be symptomatic. A similar pattern was shown in those subjects with fewer symptoms. Observation of routine primary care practice shows that decisions to alter treatment are independent of the level of morbidity and resulted in no significant improvements. We conclude that altering medication may give an impression of treating asthma, but without short-term reassessment the same levels of morbidity can persist.

LD Rimington L Aronoffsky A Mowatt E Warburton and MG Pearson (1997).

THE RELATIONSHIP BETWEEN ASTHMA SYMPTOMS, ANXIETY AND DEPRESSION. *Thorax* **52**; Suppl 6: A47.

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The prime aim of asthma management is to reduce symptoms but symptom reporting depends on both disease severity and on the threshold for perception of symptoms which is linked to psychological state (Janson-Bjerklie, 1993). We studied 90 patients, age 43(±12), 32 male, $FEV_1$ 2.21L(±0.94), by selecting every 8$^{th}$ patient from the asthma register of 4 GP practices. Each subject completed an Asthma Quality of Life Questionnaire (AQLQ, Juniper et al, 1993) the Hospital Anxiety and Depression scale (Zigmond and Snaith, 1983), spirometry and details of current treatment. 73 (81%) were on regular inhaled steroids of which 19 (21%) were on high dose (steps 3-5 of BTS guidelines). Mean PEF 347L/min.(±137), 74% predicted, was significantly correlated with the AQLQ ($p<0.001$) and negatively correlated with increasing treatment step ($p<0.001$). HAD scores for the depression ($p<0.001$) but not anxiety correlated with the worse functioning in both the symptom domain and overall AQLQ but were not related to the level of PEF. Despite the expected univariate relationship between increasing symptoms and lower PEF, multiple regression analysis showed that symptom levels were most sharply linked to depression scores of the HAD rather than the level of treatment or to the level of PEF. These data suggest that using reported symptoms as a measure of asthma control may be misleading, because non asthma factors may be even more important in individuals.

LD Rimington L Aronoffsky A Mowatt E Warburton and MG Pearson (1997).

# USE OF A SIMPLE PATIENT FOCUSED ASTHMA MORBIDITY SCORE.

*ERJ* **10**; Suppl 25: 194.

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Established and validated questionnaires have been shown to be useful research tools with which to assess asthma morbidity (Juniper et al, 1993) but they are too time consuming for routine clinical practice. We have used 4 questions that a doctor would usually ask in each consultation (covering nights waking, reliever inhaler use, daytime wheezing and disruption of activities) to produce an 8 point score that requires no extra time from the clinician. We have assessed this short questionnaire (Q score) with the Juniper morbidity score (total score and symptom score), with levels of PEF and with the UK Asthma Guidelines Treatment Step in 81 patients randomly selected from 3 general practices (mean (SD) age 43 (12) 26 male, PEF 345 (138) $FEV_1$ 1.2 (0.9) and repeated the observations two weeks later in subset of 21 patients. The paired observations showed that both Juniper ($r=0.87$) and Q score ($r=0.79$) were repeatable with similar variability. The Q score was negatively correlated with the Juniper symptom score ($r=0.79$, $p<0.01$) and total score ($r=0.73$, $p<0.01$) and both Q score and Juniper correlated with levels of resting $FEV_1$ (Q:$r=0.44$, J:$r=0.42$) and with the severity of asthma as indicated by the treatment step (Q:$r=0.47$, J:$r=-0.36$. all$<0.01$) although there was considerable scatter for the latter. The Q score correlates well with both the established longer questionnaire and also shows similar relationships to lung function and to levels of severity . If it also shows sensitivity to changes in asthma status over the next year it may provide a practical tool with which to estimate asthma morbidity in routine practice.