

**A3D3**

**2012/13 NHS STANDARD CONTRACT  
FOR ACUTE, AMBULANCE, COMMUNITY AND MENTAL HEALTH  
AND LEARNING DISABILITY SERVICES  
(MULTILATERAL)**

**SECTION B PART 1 - SERVICE SPECIFICATIONS**

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| <b>Service Specification No.</b> | <b>A3D3</b><br>Specialised Respiratory Services (adult) – Definition No. 29   |
| <b>Service</b>                   | Specialised Respiratory Services (adult) – Severe difficult to control asthma |
| <b>Commissioner Lead</b>         | Teresa Warr   |
| <b>Provider Lead</b>             |   |
| <b>Period</b>                    | 3 Years   |
| <b>Date of Review</b>            |   |

**1. Population Needs**

## 1.1 National/local context and evidence base

- Patients with severe difficult to control asthma are a separate entity from the majority of asthmatics with mild to moderate disease.
- They require systematic assessment and specialist care in tertiary respiratory centres.
- Severe difficult to control asthma has an estimated prevalence of 140 patients/million population with an annual incidence of approximately 14 patients/million.
- One of the key roles of the specialist centres will be to act as gatekeepers for the use of bronchial thermoplasty and high cost novel biological agents, currently in development, to prevent inappropriate use, unnecessary risk to patients and spiralling costs to the NHS.
- Over 5 million people suffer from asthma in the UK and it remains responsible for more than 1,200 deaths per year. Asthma exacerbations lead to over 50,000 hospital admissions with an annual spend of £800 million on pharmaceutical costs alone. In addition, it is estimated that asthma leads to a direct cost to the NHS of £1 billion and an indirect cost to society, due to time off work and loss of productivity, of £6 billion (1).
- The vast majority of patients with asthma have mild to moderate disease and have the potential to be well controlled with existing therapies, assuming that well established national guidelines are followed (2). A small proportion of patients, estimated at less than 5% of all asthmatics, have severe difficult to control asthma. These patients have ongoing daily symptoms despite maximal medical therapy and are more likely to be admitted to hospital and to access out of hours' emergency healthcare than asthmatics with mild or moderate disease (3).
- There is a common misconception that severe difficult to control asthma patients are an extreme example of the milder version of the disease. There is a growing body of evidence to support the presence of several different phenotypes of severe asthma, some of which have markedly different mechanisms driving their symptoms. It is therefore essential to differentiate severe from milder versions of the disease and to consider it as a separate condition that requires specialist services to improve the health of this patient group which continues to have a clear unmet need.
- In a publication attempting to calculate individual patient costs, it was estimated that a patient controlled at the mildest end of the spectrum (step 1 British Thoracic Society (BTS) guidelines, with no exacerbations), would cost 50 times less to provide their package of care than a patient with severe difficult to control asthma (step 5 BTS guidelines, having exacerbations) (4). Given the discrepancy in medication burden, exacerbation frequency and healthcare utilisation, it has been calculated that the 5% of patients with the most severe asthma invoke at least 50% of the total health care burden for this disease (3).

- The above calculated costs do not include the long term morbidity due to the side effects of frequent rescue or maintenance oral corticosteroids, which will affect the majority of patients with severe difficult to control asthma. The side effects include diabetes, cataracts, osteoporosis, glaucoma, skin disease, reflux oesophagitis and obesity. The additional health care costs required to manage these side effects are currently unquantified and not included in the costs calculated above. Hence, the quoted values are likely to be significant under-estimates of current costs.
- No gold standard diagnostic test exists for severe difficult to control asthma. The condition is more akin to a syndrome with multiple different causes, rather than a single disease entity. This has hampered the production of a clear definition of severe difficult to control asthma. In the BTS/Scottish Intercollegiate Guidelines Network (SIGN) asthma guidelines, “difficult asthma” is defined as patients having symptoms despite being prescribed step 4 drug therapy. This definition is vague and will include a significant proportion of patients for whom appropriate care could be provided in secondary care if attention were paid to co-morbidities, therapy adherence and alternative diagnoses that mimic asthma.
- The most up to date definition is provided by an international consensus statement from the Innovative Medicines Initiative (5). The subgroup with truly severe refractory asthma can be defined and distinguished from patients with ‘problematic’ or ‘difficult’ asthma. The term ‘problematic severe asthma’ includes all asthma and asthma-like symptoms that remain uncontrolled despite the prescription of high-intensity asthma treatment. It is an umbrella term that comprises patients with ‘difficult’ asthma as well as patients with ‘severe refractory’ asthma. The term ‘difficult asthma’ is reserved for asthma that remains uncontrolled despite the prescription of high-intensity asthma treatment due to:
  - persistently poor compliance
  - psychosocial factors, dysfunctional breathing, vocal cord dysfunction
  - persistent environmental exposure to allergens or toxic substances
  - untreated or under treated co morbidities such as chronic rhinosinusitis, reflux disease or obstructive sleep apnoea syndrome
- The term ‘severe refractory asthma’ should be reserved for patients with asthma in whom alternative diagnoses have been excluded; co morbidities have been treated; trigger factors have been removed (if possible); and compliance with treatment has been checked, but still have poor asthma control, or frequent severe exacerbations, despite the prescription of high-intensity treatment, or can only maintain adequate control when taking systemic corticosteroids and are thereby at risk of serious adverse effects of treatment.
- Previous studies have demonstrated the difficulty in making an accurate diagnosis in this patient population, which in combination with psychological

and social interaction on health care beliefs and self management, make a systematic assessment essential in order to accurately target therapy when standard asthma inhaler therapy and add-on drugs have failed (6, 7).

- Given the above, there is a clear consensus that patients with severe difficult to control asthma should be systematically evaluated by a dedicated multi-disciplinary service utilising a team experienced in the assessment and management of difficult asthma (BTS/SIGN Asthma guidelines 2009 Section 7.1 Difficult asthma (2)). The benefits of systematic assessment include confirmation of the diagnosis, improved adherence with prescribed therapies, treatment of co-morbidities or alternative diagnoses and a reduction in important healthcare outcomes, specifically hospital admission, unscheduled healthcare visits and rescue courses of oral steroids (8).
- There is limited evidence to help define the number of patients with severe difficult to control asthma in England. A study by Roberts et al, examined a questionnaire sent to all BTS members with a 50% response rate. This identified 7,027 patients with severe difficult to control asthma, 50% of these patients were under the care of a consultant who stated that they had an interest in difficult asthma.
- In the North West of England, with a referral population of approximately 5 million, currently 120 patients per year are referred to the Manchester severe asthma service. Of these, 45% fulfil the definition of severe asthma on the basis of steroid requirements, 5% on previous intensive care unit admission, 40% on FEV<sub>1</sub> criteria and approximately 30% on 2 hospitalisations in the previous 12 months (9). Extrapolating this to the population of England would suggest approximately 1,000 new referrals per year. These annual referrals represent approximately 0.001% of the total asthma population. This data suggests an annual incidence of 14 patients/million and prevalence of 140 patients/million.
- Severe difficult to control asthma is recognised as an area of unmet therapeutic need and multiple high cost novel biological therapies are currently in multinational phase III studies. These treatments are likely to be expensive and will require careful monitoring to ensure that they are prescribed to the correct patient population with specialist assessment of efficacy to prevent inappropriate prescribing.
- Bronchial thermoplasty has also recently been reviewed by the National Institute of Clinical Excellence (NICE) and the details of all patients undergoing this procedure need to be submitted to the BTS severe asthma registry.

IPG 419 *Bronchial thermoplasty for severe asthma:*

<http://guidance.nice.org.uk/IPG419>

<http://publications.nice.org.uk/bronchial-thermoplasty-for-severe-asthma-ipg419>.

- Without specialist assessment the targeting of this and other high cost novel

therapies for severe asthma will not be possible, leading to the potential of inappropriate use, unnecessary risk to patients and spiralling costs.

- The severe difficult to control asthma service will be based at pre-existing regional specialist units. The service will provide a multi-disciplinary diagnostic, assessment and treatment service for individuals with severe asthma. It is anticipated that the service will reduce inequalities in asthma care and will lead to reductions in hospitalisations and death for individuals with severe difficult to control asthma.
- Successful implementation of existing policy will depend on these specialist units. Without them it will not be possible to meet the commitment of the COPD and Asthma Outcomes strategy to address the needs of people with the most severe asthma and provide appropriate care for them. As the strategy acknowledges, these people need multidisciplinary support and face lack of recognition in non-specialist health services.

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_127974](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_127974)

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*asthma in the UK – cross-sectional findings from a UK Multicentre Registry.*  
Thorax 2010 Sep; 65(9):787-94.

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## 2. Scope

### 2.1 Aims and objectives of service

- The core aims of the severe difficult to control asthma service will be to improve patient outcomes, including decreased exacerbation frequency, measured by reductions in emergency visits, hospital admissions and oral steroid courses, as well as improved mortality, improved lung function and improved quality of life.
- These aims will be met by the following core objectives of the severe difficult to control asthma service:
  - To confirm the diagnosis and severity of individuals referred with suspected severe difficult to control asthma.
  - To identify and remove aeroallergen and occupational triggers.
  - To diagnose and appropriately treat alternative conditions mimicking severe difficult to control asthma.
  - To diagnose and appropriately treat co-morbidities contributing to severity of asthma (e.g. allergic bronchopulmonary aspergillosis or Churg Strauss syndrome).
  - To improve adherence to prescribed therapies using patient education and health psychology when required.
  - To diagnose and treat co morbidities associated with severe difficult to control asthma, such as gastroesophageal reflux disease (GORD) and obstructive sleep apnoea.
  - To treat and where possible prevent the complications of long term oral corticosteroids.
  - To decrease exacerbation frequency and improve patient quality of life through effective self management and appropriate patient support, including telephone clinics, rapid access review and other appropriate support when required.
  - To optimise disease management by using existing therapies in a patient specific fashion by quantifying each patient's asthma phenotype.
  - To use measures of airway inflammation to guide therapy where appropriate.
  - To use novel therapies for the correct patient groups and objectively assess response to new treatments/interventions.
  - To enhance research and education in this area of unmet clinical need.

## 2.2 Service description/care pathway

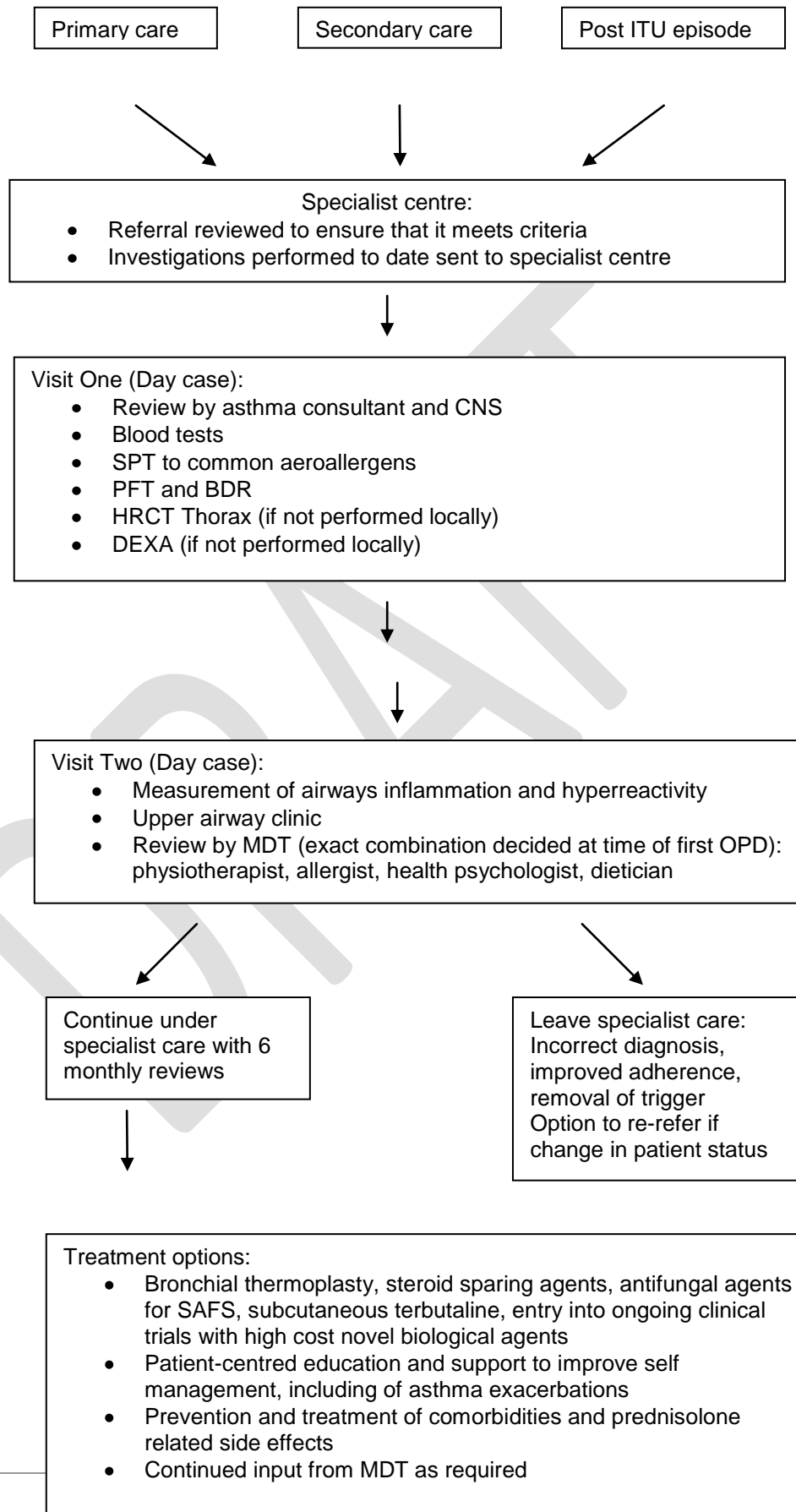
- Full multi-disciplinary assessment spread over 2 day case visits.
- Pre-planned investigations to include measures of airway inflammation and airways hyper reactivity, which are only available at specialist centres.
- Assessment to include allergy, ENT and physiotherapy review in all cases.
- Review of adherence in all cases including measurement of blood levels of prednisolone and cortisol, which are only available at specialist centres.
- Following initial assessment the decision will be made regarding the patient's suitability for bronchial thermoplasty or high cost novel biological therapies, as they become available.
- Majority (approximately 70%) of patients will stay under long term follow up at the specialist centre.
- The following investigations will be required, assuming that they have not already been performed by the referring centre:
  - Full pulmonary function tests (PFT) and bronchodilator reversibility (BDR).
  - Airways hyper-reactivity measured by histamine or methacholine challenge.
  - Induced sputum for measurement of eosinophils and other measures of airway inflammation.
  - High resolution computed tomography (HRCT) thorax.
  - Skin prick tests to the common aeroallergens.
  - Bone densitometry (DEXA).
  - FBC, IgE, Aspergillus IgE and IgG, ANCA. Total immunoglobulins and vaccine responses.
  - Measurement of adherence including serum theophylline and prednisolone and cortisol levels.
  - Assessment in upper airway clinic.
  - Oesophageal pH probe.
- During this period of assessment the patients will require a full multi-disciplinary assessment including review by a physiotherapist, asthma nurse specialist, health psychologist, dietician and allergist.
- Each service will be run by at least two Consultant Respiratory Physicians with an interest in severe asthma. They will require access to the members of the multi-disciplinary team listed above and also be able to refer patients to a consultant in occupational lung disease and consultant psychiatrist when required. Each service will require the facilities to provide patients



with high cost novel biological therapies that are currently in clinical trials. Other treatment options that will be available at the specialist centres will include bronchial thermoplasty, antifungal agents for severe asthma with fungal sensitisation, administration and monitoring of steroid sparing agents, such as methotrexate and cyclosporine, and continuous subcutaneous brianly infusion.

- The specialist centre will act as an advisory lead on high cost novel biological therapies for the region they serve. The decision to treat and the initial assessment of efficacy will occur at the specialist centre. If the trial is successful then the drug may be delivered locally in the longer term. The specialist centre will continue to oversee this process via outpatient review every 6 months. Regular specialist review will allow decisions on duration of therapy and switch to alternative options to be made when required.
- Every centre will require the capacity to review patients on a day unit or similar to provide expert care at the start of an exacerbation in an attempt to prevent hospital admission. Every centre will need the capacity to admit patients in an emergency or semi-elective fashion for intravenous hydrocortisone, aminophylline and antibiotics when required. Each centre will have an identified bronchoscopist that is competent to perform diagnostic bronchoscopies and bronchial thermoplasty in patients with severe asthma.
- Patients will initially be reviewed 3 months after their initial assessment and then every 6 months if clinically stable.
- The majority of patients with confirmed severe difficult to control asthma will need to stay under the long term follow up of the specialist centres. Those who remain under long-term care of specialist centres will receive ongoing patient education and support to self-manage and to improve their quality of life via the most appropriate services. However, a significant percentage of patients, approximately 20 to 30%, will be able to return to primary or secondary care after their initial assessment, when they turn out to have a different disease, poor adherence to prescribed therapies or after removal of triggers, such as aero or occupational allergens.

**Figure 1: Patient journey:**



- The specialist centres will also play a wider role in education of primary and secondary care physicians as well as other members of the multidisciplinary team and liaise closely with patient support organisations to ensure that they are providing the services that the patients want. The centres will continue their successful research collaborations which have already led to key publications in the area and generated successful research funding. The centres will provide national leadership on severe difficult to control asthma and continue to train specialist respiratory trainees in this important part of their Joint Royal Colleges of Physicians Training Board (JRCPTB) curriculum.
- The specialist centres will form a resource to improve the care of all asthma patients that do not fulfil the specific criteria listed above. The centres will develop regional MDT meetings arranged geographically to provide national coverage of patients with moderate to severe disease.

- **Pregnancy**

- *Pregnant women with pre-existing conditions as discussed in this specification require assessment and/or management from highly specialist tertiary maternity care delivered within a dedicated multi-disciplinary service staffed by a maternal medicine specialist, a physician, and supporting multi-disciplinary team with extensive experience of managing the condition in pregnancy.*
- *In view of this, nationally commissioned condition specific services must have outreach arrangements with highly specialised tertiary maternity units with access to appropriate tertiary medical, surgical, fetal medicine, clinical genetics and level 3 Neonatal Intensive Care services. These specialized maternity services must have a critical mass of activity to maintain expertise, ensure best practice, training opportunities and for the organisational infrastructure, staffing, facilities and equipment to be clinically and economically efficient. They should have robust risk management and performance monitoring processes.*
- *All such women must receive personalised pre-pregnancy and maternity care planning from specialised tertiary maternity services to allow optimal disease management in the context of the pregnancy. This will reduce avoidable morbidity, mortality and unnecessary intervention for mother and baby.*
- *Women with conditions discussed in this specification must be referred immediately once they are pregnant to plan their care. This must include access to termination of pregnancy and specialist advice re contraception. The individualised care plan must cover the ante natal, intrapartum and postnatal periods. It must include clear instructions for shared care with secondary services, when appropriate including escalation and transfer protocols and clear guidelines for planned and emergency delivery.*

## 2.3 Population covered

- The service outlined in this specification is for patients ordinarily resident in England\*; or otherwise the commissioning responsibility of the NHS in England (as defined in *Who Pays?: Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).
- Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP practice in England.
- Access to the specialist service will be for all adults and adolescents over 16 years old with asthma fulfilling the criteria described in section 2.4.
- Data published by the BTS severe asthma network has demonstrated a variation in referral patterns to specialist care across England (9). This initiative with its clear referral pathway will enable the correct referral of patients to specialist care across the whole of England.

## 2.4 Any acceptance and exclusion criteria

- Referrals will originate primarily from Respiratory Physicians in secondary care. Primary care physicians will also be able to refer patients as long as they meet the criteria defined below. All patients discharged from ICU following an admission with an acute exacerbation of asthma will be referred either by an intensive care or respiratory physician. Consultant paediatricians will be able to refer patients to the service to allow transitional care of adolescents with severe asthma.
- The service will only be for individuals that meet the criteria defined below. Individuals who do not fulfil the criteria or who have chronic obstructive pulmonary disease will not be covered by the service.
- The receiving service will confirm that the patient meets the specified criteria before accepting the referral.
- The BTS Specialist Advisory Group on Asthma and the BTS Difficult Asthma Network has proposed the following pragmatic and targeted definition, which will be used to determine which patients can be referred to the specialist centres:
- Patients fulfilling the BTS definition of difficult asthma **and** one of the following:
  - An event of acute severe asthma which is life threatening, requiring invasive ventilation within the last 10 years
  - Requirement for maintenance oral steroids for at least 6 months at a dose equal to or above 7.5 mg prednisolone per day or a daily dose equivalent of this calculated over 12 months.

- Two hospitalisations within the last 12 months in patients taking and adherent to high dose inhaled steroids (greater than or equal to 1000mcg of Beclomethasone or equivalent).
- Fixed airflow obstruction, with a post bronchodilator FEV<sub>1</sub> less than 70% of predicted normal.
- Referred as an adolescent transition patient from a paediatric severe asthma service.
- Patients will be referred to the centre that is geographically most convenient for them.

## **2.5 Interdependencies with other services**

- Co-located services:
  - Immediate onsite access to critical care.
  - Advanced diagnostics including lung physiology, bronchial provocation testing and measurement of airways inflammation.
  - Day unit available for patient assessment, high cost novel biological agent administration and challenge testing.
  - In patient beds available for management of acute exacerbations of asthma.
  - Upper airway assessment for diagnosis of upper airway dysfunction mimicking asthma at time of acute attack.
  - Physiotherapy for acute management of breathing pattern dysfunction.
- Interdependent services:
  - Allergy
  - Clinical Immunology
  - ENT
  - Physiotherapy for exercise and pulmonary rehabilitation
  - Health psychology
  - Liaison psychiatry
  - Dietetics
  - Metabolic medicine for osteoporosis management.
- Related services:
  - Occupational lung disease

### 3. Applicable Service Standards

#### 3.1 Applicable national standards e.g. NICE, Royal Colleges

- Each service will see at least 75 new referrals per year and be staffed by at least 2 respiratory physicians with sub-specialty training in severe asthma to allow for cross cover and service resilience.
- Each service will contain a consultant respiratory physician fully competent to perform bronchial thermoplasty independently and performing at least 10 procedures per annum.
- Every centre will participate in weekly MDTs involving consultant respiratory physicians, clinical nurse specialists, physiotherapists, dieticians and health psychologists.
- Each centre will enter patient data into a national severe asthma registry. The BTS severe asthma network has a fully functional web based database, which will be used to facilitate this process and enable bench marking between centres, data submission to this database will be a routine requirement for all centres.
- These are addressed in the current NICE guidance and the National COPD and Asthma Outcomes strategy. The NICE quality standards for asthma are currently in production.
- An outcomes strategy for people with chronic obstructive pulmonary disease (COPD) and asthma in England : Department of Health - Publications

#### 4. Key Service Outcomes

- Annual exacerbation frequency.
- Number of ITU admissions.
- Asthma mortality.
- Asthma related quality of life using Juniper AQLQ and ACQ-7.
- Prevention of decline in lung function (FEV<sub>1</sub>).
- Adherence with prescribed therapy measured by the Medication Adherence Report Scale for Asthma (MARS-A)  
<http://www.ncbi.nlm.nih.gov/pubmed/19852197>

- Percentage of patients with an agreed written asthma management plan.
- Percentage of patients receiving bone protection to prevent/ treat steroid induced osteoporosis according to the RCP Glucocorticoid-induced osteoporosis guidelines for prevention and treatment

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