Healthcare professional group/clinical specialist statement

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Anna Murphy

Name of your organisation (if applicable):
The Royal Pharmaceutical Society of GB (RPSGB)
The UK Clinical Pharmacy Association (UKCPA)

Are you (tick all that apply):

☑ a specialist in the treatment of people with the condition for which NICE is considering this technology?

- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?

☑ an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)?

Consultant Respiratory Pharmacist, University Hospitals of Leicester NHS Trust

- other? (please specify)

What is the expected place of the technology in current practice?
How is the condition currently treated in the NHS?
Is there significant geographical variation in current practice?
Are there differences of opinion between professionals as to what current practice should be?
What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Despite national (BTS / SIGN guidelines)[1] and international recognised evidence based guidelines for managing asthma, the disease remains inadequately controlled in a significant number of patients. In the UK 2.1 million people with asthma continue to experience symptoms regularly because they are not receiving appropriate care.[2] Many factors may influence the quality of care the patient receives and therefore current practice varies across the UK. There appears to be a cohort of patients with severe persistent asthma who are inadequately controlled despite treatment according to current asthma management guidelines. These patients have a significant unmet medical need. Such patients are at high risk of serious exacerbations and asthma-related mortality.

Omalizumab is licensed as add-on therapy to improve asthma control in adult and adolescent patients (12 years and above) with severe persistent allergic asthma. The role of omalizumab in the management of asthma has not yet been precisely defined.
The Scottish Medicines Consortium SMC placed omalizumab at step 4 of the BTS/SIGN asthma guidelines[1], analogous to the key clinical trial; INNOVATE[3] and other trials[4,5]. Other clinicians argue that omalizumab is better placed at step 5 of those guidelines where asthma control is particularly difficult to achieve and continuous or frequent use of systemic corticosteroids is required.[1]

Opinion
The points below are made on behalf of pharmacists in the UK who have a special interest in asthma management and are responsible for managing this disease.

- Omalizumab should only be considered in those patients who satisfy the licensed indications as per the SPC
- Respiratory clinicians need a steer from NICE to clarify where omalizumab should be placed in the stepwise approach to asthma management provided by the BTS/SIGN guidelines. As a group we acknowledge that this is a complex and contentious area – our views are summarised as follows:
  - At step 5 of the British asthma guidelines[1] patients will be taking regular to frequent systemic corticosteroids and have had a trial of a leukotriene receptor antagonist, slow release theophylline or oral beta-2 agonist in addition to a regular prescription of an inhaled corticosteroid and long-acting beta-2 agonist. The overall aims of pharmacological treatment are the control of symptoms, prevention of exacerbations and the achievement of best possible pulmonary function, *with minimal side-effects*[1]*.* It is at this step of the guidelines that we would welcome additional treatments to achieve these goals and reduce the quantity of steroid medication given to these patients. These patients will often be prescribed regular oral corticosteroids, intramuscular triamcinolone and immunosuppressants such as methotrexate. All associated with an increase risk of adverse effects. In practice, at University Hospitals of Leicester NHS Trust, it is patients at step 5 that omalizumab has been considered if they are still symptomatic. Unfortunately, the effects observed in trials to support this practice in patients at this level of treatment were generally small. Holgate et al,[4] evaluated patients with severe asthma, equivalent to step 5, who required high dose inhaled corticosteroids (fluticasone > 1000 microgram / day). In this trial, no significant effect on frequency of exacerbations was seen, although the dose of inhaled corticosteroids required to control symptoms was significantly lower among

patients treated with omalizumab. It is noteworthy that participants treated with placebo were also able to reduce their dose, which makes us question the true steroid sparing effects of Omalizumab. A systemic review of omalizumab found that omalizumab increased the proportion of people achieving complete inhaled steroid withdrawal (42% versus 21%).[5] Therefore, to achieve total health economic benefit from omalizumab it is paramount that patients with severe asthma have a reduction in their steroid dose during a trial of omalizumab. We are aware that sub analyses of the clinical papers have shown that patients requiring daily oral corticosteroids to control their asthma may be less likely to have a response to omalizumab.[4, 5] The current data available in relation to patients on oral steroids is not sufficient to justify the extrapolation of the findings to this group in clinical practice. Further evidence of effectiveness would be desirable in people with the most severe symptoms.

- We believe that at step 4 of the asthma guidelines[1] there are already cost effective treatment options available that should decrease inflammation and provide symptomatic relief for the patient. Certainly all patients should have a controlled trial of either a leukotriene receptor antagonist or a slow-release theophylline, in addition to a drug regimen already including an inhaled corticosteroid and a long-acting beta-2 agonist. Adherence to medication must also be checked.

Whichever step of the guidelines omalizumab is placed the comparators have the advantage of being less expensive and easier to manage. However the benefits obtained from the prescription of oral corticosteroids at step 5 is at the expense of potentially severe side effects such as osteoporosis, diabetes mellitus or skin thinning. Likewise the overall costs of treating a patient with methotrexate may be higher than the actual acquisition costs of the drug; regular blood tests and a high incidence of adverse effects cloud the picture.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

Analyses of pooled data from published clinical trials have indicated that patients who are particularly likely to benefit from the use of omalizumab include those with evidence of sensitisation to perennial aeroallergens who require high doses of inhaled corticosteroids (equivalent to more than 800 microgram of beclometasone dipropionate or equivalent) per day, those who had a ratio of observed to expected forced expiratory volume in one second (FEV_1) of less than 65 percent, and had at least one visit to the accident and emergency department in the past year.[6,7]

The ultimate goal of asthma management is to prevent death from asthma. The BTS / SIGN guideline describes an enquiry into over 200 asthma deaths in the UK.[1] Most patients who died of asthma had chronically severe asthma. The studies concluded that there are factors associated with the disease, the medical management and the patient's behaviour or psychosocial status that contributed to the death of the patient.

Opinion

The prescribing of omalizumab could be further controlled by considering the following patient selection factors:

- Patients with severe asthma, documented by a FEV1 < 65% predicted.
- Patients identified as being at high risk of fatal or near fatal asthma. The BTS/SIGN guideline identifies these patients as having the following characteristics.
  - previous near fatal event e.g. previous ventilation or respiratory acidosis
  - previous admission for asthma especially in the last year
  - requiring three or more classes of asthma medication
  - heavy use of beta-2 agonist

- repeated attendances at A&E for asthma care especially if in the last year
- brittle asthma

And adverse behavioural or psychosocial features.

- For practical help on patient selection the above factors would need to be defined and incorporated into a prescribing guideline.
- Patients should be non-smoking and if not, actively receiving approved smoking cessation treatment.

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

A difficult asthma clinic has been established at Glenfield hospital, University Hospitals of Leicester NHS Trust, Leicester. It is a multidisciplinary clinic, involving respiratory consultants, specialist registrars, consultant respiratory pharmacist, research nurses and nurse consultant. Social, psychological and pharmacological issues are addressed. It is within this clinic that patients are considered for omalizumab treatment. The process of selection is as follows:

- The respiratory consultant identifies the patient who may be suitable for omalizumab therapy either:
  - Patients have poorly controlled asthma despite maximal conventional therapy, including 2000 micrograms of inhaled beclometasone or equivalent daily, plus long-acting beta-2 agonist plus have had a trial of a leukotriene receptor antagonist and oral theophylline.
  - Patients well controlled on maximal therapy as above, but also on significant (greater than 10mg or equivalent) daily maintenance dose of oral corticosteroid for greater than 6 months. These patients usually have also received a trial of methotrexate therapy.
- The patient is referred to the consultant respiratory pharmacist and reviewed within the difficult asthma clinic. The consultant pharmacist's role includes:
  - Review of the patient's medication regimen to ensure that the patient has previously had a well controlled trial of first line therapy for their asthma.
  - Assessment of the patient's beliefs about medication taking.
  - Assessment of the patient's adherence to their medication regimen. A concordance assessment tool is completed by the consultant pharmacist (copy attached). This assessment tool is currently being validated as part of a doctorate level degree. Adherence is assessed by discussion with the patient, identification of potential risk factors and by a review of compliance with refilling prescriptions during the last 12 months. Prescribing and dispensing records are checked within primary and secondary care to establish a true picture of the patient's medication behaviour.
  - Ensuring the patient fulfils the prescribing criteria for omalizumab (SPC and locally agreed criteria)
  - Applying for funding on a case by case basis.
  - Ensuring that all baseline data is collected.
  - Organising prescription of omalizumab (supplementary prescribing)
  - Completing the University Hospitals of Leicester NHS Trust prescribing proforma.
  - Counselling the patient on omalizumab treatment
  - Ensuring the completion of the 16 week review
  - Liaison with the funding committee if omalizumab is effective to secure continued funding.
- The respiratory nurse specialist administers the treatment within the clinic, discusses treatment and monitors effects of treatment over the 16 week period.

- During each clinic the multidisciplinary team meet to discuss the management of the difficult asthmatics.

Opinion

- As omalizumab may only be of benefit in a small group of patients it is important that the introduction of the drug is within a controlled setting, after vigilant patient selection. The difficult asthma clinic described above is an example of good practice, it attempts to restrict the prescribing of omalizumab to patients with the greatest need and who are likely to respond to treatment.
- The pharmacist has an essential role in the management of patients with asthma and is an important member of the multidisciplinary team. Many pharmacists will be involved with securing funding for the treatment but we would also advise clinicians to utilise the expertise of pharmacists similar to the Leicester experience.
- We would advocate the assessment of patient adherence to treatments before omalizumab is considered and promote the pharmacist in this role. In the Leicester clinic any patient deemed as being non-adherent to their asthma treatments would not receive omalizumab until they had received counselling from the pharmacist, supported by other members of the MDT.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Omalizumab has been available on the NHS since October 2005. Prescribing of omalizumab within the Leicester difficult asthma clinic has followed the SPC, within licensed indications. Following discussion with other pharmacists around the UK the opinion is that omalizumab is prescribed only within licensed indication in clinical practice.[8]

*Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.*

A prescribing proforma has been developed by University Hospitals of Leicester NHS Trust and is used for patient selection, to apply for funding and to monitor the effects of omalizumab treatment. This proforma has been attached for your information and we have provided a rationale for the categories below:

The Juniper Adult Asthma Quality of Life Questionnaire (AQLQ) is included in the proforma to assess the patients' quality of life. The same scale was used to monitor the secondary efficacy variable of quality of life in the INNOVATE study[3] and we would suggest such measures need to be in place to monitor response to therapy so that non-responders can be detected. Currently, any patient prescribed omalizumab in the Leicester clinic are reviewed after 16 weeks of treatment, following the guidance included in the SPC.[8] However, we are considering a review of this practice in light of the data that showed that 87 per cent of patients, who had had a response to omalizumab at 16 weeks, had done so by 12 weeks.[6] Further studies are required in clinical practice to assess the optimum time for the final trial assessment. In our opinion outcome data should be collected after 12 weeks of therapy and if patients have had no or limited response at 12 weeks the patient is referred to the respiratory clinician for assessment.

The measurements of sputum eosinophil count and nitric oxide levels of exhaled air are common practice in the management of patients within the difficult asthma clinic, University Hospitals of Leicester NHS Trust and are measures of inflammation within the lung. Sputum eosinophil count and nitric oxide levels were not collected in the main clinical trials for

omalizumab. However, studies have shown an association between reductions in circulating and sputum eosinophilia and non-specific bronchial hyper responsiveness, such as nitric oxide with omalizumab therapy.[9] Further studies are required. It is unlikely that these tests will become available for routine asthma monitoring in the UK but may be available in specialised clinics.

As discussed previously a concordance assessment is performed to establish the patients' adherence to their regular asthma therapy. The other data collected by the proforma is based on the licensing criteria for omalizumab as per the SPC.

We strongly recommend the collection of objective patient data to assess the outcome of treatment. There is an important placebo effect, with improvements in quality of life noted in control subjects as a result of close medical monitoring.

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK.
Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

Opinions
We recommend that the selection of patients and initiation of treatment is carried out by respiratory specialists in secondary care and ideally within specialist difficult asthma clinics. Many patients for whom omalizumab may be considered will already be under the care of a specialist. Service delivery implications should be considered – these include:

- Facilities must be available for IgE levels to be measured prior to treatment and patients must have a positive skin prick test (or in vitro reactivity)
- The practicalities of reconstituting and administering omalizumab will have implications for staff time and organisation of clinics.
- All staff involved in the delivery of omalizumab to the patient may require education and training in the practicalities of administration of the drug, potential adverse effects and monitoring.
- Resuscitation facilities must be available.

With regards to the future use of the technology if a patient were to tolerate the drug and continue to respond then there is a good scope for ongoing treatment to be carried out within primary care.

If primary care were to continue the long term prescribing of omalizumab we would welcome the consideration of the following points:

- The development of a shared care agreement to improve communication between primary and secondary care and to facilitate the appropriate prescribing and monitoring of the technology.
- To consider the roles of the multi-disciplinary team in the delivery of the service to patients. The community pharmacist and/or practice based pharmacist can contribute to the selection and monitoring of patients as well as the training of nurses in drug administration.
- The accessibility of the community pharmacist, particularly during the evenings and at weekends, can provide essential support to the patient when they are unable to contact other professionals. It may also be more convenient for the patient to attend their local pharmacy for a monitoring check.

This would however, require additional resources such as staff education and training, and additional clinic time.

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

Patients with severe persistent asthma have several treatment options. These include environmental control (i.e., the elimination or minimisation of exposure to aeroallergens), pharmacologic control (i.e., the use of inhaled corticosteroids, inhaled beta-2 agonists, leukotriene receptor antagonists), and possibly, immunologic control (i.e., immunotherapy for relevant antigens). In addition, evaluation for coexisting conditions such as allergic rhinitis, sinusitis, and gastroesophageal reflux disease may prove beneficial. These treatment options should be explored before a trial of omalizumab is initiated. The appropriate selection of patients is paramount. The clinical trails offer some guidance but further studies are required.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

The clinical trials of omalizumab enrolled patients with precisely defined characteristics of asthma, for example, sensitivity to specific perennial aeroallergens (i.e., dust mites, cockroaches, and dog or cat dander). The role of omalizumab in patients with asthma who have allergies to other aeroallergens, such as moulds or pollens, or who have negative allergy skin tests, has not been defined. It is also not clear to what extent omalizumab might be effective in patients with total serum IgE levels outside the trial ranges (30 to 700 IU per millilitre for patients 12 to 75 years of age).

The clinical trials performed to date have evaluated omalizumab only as adjunctive therapy with inhaled corticosteroids as compared with placebo. They have not evaluated the relative benefit of this agent in comparison with other available therapies, such as leukotriene receptor antagonists or theophylline. Given that the cost of omalizumab is substantially greater than that of conventional asthma therapy, the potential cost-effectiveness of this form of treatment will be important to assess.

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

Opinion

The efficacy and safety of omalizumab has not been established for durations of treatment that exceed one year, and it is not known how long clinical effects may persist after therapy is discontinued. Since asthma is a chronic disease, long-term studies, especially in children, are needed to evaluate the effect of serum IgE suppression throughout development; adverse effects may become apparent only with follow-up into adulthood. We know of only one study to date that has been performed exclusively in the paediatric age group.

Efficacy and safety studies are also needed for elderly and non-white patients

In clinical practice, there is considerable variability of response to omalizumab therapy. The reasons for this variability have not been established; studies are needed to determine whether specific characteristics of individual patients may help to predict response.

In clinical trials there was an increased incidence of cancer developing in patients exposed to omalizumab compared to in those who received placebo (20 of 4127 [0.5 percent] and 5 of 2236 [0.2 percent], respectively).[10] Since the majority of patients treated with omalizumab have been observed for only a year, the effect of longer exposure or of use in patients who are at increased risk for cancer is not known. Therefore, omalizumab probably should not be used in patients with a history of cancer or a strong family history of cancer until this risk relationship is better understood.

Omalizumab by its mechanism of action should prevent any risk of anaphylaxis, since the agent cannot interact with IgE that is already bound to cell surfaces. However, in clinical trials three patients (<0.01 percent) had anaphylaxis.[10] Two of the reactions were temporally associated with omalizumab administration; the reactions were not immediate but occurred within two hours after the first injection. This may have implications for administration of omalizumab in clinics as there should be resuscitation facilities available and the patient should be monitored post injection.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

No further information

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within
3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

Patients prescribed omalizumab would be required to attend clinics every 2 or 4 weeks depending on their weight and IgE levels. In areas where there may be a number of patients that fulfil the prescribing criteria the provision of these clinics will require further resources, i.e. pharmacists, nurses, clinic preparation staff. Staff within these clinics may require

education and training in the monitoring and administration of the drug. Currently in the UK, the injection is available only as a single strength (150mg), although it is available in the US as an additional strength (75mg). The availability of the 75mg in the UK would help to reduce nursing time in reconstitution, drug wastage and subsequent costs. The establishment of omalizumab clinics may avoid product wastage resulting from part used vials. NICE's influence upon the manufacturer in this regard would be appreciated.

26 January, 2007

References

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2. Where do we stand? Asthma in the UK Today. London: Asthma UK; 2004.
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4. Holgate ST et al. Efficacy and safety of a recombinant anti-immunoglobulin E antibody (omalizumab) in severe allergic asthma. Clin Exp Allergy 2004; 34: 632-38
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9. Djukanovic R et al. Effects of treatment with anti-immunoglobulin E antibody omalizumab on airway inflammation in allergic asthma. Am J Respir Crit Care Med 2004;170:583-593.
10. Food and Drug Administration, Centre for Biologics Evaluation and Research. BLA STN 103976/0, review of clinical safety data: original BLS submitted on June 2, 2000 and response to complete review letter submitted on December 18, 2002. Rockville, Md.: Department of Health and Human Services, 2003.

University Hospitals of Leicester NHS Trust OMALIZUMAB (XOLAIR®) PROFORMA

Patient Addressograph Hospital No. Name Address Date of Birth

Diagnosis _____

Consultant _____

DAC ☐

Baseline Information

***** Exacerbations defined as: course oral corticosteroid, acute or severe asthma
****** Best or highest recorded in the last 12 months

Weight (kg)		Date:	No.severe asthma exacerbations (last 12 mnths)*****	
IgE levels		Date:	Life threatening symptoms	
FEV_1 (% pred)******		Date:	No. hosp admissions in last 2 years	
Sputum eosinophil******		Date:	Any other information	
Exhaled nitric oxide		Date:		
PEFR******		Date:		

Juniper Asthma Control			
Nocturnal symptoms		Symptoms at waking	
Breathlessness		Activities	
Wheeze		Bronchodilator use	
		Total score	

Expected Patient Outcome

Primary:

Secondary:

Baseline medication **(please note if previously prescribed but unsuccessful)**

	Drug	Dose / Frequency	Comments	Continued
Inhaled SABA				Yes / No
Inhaled corticosteroid				Yes / No
Inhaled LABA				Yes / No
Oral corticosteroid				Yes / No
LTRA				Yes / No
Oral methylxanthine				Yes / No
Inhaled Anticholinergics				
Other medications (please tick)	Parenteral steroid ☐	Methotrexate ☐	Ciclosporin ☐	Etanercept ☐

Prescribing Criteria (for License)

Either: Positive skin prick test to perennial aero-allergen ☐

Or: Positive IgE to perennial aero-allergen ☐

FEV_1 < 80% predicted ☐

Frequent daytime or nocturnal asthma symptoms ☐

Total serum IgE >30*<700 iu/ml ☐

* patients with IgE below 76 IU/ml must have unequivocal *in vitro* reactivity (RAST) to a perennial allergen before starting therapy

Weight appropriate for IgE level ☐

Local Prescribing Criteria

1. Concordance assessment passed: ☐

Either one of:

2. Four or more severe exacerbations in the last 12 months **or** ☐
   One life threatening within the last 3 years
3. Patient on maintenance oral corticosteroids > 10mg ☐
4. Fixed airflow obstruction FEV_1 < 60% predicted ☐

Agreed By: Consultant 1 _____ Consultant 2 _____

Approved By: Pharmacist _____ (ACM / HK) HCT form sent ☐

Omalizumab (Xolair®)	**Starting dose:** **Frequency:** Please note: Maximum dose 375 mg every two weeks **Starting date:** **Date of review:**

Omalizumab (Xolair®) Administration Record

Admin. No.	Date Given	Weight (kg)	BP (mmHg)	HR (per min)	Dose	Freq	Route deltoid region of the arm	Prepared by	Given by:
1							s/c		
2							s/c		
3							s/c		
4							s/c		
5							s/c		
6							s/c		
7							s/c		
8							s/c		

16 week Assessment (Date _____)

FEV_1 (% pred)		Date:	No.severe asthma exacerbations (last 16 weeks)	
Sputum eosinophil**		Date:	No.mild asthma exacerbations (last 16 weks)	
Exhaled nitric oxide		Date:	Daily Dose of oral corticosteroid	
Comments				

Juniper Asthma Control			
Nocturnal symptoms		Symptoms at waking	
Breathlessness		Activities	
Wheeze		Bronchodilator use	
FEV_1 predicted		**Total score**	

Prescription recommendations:

Continued		Discontinued	

Reviewed by:		Date:	
Approved by:		Date:	

Difficult Asthma Clinic

LACQ ASSESSMENT

Patient Details

Assessment Date: _____
Home Visit □ Clinic □ Other:

Referred by: _____

Consultant: _____

Medication Regimen

Regimen prescribed by Respiratory Specialist				Patient's regimen (if different)	Repeat prescription regimen (if different)
DRUG	ROUTE	DOSE	FREQ		

Patient able to remember regimen YES □ NO □ REQUIRED PROMPTS □
Use of oral steroids in the last 6 months YES □ Number of courses: _____

Risk Factors for poor concordance

Lives alone	□	> 4 medications	□
Age > 65	□	Responsible for own medications	□
Problems collecting medications	□	Pays prescription charges	□
Prescriptions not ordered via repeats	□	Dexterity problems	□
Poor knowledge of disease	□	Poor knowledge of medicines	□
BTS stage of asthma	□	Low socio-economic status	□

Patient Assessment

Ethnic origin: _____ English speaking: YES □ NO □ DEAF YES □ POOR EYESIGHT □

	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
My medication does not help me very much					
I get embarrassed using my medication in public					
I have unpleasant side effects from my medication					
I worry about side effects from my medication					
I do not like taking so many medicines					
My medication intereferes with my life a lot					
On a scale of 1 to 10 (one being never and 10 being always as directed by my doctor) – I take my medications ……	_____ out of 10 (%)				

Medication Check

All medicines available to review YES □ NO □ If not which are missing:
Dates of dispensing within last 3 months YES □ NO □ If not which ones are not:

"Pill" count comments:
Storage of medicines GOOD □ POOR □

Community pharmacist report: Community pharmacy: _____ Tel.No. _____

(Confirm patient always uses the same pharmacy YES □

DRUG	DATE DISPENSED IN LAST 6 MONTHS						COMPLIANT ✔

GP computer system report: **General Practitioner:** _____
Tel.No. _____

DRUG	DATE PRESCRIBED IN LAST 6 MONTHS						COMPLIANT ✔

Therapeutic Drug Monitoring

DRUG / DOSE	DATE LEVELS TAKEN						COMPLIANT ✔

PHARMACIST CONCORDANCE ASSESSMENT:

From the information collected an assessment of the patients concordance with their medication can be determined. However there are many factors that can influence patient's adherence to a regimen and not all these can be assessed. This is therefore only a guide.

The patient appears to be: NON-CONCORDANT (physical / mental factors) □

INTELLIGENT NON-CONCORDANT □

>80% CONCORDANT WITH THEIR MEDICATION □

FURTHER COMMENTS & RECOMMENDATIONS: