Research & Evaluation Protocol

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Title

Evaluation of
Rotherham Breathing Space Programme For
Chronic Obstructive Pulmonary Disease

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2 Summary

The Rotherham “Breathing Space” initiative is a comprehensive and systematic programme aimed at reducing the burden of chronic obstructive airways disease in a high-risk population. The programme includes mechanisms for:

- The prevention of COPD by raising the profile of the disease in the local health community, better health education, and enhanced smoking cessation programmes
- Earlier detection and treatment of COPD
- Enhanced pulmonary rehabilitation and disease management
- Respite provision for carers
- Enhanced support and care in late stage disease

An important dimension of the Breathing Space initiative is to use the high profile of a new “Breathing Space Centre” and the emphasis on pulmonary rehabilitation to act as a catalyst for changes across the whole COPD care pathway. It is anticipated that such a shift could facilitate a move towards a more “public health” orientated model of care with accurate early diagnosis and effective primary care management.

This paper sets out a protocol for the Breathing Space Research and Evaluation Project. The document summarises all of the components that will be used to evaluate whether the programme has met its objectives and what can be learned from the experience of a "whole system" change in the delivery of care for people with COPD.

In an endeavour to explore the impact of the programme across the full spectrum of COPD, the evaluation has been constructed using seven individual audits / evaluations which are brought together to facilitate an impact assessment on the overall burden of disease and a cost effectiveness model to estimate the impact of the programme beyond the evaluation period (see fig 1).

The individual components of the evaluation are:

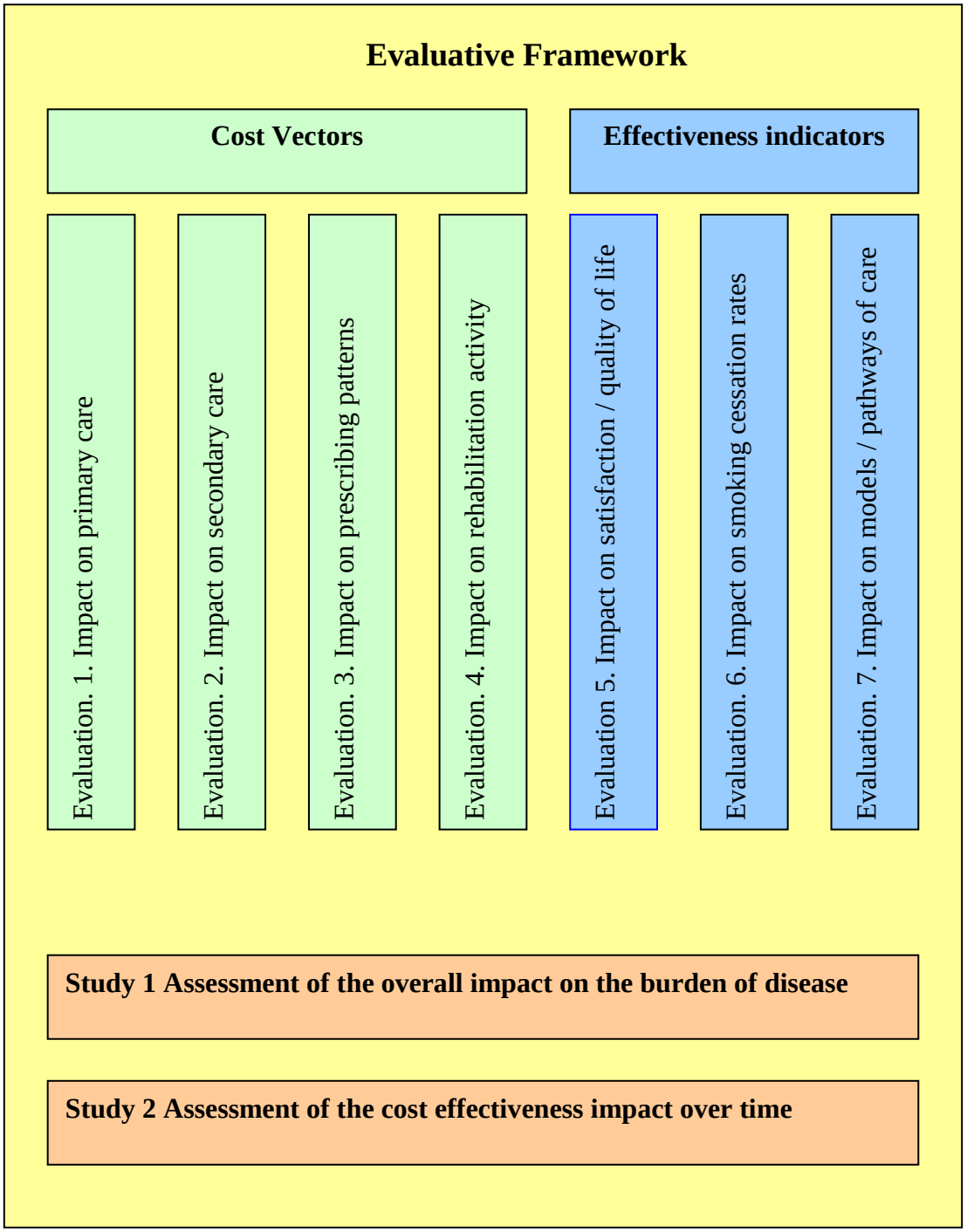
1. An audit of the impact of the programme on primary care
2. An evaluation of the impact of the programme on utilisation of secondary care services
3. An evaluation of the impact of the programme on prescribing patterns and costs
4. A qualitative and quantitative description of the programme’s pulmonary rehabilitation activity and impact
5. An evaluation of the impact of the programme on patient satisfaction/quality of life
6. An evaluation of the impact of the programme on smoking cessation rates
7. A qualitative assessment of the perceptions of service users and staff on the impact of the service

The results from these audits / studies will feed into:

1. A study of the potential impact of the programme on the baseline burden of disease
2. A study of the cost effectiveness of the programme and the modelling of future impact

As the titles of the components suggest, some of the evaluation components require the collection of research data and so will require formal ethical approval; other components are clinical audit or the analysis of routine information collected for the management of the project.

Fig 1: The evaluation framework



3 Key words

Chronic Obstructive Pulmonary Disease, Breathing Space.

4 Project title

Evaluation of Rotherham Breathing Space Programme for Chronic Obstructive Pulmonary Disease.

5 Research Questions: Principal and subsidiary

It is envisaged that the Breathing Space initiative will have a direct impact on the care of people with COPD in Rotherham through the introduction of comprehensive pulmonary rehabilitation and carer support services and an indirect impact on the provision of existing care through enhanced education, awareness, focus and research in this long neglected area of disease management.

On this basis the research project has been designed to evaluate, where possible, both the direct and indirect impacts of the programme.

○ Principal research question

- What are the direct benefits for patients with COPD / carers and the financial implications for stakeholders resulting from the addition of the Breathing Space Programme to existing COPD services in Rotherham?

○ Subsidiary research questions

- To what extent has the addition of the Breathing Space initiative indirectly affected the baseline burden of disease from COPD in Rotherham in terms of increased case detection, enhanced disease management, improved smoking cessation and improved quality of life for patients and carers?
- To what extent has the addition of the Breathing Space initiative indirectly impacted upon the progress Rotherham Health Community has made towards becoming fully concordant with NICE guidelines on the treatment of COPD?
- What lessons can be learnt from the implementation of comprehensive multidisciplinary pulmonary rehabilitation at a whole system level in Rotherham that have general implications for COPD management elsewhere?

6 Background: clinical and scientific justification

○ COPD

COPD is characterised by airflow obstruction that is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking. There is no single diagnostic test for COPD but the confirmation of airflow obstruction can be made accurately by spirometry.

In Rotherham 5800 people are identified with COPD on GP Quality and Outcome Framework registers – this is 1.7 times the national average prevalence. It is acknowledged that there are major inaccuracies in COPD case identification; on the one hand some patients on GP COPD registers may in fact turn out not to have COPD when given a comprehensive assessment including spirometry, whilst on the other hand NICE estimates that only half the people with COPD have been clinically identified. COPD prevalence is believed to have reached a plateau in men but is still rising in women.

To assess whether clinical care is in line with NICE guidelines, categorising COPD by severity is essential. However NICE recognises that this is quite a complicated issue (NICE full guidance 2004, section 6.8). Although no one measure can assess the severity of COPD, NICE have recommended a simple categorisation of airflow obstruction (mild: FEV1 50-80% of predicted, moderate: FEV1 30-49% of predicted' severe: less than 30% of predicted). Nationally there are very limited COPD prevalence data categorised by severity. In Rotherham we do not know how many practices are attempting to categorise COPD by severity category and what method they are using.

COPD was recognised by the Chief Medical Officer as one of the most important clinical conditions that did not have its own NSF and this situation was rectified by the announcement in June 2006 that there is to be a COPD NSF. COPD is particularly important in Rotherham because of its industrial legacy. NICE guidelines point out that in the past COPD has not received the priority that it deserves because of the false belief that there is little that can be done for it.

Breathing Space has conducted three literature reviews on the impact of pulmonary rehabilitation: the impact on quality of life; the impact on secondary care activity; and the impact on life expectancy. The findings of the reviews are summarised in Sections 5.2 to 5.6. The reviews are available on the PCT Intranet and will be available on the Internet as soon as the Breathing Space Website is set up. PCT Intranet link:
http://195.104.72.160/pctIntranet/Departments/PageStyle4.asp?WebPageID=764

○ Effect of pulmonary rehabilitation on quality of life

Pulmonary rehabilitation is a multidisciplinary programme of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise each patient's physical and social performance and autonomy (NICE 2004).

There is consistent evidence that pulmonary rehabilitation improves quality of life, although RCTs tend to have been small and often in highly selected secondary care settings. NICE made a strong recommendation for pulmonary rehabilitation because it produces statistically significant and clinically meaningful improvements in health related quality of life and exercise capacity.

The 1997 joint ACCP/AACVPR evidence based guidelines found that two of the three RCTs showed improved quality of life using the Chronic Respiratory Disease Questionnaire (CRQ) (Ries and others 1997). A Cochrane review concluded that pulmonary rehabilitation has a clinically significant effect on the Chronic Respiratory Questionnaire Domains (fatigue, mastery and dyspnoea) as well as exercise capacity (Cochrane collaboration 2001). There has also been one other meta-analysis (Salmon and others 2003) and two other systematic reviews (Sin and others 2003, Puhan and others 2005). Two RCTs have shown that improvements in quality of life can be maintained for 3 and 18 months of follow up (Puhan and others 2005).

The NICE guideline consensus statement was that the magnitude of the effects of pulmonary rehabilitation on exercise capacity, dyspnoea and health related quality of life are significantly greater than the effects of bronchodilator drugs.

NICE recommended pulmonary rehabilitation at all stages where symptoms and disability are present, not at a pre-determined level of impairment.

Despite this recommendation, pulmonary rehabilitation has very limited availability in England and Wales with less than 2% of COPD patients currently receiving it (British Lung Foundation 2003). In Rotherham access to pulmonary rehabilitation tends to be limited to secondary care patients following hospital admission, and current capacity is very small compared to the number of hospital admissions, let alone the population prevalence.

- **Effect of pulmonary rehabilitation on secondary care resource utilisation**

There is less RCT evidence to show that pulmonary rehabilitation has an effect on the utilisation of other health care resources.

Joint ACCP/AACVPR evidence based guidelines found no significant decrease in hospitalisation and duration of in-patient stay in controlled studies although observational studies did show significant results (Ries and other 1997). A similar conclusion was reached by NICE (2004) who stated that several non-randomised and observational studies show a trend towards a decrease in the total number of admissions. A 2003 systematic review concluded there is no significant effect on hospitalisation rates (Salman and others), but a systematic review in 2005 concluded there was evidence of reduced risk of hospitalisation (Puhan and others).

There is also conflicting evidence regarding the number of days spent in hospital. One RCT (Griffiths and others 2000) showed a reduction in the number of bed days in the pulmonary rehabilitation arm. However, joint American/European Respiratory Society Standards (ARS/ERS 2004) point to conflicting evidence; one RCT failing to show a beneficial effect on hospitalisations and another study showing that the rehabilitation group has a similar frequency of hospitalisation but a smaller number of hospital days than a control group in the year following the intervention.

Overall the limited evidence available suggests that if pulmonary rehabilitation is to impact on subsequent hospitalisation, it is likely to have a greater effect on the number of days in hospital rather than the number of hospitalisations.

○ Effect of pulmonary rehabilitation on life expectancy

NICE acknowledge that there are very few data to make life expectancy predictions for patients with COPD, with just one study which was limited to working age men (Fletcher & Peto 1977). There is also very limited evidence on the impact of pulmonary rehabilitation on life expectancy.

The 1997 joint ACCP/AACVPR evidence based guidelines found that one RCT showed no significant difference in survival, while a non-RCT reported greater survival. Observational studies also indicated a possible survival benefit of pulmonary rehabilitation when compared with historical controls (Reis and other 1997).

A systematic review (Sin and others 2003) concluded there was no material effect on long-term survival. Puhan and others (2005) did conclude that studies indicate that pulmonary rehabilitation could have a positive impact on survival; however, the overall RCT literature is based on very small numbers of patients (230 in total).

○ Cost effectiveness of pulmonary rehabilitation

NICE identified two UK cost effectiveness studies of pulmonary rehabilitation, with a cost per QALY of £2000 to £8000. In addition, an RCT estimated pulmonary rehabilitation to be cost saving, with the probability of cost per QALY being below zero at 0.64 (McBride & Milne).

NICE has modelled the implications of opportunistic case finding in primary care and concluded that this is cost effective mainly because of the impact on smoking (NICE full guidance, Appendix B).

○ Evidence for other interventions on COPD outcomes

The majority of studies of pulmonary rehabilitation have been based on cohorts who have had other treatments optimalised prior to the study. Table 5.1 summarises evidence for other treatments, and is derived mainly from the review of Sin and others (2003) and the NICE guidelines (2004).

Table 1: Evidence for different interventions on COPD outcomes

Intervention	Outcomes
Smoking cessation	– Only intervention proved to slow the decline of airways obstruction
Pneumococcal and influenza vaccination	– Assumed to be effective; studies are not specific to COPD but studies in the elderly show reductions in deaths by 30-40%
Long term oxygen therapy	– Prolongs survival in patients with low oxygen saturation
Multidisciplinary pulmonary rehabilitation	– Improves quality of life and dyspnoea domain on CRQ – 2 trials show maintenance of improved quality of life for 3-18 months of follow up – Some mainly non-RCT evidence for a reduction in the number of days in hospital, less evidence for a reduction in number of hospitalisations – Some evidence for improvements in survival, however only in small numbers or observational studies
Disease management programmes	– Heterogeneous approaches, no proven meaningful impact on hospitalisation rates – Similar conclusions from systematic review of nurse led chronic disease management programmes (Taylor and others)
Long acting bronchodilators and inhaled corticosteroids	– Reduce exacerbations in patients with moderate and severe airways obstruction
Non-invasive ventilation	– Evidence for improvements in resting dyspnoea and quality of life in persistent hypercapnic ventilatory failure

7 Breathing Space Programme

Breathing Space is a unique partnership between Rotherham PCT and the Coalfields Regeneration Trust (CRT) to deliver a new model of care for patients with chronic respiratory disease. The Office of the Deputy Prime Minister, the CRT, the PCT and South Yorkshire Strategic Health Authority have contributed to a funding package of over £11 million to revolutionise care for patients with chronic pulmonary disease. The programme will implement a controlled shift from an NHS sickness service to a public health model based on comprehensive prevention, rehabilitation and respite services.

A purpose built community centre in central Rotherham will act as a catalyst for the largest respiratory rehabilitation programme in the country, providing individually tailored pulmonary rehabilitation for 40 people each day with overnight accommodation for 20 patients and their carers. The emphasis is on a non-clinical approach with the building as the hub for a whole system change that will include promoting the awareness of lung disease, empowering patients and carers, and driving up the quality of primary care.

The approach is based on the Macmillan model of pump priming funding. During the period of programme funding there will be sufficient resources to provide comprehensive pulmonary rehabilitation whilst maintaining a level of investment in acute services.

The programme will be an exemplar of whole system change for an important long-term condition and contribute to the evidence base for national policy making for chronic diseases in the context of a rapidly changing health economy with changes such as 'Payment by Results' and 'Commissioning a Patient led NHS'.

The expected benefits and changes for Rotherham residents from the Breathing Space Programme are shown in Appendix 1.

8 Breathing Space Evaluation Project

Research and evaluation is fundamental to the Breathing Space Programme Vision and will be fully integrated into the programme design. The reason for this is twofold:

- From a national perspective, the unique nature and substantial funding makes it obligatory that learning from the programme is maximised
- From a local perspective, the local Health Community requires robust evaluation to inform decisions on long-term sustainability after pilot funding finishes in 2009

The research and evaluation has three overall aims:

a) To determine whether the programme has met its success criteria and make recommendations to Rotherham PCT Board and other stakeholders about funding beyond the pilot period

b) To maximise learning from the programme and the development of a research culture around chronic respiratory disease in Rotherham

c) To ensure that lessons from the programme can be disseminated nationally

9 Plan of investigation

The overall design of the research project is a before and after descriptive study combined with health economic modelling of benefits that can be predicted to continue after the initial evaluation period.

In addition to the basic before-and-after design, a limited number of readily available COPD measures will be collected from two neighbouring health communities to allow some comparisons. Generic measures such as QOF achievements including COPD smoking prevalence, prescribing data for respiratory drugs and COPD secondary care activity will be requested from two neighbouring Health Communities (Doncaster and Barnsley). Data listed in Appendix 8.

As described in fig 1, the evaluation will consist of seven individual components (which are briefly described below). These individual evaluations will feed into an overall study of the impact of the programme on the burden of disease and an economic model of the cost effectiveness of the programme. Appendix 2 gives key milestones for the evaluation components.

○ Evaluation 1: Impact on the use of primary care services

Engagement with primary care is an essential part of the Breathing Space Programme: The vast majority of patient contacts for COPD occur in primary care; primary care databases are the easiest way of assessing COPD data from a whole population perspective; and primary care will be the most important source of referrals to the Breathing Space Centre. A Breathing Space Specialist Respiratory Nurse took up post on 1 April 2006 to start the process of engaging with primary care about the effective management of COPD. As part of capturing the impact of this work, Breathing Space will work with primary care to deliver a series of before-and-after audits.

The overall aims of this aspect of the evaluation is to audit the extent to which:

- awareness of the need for pulmonary rehabilitation has been raised
- active case finding among people with undiagnosed COPD has been encouraged
- all people diagnosed with COPD have been diagnosed accurately
- all people with COPD have been accurately categorised into NICE airflow obstruction severity categories
- before and after information has been provided at both practice and individual patient levels of achievement against Primary Care Audit Standards (which are derived mainly from NICE standards)
- optimisation of medicines management for COPD patients has been encouraged

The process of the audits will include:

- An introductory visit which will engage practices with benchmarking data on their COPD prevalence, introduce the Breathing Space COPD standards and carry out a baseline practice level audit
- The extension of an offer for Breathing Space staff to work with practices to carry out a baseline patient level audit
- The extension of an offer to give practices the opportunity to participate in quarterly electronic audits to provide benchmarking information on case finding and those quality standards that can be assessed electronically
- The extension of an offer to work with practices on a re-audit in 2008/09

The full protocol for primary care audit is given in Appendix 3

It is anticipated that the audit process will enable practices to:

- Increase the level of early diagnosis and treatment of people with COPD
- Accurately assess the level of COPD using the NICE categorisation process in-order to optimise prescribing and the overall treatment plan
- Actively monitor the patients condition and encourage the use of Breathing Space facilities as appropriate

Evaluation 1: data collection to inform model

Whilst the primary care audit is being undertaken to achieve a range of objectives in its own right, a secondary purpose will be to provide core data for the overarching burden of illness study and cost effectiveness studies. The core data required from the audit in this respect are as follows:

Data	2006/07	2007/08
Aggregate data		
Incidence data		
New cases (Mild)		
New cases (Moderate)		
New cases (Severe)		
Unclassified		
Prevalence		
Total cases (Mild)		
Total cases (Moderate)		
Total cases (Severe)		
Unclassified		
Patient level data		
Unique identification number		
Age		
Sex		
COPD status (mild, moderate, severe)		
GP code		
Smoking status		
Resource utilisation data		
General practice		
Primary care contacts		
Primary care out of hours contacts		
Wider primary care		
Acute homecare assessments (CARATS)		
Acute homecare visits (CARATS)		
Quality of life measure		
SF36 score		

Data collection

Most of the data required from the primary care audit will be collected through the COPD registers held within primary care. It is acknowledged that the registers are in the early stages of development and the quality of the data available will vary across practices. It is important therefore that the audit process incorporates a mechanism for checking the completeness of the registers in each practice and ensuring that the classification of disease levels, i.e. mild, moderate, severe, is as robust as possible.

Utilisation data will be collected for the subset of patients of the COPD registers. Although patient identifiers such as NHS numbers are not required for the study, it is important that data on the resource utilisation of primary care service by individual patients can be linked to resource utilisation in secondary care and other arms of the evaluation. It is likely, therefore, that individual patient data will be compiled using NHS numbers at the level of the GP practice or the PCT then transferred for analysis by the research team with the NHS number removed and a unique identifier number in its place. Quality of life data will be collected using a patient survey format.

o Evaluation 2: Impact upon the use of secondary care services

A key driver of cost in the care of COPD is the occurrence of unplanned emergency admission to hospital as a result of an acute exacerbation of the disease.

The PCT FACT team will produce monthly reports that will show any impact the programme is having on secondary care activity. This information will be important to help the Rotherham NHS Foundation Trust adjust to the changes that will occur as a result of the implementation of the new care pathway, and also inform the assessment of the sustainability of the Breathing Space Programme after pilot phase funding ceases.

Information from the monthly reports will be aggregated for the summary evaluation reports to show any impact on outpatient rates, accident and emergency rates, hospital admission rates and length of stay.

For the purpose of the overarching burden of illness study and cost effectiveness model, however, individual patient level data will be required.

The overall aims of this aspect of the evaluation is to audit the extent to which:

- Improved diagnosis, treatment and chronic disease management have reduced the need for acute hospital admission as a result of acute exacerbation
- The use of patient education and pulmonary rehabilitation has impacted upon the length of stay in hospital following acute admission
- Improved awareness and training in primary care facilitates better chronic disease management and a consequent reduction in specialist outpatient activity.

The process of the audits will include:

- Regular monitoring of acute admission activity relating to COPD HRG codes
- Monitoring and reporting of all COPD related activity undertaken by the FACT community service either in relation to hospital avoidance activity or post discharge activity.
- Monitoring of out patient referral and follow up activity levels.

Draft monthly impact reports have been developed and monthly impact reports will be produced monthly from December 2006 and shared with the Programme Team and Research and Evaluation Steering group.

Evaluation 2: data collection to inform model

Whilst the secondary care audit is being undertaken to achieve a range of objectives in its own right, a secondary purpose will be to provide core data for the overarching burden of illness study and cost effectiveness studies. The core data required from the audit in this respect are as follows:

Data	2006/07	2007/08
Aggregate data		
A&E attendances		
Total number of attendances		
In-patient activity data		
Total admissions (<48 hours)		
Total admissions (>48 hours)		
Total admissions (with LOS beyond the tariff trim point)		
Out-patient activity		
Total first attendances		
Total follow up sessions		
Patient level data		
Unique identification number		
Age		
Sex		
COPD status (mild, moderate, severe)		
Consultant code		
Resource utilisation data – patient level		
A&E attendances		
Number of attendances		
In-patient activity		
LOS <48 hours		
LOS >48 hours		
LOS total number of days		
Out-patient activity		
first attendances		
follow up sessions		

Data collection

Most of the data required from the secondary care audit will be collected through the HES data system, supplemented by OPD data from the commissioning systems.

Admission and OPD data will be searched by NHS number of patient on the COPD database. This will allow the stratification of secondary care activity by the level of disease, i.e. mild, moderate, severe, as classified on the COPD register.

This subset of data relating to patients on the COPD register can be further refined to exclude non-COPD activity i.e. gynaecology, orthopaedic, dermatology etc. It will be assumed that all chest related activity and non-specified medical activity will relate to the treatment of their COPD.

Again it is likely that individual patient data will be compiled using NHS numbers at the level of the GP practice or the PCT, then transferred for analysis by the research team with the NHS number removed and a unique identifier number in its place.

o Evaluation 3: Impact on prescribing behaviour

The Breathing Space Programme aims to optimise prescribing for all patients with COPD in Rotherham in the context of NICE guidelines. This aim will be monitored through primary care audits and by reviewing medication against NICE standards before or during pulmonary rehabilitation for all those people who receive it.

Although there are anticipated to be a large number of prescription changes, the overall impact on prescribing costs is expected to be neutral. This is because it is anticipated that currently there is substantial over-use of medication against NICE guidelines in some patients, but also under-diagnosis of COPD and under-use of some medication. For example, we expect cost savings from reducing the inappropriate use of combination steroids but also cost increases resulting from increased use of long acting anticholinergics (where there is evidence that it can reduce exacerbations and admissions, Brusacao and others 2003). There will also be cost increases from improved case finding.

Prescribing for COPD is difficult to evaluate in isolation to prescribing for other respiratory conditions using routine electronic prescribing data (ePACT) because many drugs used for COPD are also used for other indications, particularly asthma. The overall aims of this aspect of the evaluation is to audit the extent to which:

- Prescribing activity changes towards a range of key prescribing standards to be determined. Preliminary investigation suggests that examples of these standards could include:
    - Cost savings from reductions in prescribing combinations of steroids and long acting beta agonists
    - Cost savings from reducing the prescribing of steroids in patients unless their FEV1 is less than 50% of predicted or they have had two or more exacerbations
    - Cost increases with regard to long acting anticholinergic prescribing
- The extent to which ePACT data highlights any difference in trends in Rotherham against respiratory prescribing trends in Doncaster and Barnsley over the period from 2006 to 2009. The aim of this high level analysis will be to show that improvements in the accuracy of prescribing and increased case finding have been delivered without an overall growth in real prescribing costs.
- The link between any prescribing changes and any change in use of domiciliary oxygen.

The process of the audits will include:

- Regular monitoring of ePACT data
- Comparative analysis of changes in prescribing patterns in Rotherham and surrounding areas.
- Monitoring of prescribing costs in COPD related areas.

A draft prescribing report was prepared for the October 2006 Research and Evaluation Steering Group. This draft will be updated after the COPD audit is completed and shared with the Research and Evaluation Steering Group.

Evaluation 3: data collection to inform model

Whilst the prescribing audit is being undertaken to achieve a range of objectives in its own right, a secondary purpose will be to provide core data for the overarching burden of illness study and cost effectiveness studies. The core data required from the audit in this respect are as follows:

Data	2006/07	2007/08
Aggregate data		
Prescribing costs		
Changes in overall prescribing costs		
Oxygen service		
Changes in overall O^2 costs		

Data collection

Because prescribing costs at the level of the individual can vary greatly with influences such as concordance, co-morbidities, patient preference etc, it is felt by the research team that there are too many confounding variables for assessment to be made at anything but an aggregate level.

It is very likely that patterns of prescribing will be influenced by other factors during the study period including resource constraints, NICE guidance, the GP contract, practice based commissioning etc. To try to isolate any changes which could be linked to the Breathing Space initiative, changes will be compared with prescribing profiles from neighbouring PCTs to see if any difference can be detected.

It is anticipated that changes in the use of O_2 therapy are likely to occur as a result of increased pulmonary rehabilitation. The aggregate cost of this service will also be compared with trends in neighbouring PCTs.

o Evaluation 4: Impact on the use of pulmonary rehabilitation

In parallel with the above impact reports, the programme will produce regular reports on numbers of patients seen by the new Breathing Space services along with documentation of their clinical outcomes.

The overall aims of this aspect of the evaluation is to audit the:

- Numbers of patients receiving pulmonary rehabilitation and respite care in the Breathing Space Centre.
- To monitor in detail the cost of the services provided directly by the centre
- To evaluate the impact of the service on the quality of life of both the patient and their families / carers
- To monitor the impact of the services provided on the disease progression
- To monitor patient / carer satisfaction with the service provision

The process of the audits will include:

- Detailed costs data will be kept by the service and all clinical activity logged and analysed
- Detailed clinical management data will be kept by the service and all clinical outcomes logged and analysed
- Before and after data will be collected on quality of life using generic quality of life measures such as EuroQol or SF-36. These measures will be used in the modelling process to calculate incremental cost effectiveness ratios
- Before and after data will be collected on disease specific quality of life using a condition specific validated outcome tool and measured exercise capacity. Measures in this aspect of the evaluation will include the Chronic Respiratory Questionnaire and the Shuttle Walking Test

A list of data requirements highly desirable for evaluation that should be collected from all Breathing Space contacts is shown in Appendix 7.

Evaluation 4: data collection to inform model

Whilst the pulmonary rehabilitation audit is being undertaken to achieve a range of objectives in its own right, a secondary purpose will be to provide core data for the overarching burden of illness study and cost effectiveness studies. The core data required from the audit in this respect are as follows:

Data	2006/07	2007/08
Aggregate data		
Pulmonary rehabilitation attendances		
Total number of attendances		
Residential activity data		
Total number of residents and carers		
% Occupancy rate		
Total number of bed nights for residents and for carers		
Out-patient activity		
Total number of attendances for other reasons i.e. assessment, diagnostic tests, educational sessions etc		
Total activity for help line		
Patient level data		
Unique identification number		
Age		
Sex		
COPD status (mild, moderate, severe)		
Consultant code		
Resource utilisation data – patient level		
Pulmonary rehabilitation attendances		
Number of sessions		
In-patient activity		
Number of admissions		
LOS for each admission		
Associated carer stays		
Out-patient activity		
Number of attendances other than pulmonary rehab		
Number of calls to the helpline		
Outcome measures		
SF 36 (Version 2) quality of life measurement		
CQR Disease specific outcome measurement		

Data collection

Most of the data required for the pulmonary care audit will be collected through the new COPD data system, supplemented by data from the direct service evaluation.

The linking of activity data with individuals will allow the stratification of pulmonary rehabilitation by the level of disease, i.e. mild, moderate, severe, as classified on the COPD register. Again it is likely that individual patient data will be compiled using NHS numbers at the level of the GP practice or the PCT, then transferred for analysis by the research team with the NHS number removed and a unique identifier number in its place.

Outcome assessments (CRQ & SF36) will be completed at baseline (at the start of rehabilitation) and at 3 months and 12 months.

○ Evaluation 5: Impact on patient satisfaction / quality of life

In addition to the use of quality of life measures before and after treatment, it is important that quality of life in the medium to long term is monitored.

The revised business plan will include details of how the programme will maintain improvements in exercise capacity and quality of life – probably by planned follow-up telephone contact. From an evaluation perspective, knowing how long any improvements last is an important factor. A protocol will be developed to re-access patient quality of life at a point of time after completing pulmonary rehabilitation.

Current plans are for this to be done via an offer of a re-assessment contact with repeat health related quality of life measure one year after completing the programme.

The overall aims of this aspect of the evaluation is to audit:

- Monitor ongoing quality of life in patients following pulmonary rehabilitation and patient education programmes
- To detect early any deterioration in a patient's condition to reduce the occurrence or impact of acute exacerbation
- To assess how long improvements gained from pulmonary rehabilitation are likely to last

The process of the audits will include:

- Annual re-assessment and monitoring
- Annual measurement of disease specific and general quality of life

A list of data requirements highly desirable for evaluation that should be collected on follow up patients is shown in Appendix 7.

Evaluation 5: data collection to inform model

Whilst the pulmonary rehabilitation audit is being undertaken to achieve a range of objectives in its own right, a secondary purpose will be to provide core data for the overarching burden of illness study and cost effectiveness studies. The core data required from the audit in this respect are as follows:

Data	**2006/07**	**2007/08**
Patient level data		
Unique identification number		
Age		
Sex		
COPD status (mild, moderate, severe)		
Consultant code		
Resource utilisation data – patient level		
Pulmonary rehabilitation		
Clinical outcome -pulmonary rehabilitation sessions (Eval. 4)		
Quality of life assessments from Breathing Space (Eval. 4)		
Patient satisfaction assessments from Breathing Space (Eval. 4)		

Quality of life assessments from primary care audit (Eval. 1)		

Data collection

Both the burden of disease modelling and cost effectiveness modelling require information on the quality of life for people with COPD. This information will be collected from:

1. All patients who attend the Breathing Space rehabilitation programme

Evaluation 4 will include the use of both the CRQ (a COPD specific instrument, to facilitate comparison with other COPD rehabilitation interventions) and the SF-36 (version 2) (a generic measure to estimate overall impact on quality of life) for the collection of outcome data following the utilisation of the Breathing Space service.

The instruments will be completed at baseline at the start of rehabilitation and at 3 months and 12 months.

2. A stratified sample of individuals on primary care COPD registers

Evaluation 1 (Primary care audit) will use the SF-36 version 2 (a generic measure to estimate overall impact on quality of life) in the assessment of quality of life in COPD patients before the establishment of the Breathing Space Centre and again one year later.

Since it is likely that quality of life is different, and the impact of Breathing Space different, for individuals classified as mild, moderate and severe, the questionnaire will be sent by practices to a stratified sample of patients based on disease severity.

The patients with mild/moderate/severe COPD according to BTS criteria will be identified from the primary care audit. (Eval 1) Questionnaires will be sent out by practices to ensure confidentiality is maintained. A covering letter from the practice would explain that the purpose of the questionnaire is to understand how COPD/lung disease affects people's everyday life and whether new services are able to make a difference to this. The questionnaires will be coded by severity group (e.g. a different colour sent to patients with a different severity grade) and each will have a unique identifier. Responders will be asked to tick a box IF they are happy for their records to be consulted so that it is possible to match their clinical records/service use which their quality of life scores.

Sample size

To have 80% power to detect an actual clinically significant difference in quality of life of 0.05 (on a 0 to 1 scale) with a *p*-value of 0.05, assuming a standard deviation of 0.15, would require 92 individuals. We would therefore aim for at least 100 completed questionnaires from patients with mild/moderate/severe COPD respectively. Assuming a response rate of around 30-50%, since this is a relatively elderly and unwell patient group, we would aim to send out a total of around 900 questionnaires, 300 to each severity group.

A review of the literature shows that EQ5D and SF-36 perform equally well in the assessment of quality of life and utility in COPD (Liddy can Ref) although SF-36 is more sensitive and more likely to pick up the level of change anticipated in most interventions.

Each audit will use SF-36 in the assessment of quality of life to allow a degree of meta analysis using the total data set.

○ Evaluation 6: Impact on smoking cessation

Smoking is the biggest cause of COPD, and continued smoking the biggest adverse prognostic factor for those with COPD. It is anticipated that the Breathing Space programme could impact on smoking prevalence in COPD patients in two ways:

1. Breathing Space aims to maximise case finding for COPD – this includes encouraging spirometry in smokers over 35. It is possible therefore that initially the total number of identified current smokers with COPD in Rotherham will rise
2. At all stages of the care pathway patients will be supported whenever they wish to try to quit smoking

It is also recognised that Breathing Space will come into operation just before national legislation on smoke free public places. In terms of the impact of the programme on smoking prevalence, perhaps even including its impact on smoking in people who do not have COPD, this is a fortuitous opportunity, but in terms of the evaluation of the specific impact of Breathing Space on smoking rates in COPD patients it will be more difficult to ascribe any reduction in smoking rates to the independent impact of Breathing Space.

The overall aims of this aspect of the evaluation is to audit:

- The extent to which the programme enhances smoking cessation in high risk groups
- The extent to which the programme highlights the health benefit from smoking cessation in this high risk group

The process of the audits will include:

- Examining the last recorded smoking status as entered on GP computers for people identified as having COPD. This can be extracted via the QOF process and is available each April. (In 2005 30% of the 5800 people with COPD were recorded as current smokers)
- Monitor the PCT Smoking Cessation Service records smoking 'quitters' as defined by NHS protocols. The smoking cessation service database has a field for source of referral. The service will encourage the use of Breathing Space as a source of referral category so they can record the number of formal quitters attributable to the Breathing Space Programme
- The before and after primary care audit and quarterly electronic primary care audits will measure the number of people with COPD recorded as smokers in May 2006 who are subsequently recorded as non-smokers.

A baseline smoking impact report will be presented to the Research and Evaluation Steering group before April 2007.

Evaluation 4: data collection to inform model

Whilst the pulmonary rehabilitation audit is being undertaken to achieve a range of objectives in its own right, a secondary purpose will be to provide core data for the overarching burden of illness study and cost effectiveness studies. The core data required from the audit in this respect are as follows:

Data	2006/07	2007/08
Aggregate data		
Number of COPD patients recorded as smokers on QoF register at baseline and one year after breathing space		
Number of patients recorded as quitters by smoking cessation		
Number of potential quitters referred to smoking cessation by Breathing Space		

Data collection

Most of the data required for the smoking cessation audit will be collected from PCT-wide information systems. The information will be supplemented by data from the primary care audit (Eval. 1) and the Pulmonary Rehabilitation Audit (Eval 4).

The linking of activity data with individuals will allow the stratification of smoking cessation by the level of disease, i.e. mild, moderate, severe, as classified on the COPD register.

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○ Evaluation 7: Impact on model of care

This aspect of the evaluation is to gain a broad insight into the perceived impact of the Breathing Space programme on the overall model of care from the perspective of a range of stakeholders.

Two series of interviews will be carried out in this phase of the evaluation. One before the implementation of the programme and one when it is established.

The overall aims of this aspect of the evaluation is to audit:

- To use interviews with key stakeholders, conducted before Breathing Space becomes operational, to refine the development of the programme
- To use interviews with the same key stakeholders, conducted after Breathing Space becomes operational, to inform the formal evaluation of the programme

The process of the audits will include:

- Discovery interviews were carried out with patients and carers as part of the consultation process for the original business case. A small number of additional interviews with patients and carers will be carried out to obtain baseline information on experiences of services and any gaps prior to the Breathing Space Centre opening. A particular focus will be to explore potential barriers to access, such as transport difficulties or perceived reluctance of smokers to attend a non-smoking building. Dr Stephanie Taylor will help to advise ScHARR on issues to cover in the interviews.
- A second sample of patients and carers will be interviewed in 2007 to investigate the experiences of people who have been though the Breathing Space Programme.

The protocol for patient and carer interviews will be completed by June 2006 (Appendix 4).

Data	**2006/07**	**2007/08**
Qualitative assessment of patient stakeholder perception on progress and impact against pre-determined criteria		

- **Study 1: Impact of the programme on the baseline burden of disease and use of health and social care resources**

The Breathing Space programme is part of a suite of health and social care resources available for the treatment and care of people with COPD.

Because the programme aims at promoting the earlier identification, diagnosis and treatment of people with COPD in the community and the use of active pulmonary rehabilitation for people with established disease, the Breathing Space programme essentially promotes a range of interventions which are not currently available in this health community.

Initatives which aim to provide vigorous interventions to people who are not currently known to the service or quality of life enhancing treatment to people who currently have no access to such services are notoriously difficult to evaluate.

In a straight forward before and after evaluation, many of the people who will benefit from the Breathing Space project are not currently receiving services. Therefore the full cost of the new service will be apparent, but many of the benefits hidden and difficult to quantify.

It is probably more useful to consider services like the Breathing Space programme as an "invest to save" initiative rather than a "cost reducing" initiative in the more traditional view of the cost effectiveness perspective.

The question therefore is not:

"will the service including the Breathing Space initiative be a more cost effective way to treat COPD than the current system?"

but rather

"will the service including the Breathing Space initiative be a more cost effective way to reduce the burden of disease from COPD in the medium term and meet the service quality standards set out in the NICE guidance than the current system?"

It is recognised at this point in time that data relating to resource use specific to patients with COPD will not be easily identified in some areas, particularly social care and nursing home activity.

It will therefore be necessary to collect primary data in this area with a view to populating the model in the first instance, then strengthening the data and assumptions where it is clear that proxy data are weak.

Fig 2: The evaluation model (main NHS and social care cost vectors)

Current model		Breathing Space model
Smoking cessation activity		Smoking cessation activity
Number of new cases detected		Number of new cases detected
Prescribing costs		Prescribing costs
Visits to GP		Visits to GP
Pulmonary rehabilitation		Pulmonary rehabilitation
Acute exacerbations managed at home		Acute exacerbations managed at home
Outpatient activity		Outpatient activity
Number of acute admissions		Number of acute admissions
Average length of stay		Average length of stay
Respite care admissions		Respite care admissions
Domiciliary social care		Domiciliary social care
Nursing home care		Nursing home care

Potential data sources

The burden of disease model will require data from two key areas.

- The burden of disease from the perspective of the health and social care providers in terms of resource utilisation and costs
- The burden of disease from the perspective of the patient in terms of quality of life

It is possible to collect data from patients and carers to attempt to quantify costs of COPD to both patients and carers, but this would require a major patient survey and will be worthwhile only if there is an expectation that Breathing Space will be designed to have a significant impact on these costs and that any change in these costs will be important to the evaluation of the impact of the programme.

Other than hospital activity, very few health and social care data are accurately identified as specifically relating to patients with COPD.

It will be possible to undertake a targeted severity and age/sex stratified questionnaire survey of quality of life for both carers and people identified through primary care as suffering from COPD as identified in the individual evaluations set out above.

Severity stratification will not be in place for all practices in Rotherham until Feb 2007. Questionnaires will therefore need to be sent out using the practices' computed system – i.e. the Breathing Space programme will assist primary care practices' administrative staff to send out the questionnaire.

Data will be available from the hospital PAS system on hospitalisation and out-patient activity for COPD and related illness.

Data quality assurance

Since data will be obtained from a wide range of sources and audit and routine data will be collected and analysed by a number of different staff across the PCT, it will be essential to establish a process for independent data quality assurance, potentially using a small subgroup of the overall Research and Evaluation team to review data for quality issues throughout the evaluation process.

Data analysis

Service activity data will be collected for people with COPD before and after the Breathing Space programme has been introduced. The hypothesis is that the additional costs associated with early detection / treatment of patients with COPD and rigorous pulmonary rehabilitation, along with investment in education and preventative activities such as enhanced smoking cessation activity, will be partially offset by a reduction in the number of acute exacerbations of the disease and resulting hospitalisations. It is also anticipated that early detection and rigorous intervention could slow down disease progression.

Although the overall burden of disease is likely to increase in the early stages as unmet need is identified, it is expected that over time the burden will begin to fall as patients learn to reduce their risk and manage their condition.

A budget impact model will be developed that is based around the age-specific incidence and natural history of COPD. The model will attempt to describe the age-specific incidence of COPD in Rotherham as a function of relevant demographic characteristics. Disease progression will be described as movement between worsening states of COPD severity, probably described as a function of FEV. Progression rates will be informed by a review of the general COPD literature, though ideally the model would be calibrated to primary data collected in Rotherham describing age- and severity-specific incidence. It is recognised that data quality in this regard may be suspect, but the calibration process can be adjusted to account for the quality of the data.

Data describing the resource, survival, and quality of life effects of different stages of the COPD clinical pathway would ideally be sourced locally, though these data can also be supplemented with data from the general literature.

The impact of the Breathing Space initiative would be modelled by adjusting the age- and severity-specific COPD incidence rates to match the observed rates of incidence in the post-implementation phase. The longer-term effects of increased smoking cessation on the incidence of COPD would necessarily be informed by data from the general literature. It may also be possible to adjust the severity-specific disease progression rates on the basis of the observed local impacts on patients, as well as using data from the general literature (e.g. studies of smoking cessation interventions and pulmonary rehabilitation).

Data describing the resource, survival, and quality of life effects of COPD in the post-implementation phase should be more easily informed by local data collected as part of the Breathing Space evaluation.

Study 2: Cost effectiveness and modelling of future impact

Although the costs of the Breathing Space programme will be borne from day one, many of the potential benefits will be cumulative over time, with the emphasis on prevention and rigorous identification and treatment of early stage disease having the potential to slow down or indeed halt disease progression.

The modelling approach described as the analytic framework for study 1 will also form the basis of the estimation of the cost-effectiveness of the Breathing Space initiative. The model will incorporate all of the potential impacts of the initiative, i.e. reduced incidence, early diagnosis, and improved treatment.

As described in the previous section, the model will use local data wherever possible, but it will almost certainly be necessary to supplement these data with secondary sources identified from the general literature, e.g. the effectiveness of interventions implemented as a consequence of Breathing Space.

The model will predict the long-term costs and consequences of Breathing Space in comparison to the continuation of the current situation. The shorter term costs and effects will also be estimated, enabling some form of validation by comparison with observed data.

Fig 3

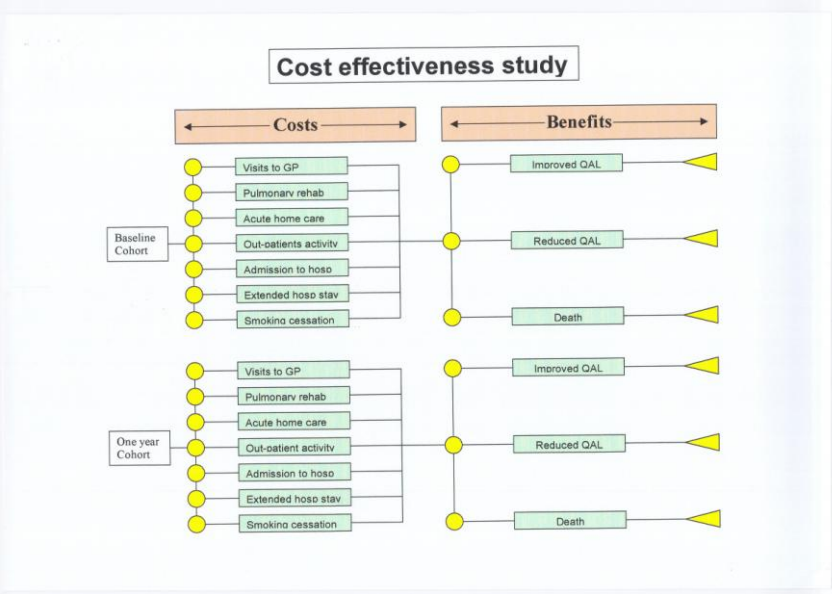


Fig 3 shows the modelling process in diagrammatic form. Essentially, today, people living with different levels of COPD are likely from time to time to visit their general practitioner. They may get access to pulmonary rehabilitation services, although these are extremely limited. During acute exacerbations they may require home care services from CARATs, to see a specialist at the hospital or indeed require hospital admission.

Their length of stay in hospital may in some cases be prolonged. In addition to the utilisation of primary and secondary care services, there is a chance that some people may stop smoking during this period.

The baseline cohort part of the model will draw data from the seven evaluations to show the probability of people with mild, moderate and severe COPD accessing the services outlined in the model, and in particular the probability of them stopping smoking.

The current pattern of service utilisation will be associated with the probability that a patient's quality of life will improve or deteriorate, or that they will die.

These factors together demonstrate the current burden of disease from COPD in terms of the cost of health service utilisation and the burden in terms of quality of life and premature death.

The one year cohort arm of the model will show how this position has changed one year after the introduction of the Breathing Space initiative.

It is assumed, for example, that increased case detection will increase GP activity through the identification of unmet need. This increase in workload could, however, be offset by a decrease in the numbers of acute exacerbations from enhanced pulmonary rehabilitation and pro-active disease management. It is also anticipated that the cost of enhanced pulmonary rehabilitation could be offset by reduced need for hospital outpatient activity or even acute hospital admission. Better patient education and training in self-management of the disease could lead to reduced length of stay in hospital.

Most importantly, increased awareness of COPD in the Rotherham community and the raising of the profile of the disease could have a positive effect on smoking cessation activity which is the one intervention which could have a dramatic effect on disease progression.

The difference in service utilisation and the consequent difference in the profile of service cost can then by related to any enhancement in quality of life scores to give an incremental cost per quality of life year. This will allow judgements to be made about the economic benefit of this intervention in comparison with other potential investment priorities.

10. Data Management and Statistical Analysis

Details of data management and analysis are specified in the individual protocols set out in appendices 4 – 11.

For ethical and data protection reasons, there is no intention to have a single Rotherham COPD database. The primary care audit will not take patient identifiable data out of practices, but will give each practice feedback so that their electronic records can be improved. In this way the whole system impact of Breathing Space on improving quality of care for COPD can be tracked using existing methods of QMAS, QUEST queries and primary care audits.

The Breathing Space Centre will be required to keep clinical records for all patients seen by centre staff, whether at home or in the centre. Given the scale of the programme over time, this will become a substantial proportion of all patients with COPD in Rotherham.

Because the GP electronic record will be used as the primary indicator of whole system impact, great efforts will be made to feed back to primary care all data collected by the programme, such as changes in smoking records.

11. Breathing Space Programme high level success criteria and key specific measures

This section is sub-divided into the five agreed high level success criteria for the Breathing Space Programme. Specific key measures are listed together with which evaluation component will report them.

○ Success Criterion 1

The Breathing Space Programme offers substantially improved care for patients with chronic respiratory disease and their carers in Rotherham.

- Increased number of patients accurately diagnosed with COPD: In 2005 there were 3942 patients with COPD diagnosed by spirometry. The Rotherham Local Area Agreement Stretch Target is to increase this by 1500 by April 2009. (Measured by QOF and primary care audit)
- Number of identified COPD patients recorded as smoking in May 2006 who are recorded as not smoking by March 2009. (Smoking impact reports and primary care audit)
- All 39 practices in Rotherham meet the 12 practice level primary care audit standards. (Primary care audit)
- Improvement in the percentage of patients meeting specific primary care audit standards between baseline and follow up audit. (Primary care audit – amount of improvement to be specified in Feb 2007 after results of baseline audit)
- Patients' and carers' views of changes in care. (Qualitative interviews)
- Prescribing for COPD will be more concordant with NICE guidelines and resources will be better targeted at those who need them. Overall these changes will have been achieved without increasing COPD prescribing costs faster than drug price inflation. (Prescribing impact reports)

○ Success Criterion 2

The programme delivers improved outcomes for chronic respiratory disease patients and carers who have direct contact with the Breathing Space Programme.

- 900 people will have received residential rehabilitation and respite care by March 2009 (Programme monitoring report)
- 800 day-cases will have completed a full course of multidisciplinary pulmonary rehabilitation by March 2009 (Programme monitoring report)
- 1600 people will have been given a lifestyle advice package by March 2009 (Programme monitoring report)
- 900 carers will have received an individual assessment and plan by March 2009 (Programme monitoring report)
- Clinically meaningful and statistically significant levels of improvement on quality of life, disease specific outcome measures and exercise capacity will be achieved for patients who complete pulmonary rehabilitation (Programme monitoring report)
- Clinically meaningful and statistically significant improvements in quality of life, disease specific outcome measures and exercise capacity will be

maintained for one year post completing pulmonary rehabilitation (Programme monitoring report)
- Interviews with patient and carers will demonstrate satisfaction with the service. (Qualitative interviews)

Success Criterion 3

Rotherham Health and Social Care Community will have successfully managed the changes in costs and resources needed to ensure the long-term sustainability of the programme (for example in the context of payment by results and choice).

- By March 2009 there will have been a 30% reduction in COPD admissions for Rotherham residents (Monthly impact reports)
- By March 2009 mean length of stay for COPD HRGs will have reduced from 7.3 days to 4 days (Monthly impact reports)
- By March 2009 the Health Community will have been able to utilise savings from decreased length of stay by investing in other parts of the care pathway (Qualitative interviews with stakeholders)

Success Criterion 4

The programme will deliver improved outcomes for chronic respiratory disease patients and carers at population level (Study 1).

Success Criterion 5

The changes in the whole system costs for chronic respiratory disease in Rotherham provide value for money for the outcomes that have been achieved (Study 2).

10 Work plan for the Evaluation

Section 8 and the protocols given in the appendices outline the timing of the work for the individual components of the Evaluation. Appendix 2 shows a summary time line of the evaluation components separating the work that will be completed before the Breathing Space Centre opens in April 2007 (Table 3.1) and work that will be undertaken afterwards (Table 3.2).

Summary reports will be produced according to the timetable outlined in Table 11.1. The reporting timetable is balanced between the need to produce evaluation reports as quickly as possible so that the Rotherham Health Community can use the information to decide how to fund the programme after pilot funding ceases in time for the April 2009 planning cycle, but also the realisation that many of the expected benefits from the programme will only just be becoming apparent as the programme completes its second year of operation. The time lines in Appendix 2 also show there will be frequent operational reports to the Programme Team.

Table 11.1 Timetable for the evaluation reports

Report	Date	Period Covered
Baseline evaluation report	February 2007	Baseline position before Breathing Space Centre opens
Interim evaluation report	May 2008	April 2007 - March 2008 data
Interim report for Rotherham PCT Board	January 2009	Indication to the Board of the probable contents of the final evaluation report. Impact on operational data will only be available up to December 2008
Final evaluation report	May 2009	April 2007 – March 2009 data

11 Arrangements for project management

Robin Carlisle, Breathing Space Evaluation Lead, will have overall responsibility for leading the evaluation project.

This will involve ensuring that the individual components are delivered according to an agreed timetable (Appendix 2), co-ordinating the reports of the individual project components, and arranging access to data so that ScHARR has the information required for health-economic evaluation and modelling.

Liddy Goyder is the lead for ScHARR, who are academic partners for the programme. ScHARR will provide advice on all aspects of the evaluation, co-ordinated by Dr Goyder. In addition ScHARR will lead on two components of the evaluation: baseline burden of disease and health economic evaluation and modelling (Protocols in Appendix 5 and 6).

A Research and Evaluation Steering group will advise on the overall evaluation framework and be a reference group for specific questions relating to the overall components.

All data used by PCT and Breathing Space Staff will be subject to existing PCT policies on information governance and data protection. In addition the Breathing Space Programme will be developing its own clinical and information governance

policies, which will be approved by the PCT Clinical Governance Committee before the programme opens in April 2007. The proposed specific governance/ethics committee requirements for the different evaluation components are detailed in Section 14 (Table 14.1).

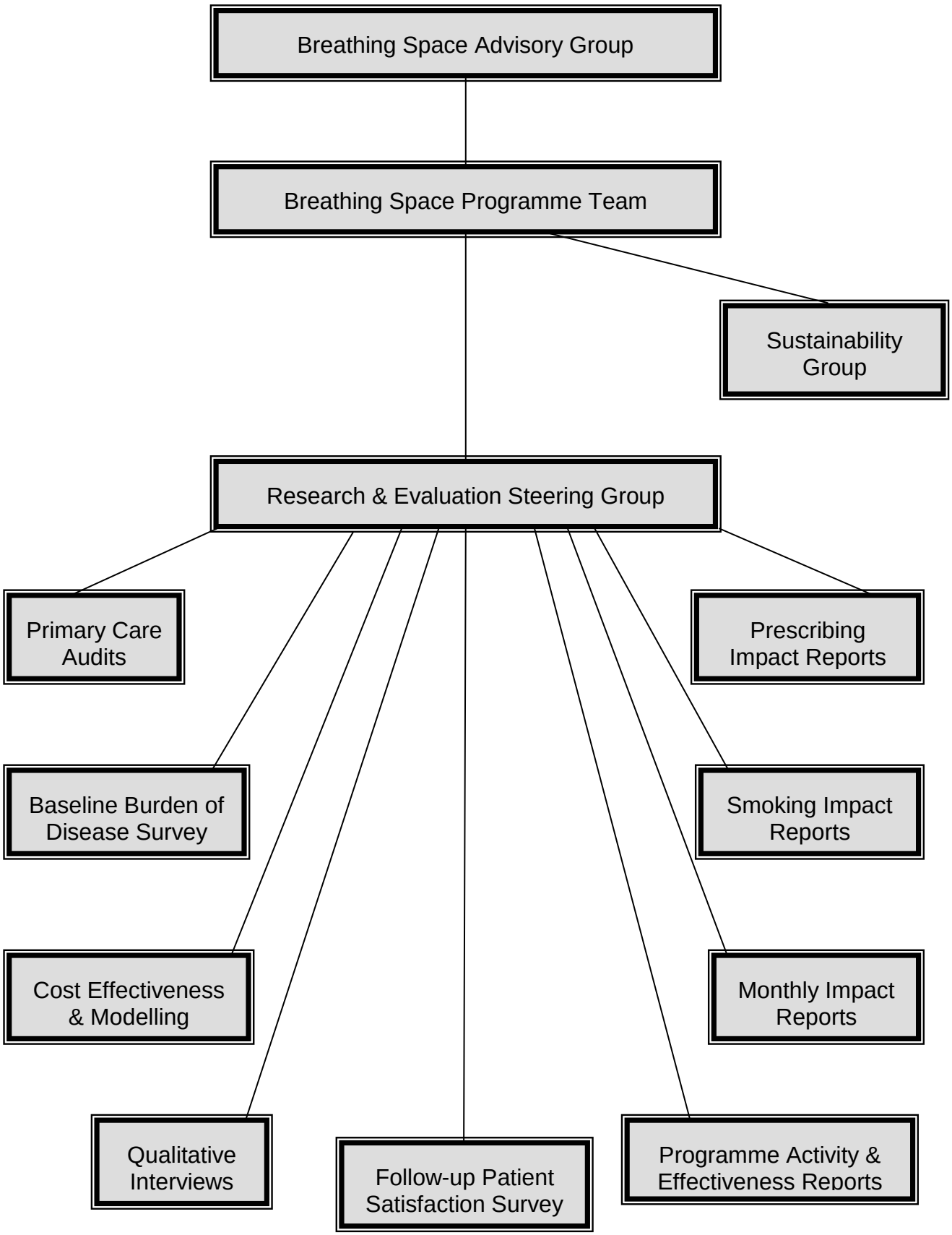
The data handling protocols for the clinical audit will be set out in the audit protocol Appendix 3, which has been agreed by the PCT Professional Executive.

Data handling for qualitative interviews and the baseline burden of disease study will be set out in separate protocols, which will be submitted to research governance.

All members of the Breathing Space team will be briefed at induction on information governance and data protection.

The relationship of the Research and Evaluation Project to the Breathing Space Programme is laid out in Figure 12.1.

Figure 12.1 The relationship of the Research and Evaluation Project to the Breathing Space Programme



Expertise of the researchers and associate organisation

The Reseach and Evaluation Project aims to develop sustainable capacity to evaluate and develop research from Breathing Space over the long term. This is one of the reasons for the choice of management structure, with an academic partner advising on research and evaluation that will partly be undertaken in-house and partly by external experts.

As academic partners, ScHARR have extensive experience of evaluation and published research. Dr Carlisle has previous experience of carrying out evaluations and publishing research as indicted in Section 20.

12 Ethical issues

o Data protection

The primary care audit component will not take identifiable data from the patient's practice. The audit will be done at the request of primary care teams and aim to assist practices in delivering care to NICE standards.

The monitoring and impact reports for the Breathing Space Programme will use information required for the management of the programme or data already available to the PCT.

Specific protocols will require Research Governance and Ethics Committee Approval as set out in Table 14.1.

o Patient Consent

This will be covered in the protocols for the individual components as set out in Table 14.1.

o Governance Issues

Components of the research and evaluation have different governance implications:

- Aspects that use existing data and resources already available to the PCT which are covered by the PCT's existing governance arrangement
- Aspects that are integral to the Breathing Space Programme design which will be reported to the PCT Clinical Governance Committee as part of the overall governance of the Breathing Space Programme
- Primary care clinical audit
- Research projects

The intention is to discuss the proposed governance arrangements (Table 14.1) with the PCT Research Governance Committee and with Rotherham Research Ethics Committee to check that they agree which components require specific ethical approval and then submit those individual components.

Table 14.1 Proposed governance arrangements

Protocol	Proposed Governance
Overall Research and Evaluation Protocol	Overall protocol will be shown to Rotherham PCT Research Governance and Rotherham Research Ethics Committees to check they agree with the proposals shown below
Primary care audit	Rotherham PCT Professional Executive will approve protocol. PCT Clinical Effectiveness and Breathing Space staff will be subject to existing PCT Governance and Data Protection agreements
Baseline burden of disease	Protocol will be submitted for research ethics approval
Cost effectiveness and modelling	Protocol will be submitted for research ethics approval
Qualitative interviews	Protocol will be submitted for research ethics approval
Prescribing impact reports	Uses routine ePACT and data from primary care audit - no additional governance requirements
Smoking impact reports	Uses routine PCT data - no additional governance requirements
Monthly impact reports	Routine PCT data – no additional governance requirements
Programme activity and effectiveness reports	Integral to Breathing Space service design – will be reviewed by PCT Clinical Governance Committee as part of the overall governance arrangements for the Breathing Space Programme
Patient satisfaction questionnaires	Integral to Breathing Space service design – will be reviewed by PCT Clinical Governance Committee as part of the overall governance arrangements for the Breathing Space Programme

13 Involvement of service users

Two members of the Rotherham Breathe Easy Group will sit on the Research and Evaluation Steering Group. In addition, the Breathe Easy Group will act as a reference group when there are specific questions we would like their views on. For example, at the June 2006 meeting the Breathe Easy Group are being asked their views on the overall anticipated benefits of Breathing Space (Appendix 1 of this document) and on the topic guide for patient and carer interviews (Appendix 4).

More generally, there has been extensive patient and carer consultation as part of the development of the business plan for Breathing Space. A key aim of the programme is empowering patients and encouraging self-management. There is a patient representative on the advisory group for the programme, and patients and carers will be involved in the ongoing planning and management of the Breathing Space Centre when it opens.

14 Methods of disseminating the research results

This is a high profile project and will be intensively disseminated locally and nationally.

a. Local dissemination

The research and evaluation results will be widely disseminated via:

- Reports and presentations to RPCT, RMBC, CRT and RNHSFT groups
- Through newsletters via the communications leads of the above organisations
- Regular presentations at the Breathing Space Centre including annual Breathing Space Stakeholder meetings
- Regular reports at Rotherham PCT In Practice Learning sessions
- Presentations at the South Yorkshire Respiratory Disease Network

b. National dissemination

Overall findings and individual research and evaluation components will be presented widely at national conferences and in peer reviewed journals.

15 Funding source

The Breathing Space Programme is funded by the Office of the Deputy Prime Minister, the Coalfields Regeneration Trust, Rotherham PCT and South Yorkshire Strategic Health Authority. Rotherham Local Authority is a key partner in delivering the building project.

16 Peer Review

The Breathing Space Programme Service Design has been subject to extensive consultation with clinicians and service users.

The Breathing Space Research and Evaluation Steering Group will review this overall protocol. Members who are not authors of this paper include:

- Jo Abbott, PCT Research Governance Lead
- Helen Barlow, Knowledge Management Specialist
- Dr Gurnam Basran, Consultant Physician
- Dr Charles Collinson, GP and PCT Professional Executive Chair
- Chris Horsfield, Prescribing Adviser
- Linda Hurst, PCT Commissioning Team

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18 Curriculum Vitae: Evaluation Project Lead

○ Qualifications

Name: Dr. Robin Dawes Carlisle

Position: Consultant in Public Health

Professional experience: 20 years

Qualifications:

- Membership of the Faculty of Public Health Medicine
- Master of Public Health, Nottingham University (Distinction)
- Doctor of Medicine, Nottingham University: Thesis entitled Socio-economic Variations and General Practice
- Membership of the Royal College of General Practitioners (Distinction and Fraser Rose Medal)
- Diploma in Child Health
- Diploma of the Royal College of Obstetricians and Gynaecologists
- MBBS (Certificates of merit in Pharmacology and Pathology)
- BSc in Neuroscience (1st class honours)

○ Career Synopsis

After qualification as a doctor in 1984 and a 3-year GP training scheme I became a full time general practitioner in Mansfield in 1989. During my 10 years as a principal I was executive partner of the practice, a GP Trainer and Vocational Training Scheme Course Organiser, gained a Doctor of Medicine degree at Nottingham University, held a Research Lectureship in the Department of General Practice at Nottingham University, was Lead Partner for the Roundwood Surgery Trent Focus Designated Research Practice and Lead Partner for the Roundwood and Millview Surgeries Culyer Project. In 2000 I became a Specialist Registrar on the Trent Public Health Training Scheme and completed the Master of Public Health course at Nottingham University. On obtaining my CSST I was appointed as a Consultant in Public Health at Rotherham PCT in April 2005.

- **Experience**

I am a Consultant in Public Health at Rotherham PCT where my responsibilities include leading for the PCT on: the implementation of NICE Guidance, public health information, equity audit, clinical audit, and leading the Breathing Space Evaluation Project.

Previous research and evaluation experience includes:

- Work for the Evidence Based Commissioning Collaborative on commissioning guidance on erythropotein in myleodysplasia and myeloma
- A health impact assessment of Doncaster health visitors' move to geographical working
- An epidemiological health needs assessment of palliative care services in Sheffield
- An investigation into clinical outcomes in the neonatal intensive care unit in Sheffield
- A DM on socio-economic variation on General Practice
- A track record of published research in high impact journals

- **Peer reviewed publications**

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13. Perrett K, Granerød J, Crowcroft N, Carlisle R Changing epidemiology of hepatitis A: should we be doing more to vaccinate injecting drug users? Communicable Disease and Public Health 2003, 6, 97-100
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15. Carlisle R, Morris R, Whittle S, Hargreaves S, Fryers P, Lindley S. The health impact of changing to geographical working. Community Practitioner 2004; 77, 10, 376-380
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- **Selected other publications**

18. Carlisle R, Parsons T, Pitt F, Ahmedzai S. Sheffield PCTs Review of Palliative and Supportive Care Services March 2002
19. Redgrave P. Carlisle R, Welsh P. Clinical Governance report on Neonatal Intensive care services. Reports to Sheffield Health Authority and Sheffield Teaching Hospital trust boards February 2002
20. Carlisle R. A Health Impact Assessment of the move to geographical working for health visitors in Doncaster. Presentation to FPH conference June 2004
21. Learning From Sure Start, Working With Young Children & Their Families. Chapter 9, Child Safety Scheme. Published 2005. Open University Press. ISBN:0-335-21638-2.

Appendix 1 Breathing Space care pathway with expected benefits and changes for Rotherham residents

Please note this table does not attempt to capture the more general benefits from the programme's role as a national pilot model for the impact of comprehensive pulmonary rehabilitation.

1.1 Table of Breathing Space care pathway with expected benefits and changes for Rotherham residents

The situation in 2006 before the Breathing Space Programme	Client Group	Expected benefits/changes from the Breathing Space Programme
– 24% of the population of Rotherham smoke and Rotherham has higher than average incidence of smoking related diseases such as COPD – Rotherham going smoke free is a synergistic opportunity for Breathing Space – Central Rotherham is an area of relative deprivation with limited employment opportunities	**THE GENERAL POPULATION WITHOUT COPD**	– The high national and local publicity associated with Breathing Space together with the effect of Smoke Free Rotherham will impact on smoking prevalence in the population. – Breathing Space will provide an educational resource for the local population including schools e.g. providing "live" experiences – Programme will provide opportunities in both employment and/or voluntary work for people who find it hard to get work e.g. those on ICB or who have disabilities or age related problems – The Programme's workforce will be provided with training to enable them to move up the skills escalator from NVQ to PhD

The situation in 2006 before the Breathing Space Programme	Client Group	Expected benefits/changes from the Breathing Space Programme
– Carers feel isolated and inadequately supported – There is an existing carers forum but it has limited capacity	**CARERS OF PEOPLE WITH COPD**	– The Breathing Space Centre will provide a focus for carers to meet and provide mutual support – All carers who want one will be provided with an individualised care plan – Breathing Space will provide specific education sessions so carers have a better understanding of COPD – Breathing Space will develop links with the Carers Forum – All the above bullet points will decrease the burden on carers
– There are anticipated to be substantial numbers with un-addressed need	**PEOPLE LIVING WITH UNDIAGNOSED COPD**	– Higher number of accurate early diagnosis of people with COPD (at least 5800 people will have had diagnostic testing with spirometry by 2009) – Increased early diagnosis gives a major opportunity for early intervention especially smoking cessation
– These patients currently have no access to pulmonary rehabilitation – Because there is no NSF for COPD there	**PATIENTS REQUIRING PREDOMINANTLY PRIMARY CARE MANAGEMENT**	– 800 people will have received day case multidisciplinary pulmonary rehabilitation by 2009 which will improve their quality of life and exercise capacity

The situation in 2006 before the Breathing Space Programme	Client Group	Expected benefits/changes from the Breathing Space Programme
has been less emphasis on the systematic management of COPD in primary care – The PCT has achieved relatively high levels of attainment of QOF standards for COPD but little evidence is available as to whether NICE standards are being met and to what extent the QOF standards give a full picture of optimal primary care for COPD – There are likely to be people in this client group with undiagnosed low oxygen saturation who would benefit from long term oxygen – There are probably some people who are wrongly diagnosed with COPD and lack of clarity over diagnosis between COPD and asthma		– 500 people will have been given a lifestyle advice package by 2009 – Patients and carers will have a much improved understanding of their condition resulting in empowerment and self management – Increased understanding and sensitive support including peer group support will make a substantial impact on smoking rates of people with COPD (applies to all client groups) – More accurate prescribing will lead to greater health gains from the same level of resources spent on prescribing for COPD – Primary Care audit shows improved concordance with NICE standards starting with accurate categorisation into mild, moderate and severe airflow obstruction – More accurate diagnosis will reduce inappropriate treatment of people who do not have COPD
– Some patients are in a revolving door situation where large amounts of	**PATIENTS WITH INCREASINGLY FREQUENT SECONDARY CARE**	– Widespread take-up of the offer of multidisciplinary pulmonary rehabilitation

The situation in 2006 before the Breathing Space Programme	Client Group	Expected benefits/changes from the Breathing Space Programme
resources are invested in their care during admissions with less resources available after discharge leading to re-admission – Inpatients are not always managed by specialist respiratory medical teams – Very limited capacity for pulmonary rehabilitation – Generic admission alternative such as CARATs service and Modern Matrons are becoming available but have no specialist respiratory component	**ADMISSIONS FOR COPD EXACERBATIONS**	will lead to improved quality of life and exercise capacity for this patient group – Education programmes through Breathing Space will lead to patients having increasing control over their condition – Breathing Space will offer admission avoidance and facilitate early discharge either directly to home or to the Breathing Space Centre – 700 people will have accessed residential rehabilitation and respite care by 2009 – 24 hour telephone support line for people with COPD will give increased confidence for management in the community – The availability of pulmonary rehabilitation and early discharge to home or the Breathing Space Centre is currently predicted to lead to a 30% decrease in admissions and a drop in LOS from 7.3 to 4 days. This will free resources for investment in the rest of the care pathway. Further work will be done by RNHSFT and RPCT to test these predictions against the agreed Breathing Space Care Pathway.

The situation in 2006 before the Breathing Space Programme	Client Group	Expected benefits/changes from the Breathing Space Programme
– Limited capacity in Social Service led nursing and residential homes – No specialist or rehabilitation input for patients in respite care – Currently very few COPD referrals to the Community Rehabilitation Team or Intermediate Care Services	**RESPITE CARE/ REHABILITATION**	– Nominal 5 beds are available for respite care in the Breathing Space Centre but the ethos will be that all patients in beds will be participating in a personalised rehabilitation plan – Positive impact on physical and mental health of patients, carers and families
– There are acknowledged gaps in end of life care pathways for non cancer conditions – Hospice services have no specific specialism in COPD – Most patients are managed in primary care with frequent admissions to hospital	**TERMINAL/PALLIATIVE CARE** This may last a period of years and is often not specifically identified	– Breathing Space will not specifically provide end of life care but will link with the hospice and hospice at home teams to facilitate better integrated care and provide an expert resource for advice and training – The education component of the rehabilitation programme will include planning for end of life – Independence will be maximised – this will impact on the physical and mental health of patients and carers and reduce the packages of care needed from social services

Appendix 2: Time line for the components & reporting of Breathing Space Research & Evaluation Project

1.1 Table showing timeline prior to opening of the Breathing Space Centre in March 2007

Evaluation		2006								2007		
		May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
1. Primary care audit		Develop & Pilot		Baseline data collection						Baseline analysis		
2. Baseline burden of disease		Develop protocol								Recruit practices & do survey		
3. Cost effectiveness evaluation & modelling		Develop protocol										
4. Qualitative interviews	Stakeholder	Develop & consult				Baseline interviews				Analysis		
	Patients & carers	Develop protocols								Baseline interviews		
5. Breathing Space Centre patient contact, outcomes & satisfaction data		Develop protocol										
6. Prescribing impact report												
7. Smoking impact report												
8. Secondary care monthly impact reports		Develop protocol & produce pilot report								Run pilot impact reports		
9. Evaluation summary report												

Milestones for completion of protocol and approval by relevant group: 1 - PCT Profession Executive; 2, 3, 4 - Rotherham Research Ethics Committee & Rotherham PCT Research Governance Committee; 6, 7, 8 - Breathing Space Programme Team

Due dates for baseline reports

1.2 Table showing timeline post opening of the Breathing Space Centre in March 2007

Evaluation		2007				2008				2009	
		Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun
1. Primary care audit							Repeat audit	Analysis & feedback			
2. Baseline burden of disease		Survey	Analysis								
3. Cost effectiveness evaluation & modelling		Data linkage	Pilot modelling				Repeat linkage	Repeat modelling			
4. Qualitative interviews	Stakeholder	Timing of repeat interviews to be decided									
	Patients & carers	Timing of repeat interviews to be decided									
5. Breathing Space Centre patient contact, outcomes & satisfaction data			Collect & analyse data								
6. Prescribing impact report											
7. Smoking impact report											
8. Secondary care monthly impact reports		Regular monthly impact reporting									
9. Evaluation summary report											

Due dates for reports

Appendix 3: Breathing Space COPD Audit Protocol

Julie Booker, Breathing Space Specialist Respiratory Nurse
Robin Carlisle, Public Health Consultant Rotherham PCT

29 June 2006

1. Introduction

This is a protocol for an audit and re-audit process from June 2006 to December 2009 to maximise the opportunity created by the Breathing Space Programme to make a step change in the standard of primary care management of COPD in Rotherham.

The audit process consist of

- A baseline practice level audit (completed by December 2006)
- A baseline patient level audit (completed by February 2007)
- Support for practices to achieve standards between the baseline audit and re-audit
- Partial re-audit by QUEST quarterly audits
- Re-audit (completed by December 2009)

2. Aims

The overall aims of these audits are:

- To raise standards of primary care management of COPD
- To raise awareness of the need for pulmonary rehabilitation
- To encourage active case finding among people with undiagnosed COPD
- To ensure that all people diagnosed with COPD have been diagnosed accurately
- To accurately categorise all people with COPD into NICE airflow obstruction severity categories
- To provide before and after information at both practice and individual patient levels of achievement against Primary Care Audit Standards (which are derived mainly from NICE standards)
- To encourage optimisation of medicines management for COPD patients

3. Process

3.1. Development, piloting and consultation on this protocol

The protocol has been developed by the following audit group:

Robin Carlisle	Consultant in Public Health
Julie Booker	Breathing Space Specialist Respiratory Nurse
Kay Vickerage	Breathing Space Service Redesign
Ian Baker	Clinical Audit Co-ordinator
Bet Rudge	Information Governance Manager
Dena Bisatt	Clinical Audit facilitator/Advisor
Chris Horsfield	Prescribing Advisor
Mary Stoddart	Clinical Effectiveness Facilitator
Bel o' Leary	Clinical Effectiveness Facilitator

GPs Drs Collinson, Viswesvaraiah and Plews have commented on drafts of the audit.

The audit is being piloted on 4 practices to test out its feasibility and resource requirements.

The protocol will be discussed by the PCT Professional Executive, the Breathing Space Research And Evaluation Steering Group (which has patient representation, external academic advice from ScHARR and representation from RNHSFT and the Coal Field Regeneration Trust) and has been sent to the LMC for their comments.

Lessons learnt from the pilot practices and comments received will be incorporated into the final protocol. Details of the QUEST queries and the re-audit process and timetable will be modified according to the experience and results of the baseline audits but the intention is to agree the final protocol for the baseline audit process by 1 July 2006.

3.2. Initial Practice visit and baseline practice audit

All practices will be offered a visit by Breathing Space Team for an approximately one hour meeting ideally with a doctor, nurse and practice manager. After the pilot phase practices will be visited starting with practices in the most deprived areas to enable patients in the most deprived areas to benefit first.

The purpose of this meeting will be:

- To have initial discussions with the practice about the overall Breathing Space Programme
- To discuss with the practices Breathing Space Primary Care Standards (section 6 in this document)
- To discuss with practices COPD equity audit data about COPD care in the practice that the PCT already has (an example is given in section 7 of this document)
- To carry out a baseline practice level audit. (section 8 in this document)

The practice baseline audit will consist of a series of questions related to:

- Diagnostic equipment
- Quality Control measures
- Training
- Record Keeping
- COPD management
- Self Management

The practice baseline audit will be completed by the end of September 2006.

3.3. Baseline patient level audit

The audit tool to be used for patient level audits is in Section 9 of this document. The first section of the audit tool will be applied to all patients identified with COPD (i.e. approximately 5800 patients). The reason for using a full sample is to attempt to stratify by NICE severity category as many of the patients in Rotherham identified as having COPD as possible. NICE severity category is a pre-requisite for several of the other audit criteria, it is also important for understanding the baseline burden of disease of COPD in Rotherham and for targeting Breathing Space resources.

The full audit tool will be applied to a 1 in 5 sample of each practices patients with over-sampling in those practices with less than 100 patients so that a minimum of 20 records are audited in each practice.

This audit will consist of searching both computerised and written records for details of:

- Disease Stratification according to NICE guidelines
- Quality of spirometry technique
- Availability of detailed verification of disease severity recorded on computer
- Recording of exacerbations
- Five criteria relating to oxygen and medicine management

A similar principle of starting the audits in practices in the most deprived areas will be followed however for audit personnel training reasons it may also be necessary to visit practices in order of the clinical computer system they use.

3.4. Process for Feeding back results

Information will be fed back to practices in the following ways:

- Once both the practice level and patient level audits have been completed a practice specific report will be sent to each practice. Practices will be invited to meet again with the Breathing Space Respiratory Nurse to discuss the findings and draw up an action plan. If Breathing Space resources allow this could, for example be combined with some training.
- Practices will be given summary reports on their overall performance against NICE derived standards.
- The audit will not give detailed commentary at an individual patient level however if the clinical auditors do come across any information about individual patients they think that practices should re-consider this will be feedback in the practice reports.
- If practices have patients where the records allow NICE category stratification but this has not been recorded this will be feedback so practices can choose to change individual patient records. This will be accompanied by strong caveats if the audit suggests less than optimal standards of spirometry.
- Once the audit has been completed a Rotherham level Report will be produced with benchmarking data.

3.5. Process for supporting practices achieve standards in the period between the initial audit to re-audit

Practices will be supported in achieving standards by 2009 in the following ways:

- The initial practice level baseline audit will have an educational component
- Audit reports will be fed back to practices both at interactive meetings and as documents that will encourage benchmarking to drive up standards.
- The QUEST audits (section 3.6.1) will give quarterly feedback on those standards that can be measured electronically and encourage case finding.
- Breathing Space will provide some COPD training to improve standards – the content of the training will be informed by the findings of the baseline audit.

- All patients that go though the Breathing Space Programme will have management review - this information will be fed back to practices so that they will achieve the criteria for these patients. The baseline audit will also allow Breathing Space to identify those practices with the most patients requiring early support.

3.6. Re-audit process

3.6.1. Partial re-audit by QUEST audits

Breathing Space will develop and promote Rotherham QUEST electronic queries that have two aims:

- To encourage accurate active case finding by providing practice bench marking data on numbers of patients who have a high probability of COPD
- To provide quarterly information on those standards of care for COPD that can be assed by electronic query

An important aspect of this work will be to review and promote the use of the Rotherham COPD template. To be acceptable to practices this template needs to be as short as possible, to be successful in driving up recorded standards it needs to include those criteria in the patient level audit that can be assed by electronic query.

QUEST queries only provide a partial re-audit because not all criteria can be measured accurately by electronic query and not all practices have easy access to QUEST. However the queries will be useful as they require minimal resources to run and so can be repeated quarterly.

The proposed QUEST audit is section 10 of this document.

3.6.2. Re-audit by December 2009

The process and timing of the re-audit will be decided in the context of the baseline audit results. It is likely the re-audit process will be a sample of the overall population.

4. Resources

4.1. Overall resource implications

The purpose of piloting is to refine the audit criteria, familiarise the audit team with the process and achieve a clearer understanding of the resources required. The audit will record those data that are easily extractable from the records so a time limit per record will be applied on the assumption that if the data can not be found in a specified length of time is of limited utility.

Initial estimates of the time taken to undertake the audit were:

- The practice level audit is estimated to take 1 hour of nurse time for each of the 39 practices.
- The severity category audit is estimated to take no longer than 15 mins per patient of a non clinical person's time (total 181, 8 hour days)

- The full audit on a one fifth sample (with over-sampling in small practices) is estimated to take 30 mins per patient of nurse/AHP time (total of 80, 8 hour days)
- After piloting the audit team estimated the most appropriate use of resource and skill mix required to complete the audit was 100 days of clinical nurse time and 100 days of audit team time.

4.2. Resource implications for practices

The commitment required by practices is for a doctor and practice nurse to meet the audit team for approximately one hour to carry out the practice level audit. Practices will also be requested to facilitate access to electronic (and if necessary paper records) so that PCT/Breathing Space audit staff can carry out the patient level audit. Practices will also be invited to meet the respiratory nurse again to discuss the results and draw up an action plan.

4.3. Resource implications for Breathing Space

The practice level audit will be led by the Breathing Space Specialist Respiratory Nurse who is already in post as part of her role in primary care engagement around COPD. The specialist respiratory nurse will also commit some time to starting and supervising the patient level audit.

Breathing Space will commit an additional 80 days of clinical nurse time to undertake the audit.

4.4. Resource implications for the PCT

The PCT clinical effectiveness team, clinical audit team, clinical effectiveness nurses and prescribing advisors have already used resources in developing and piloting the audit. It is proposed to use an additional 100 days of clinical audit team time and 20 days of Clinical Effectiveness nurse time to progress the audit until additional Breathing Space Staff are appointed. The Clinical audit team will also be involved in analysing the results.

4.5. Time scale for completion of the patient level audit

The final date for completion of the audit is February 2007 i.e. before Breathing Space staff gets heavily involved in pre-opening training. It is anticipated that the majority of practices will have been covered in time for the Breathing Space baseline evaluation report in December 2006.

4.6. Resources for Re-audit

The PCT Clinical audit team will advise on the design and analysis of the re-audit – the process will be carried out entirely by Breathing Space staff.

5. Confidentiality, governance and data handling

This is an audit protocol; Breathing Space and PCT staff will be working to support practices at practices' request. As such the protocol does not require formal ethic approval – nevertheless the high level Breathing Space Evaluation Protocol which includes reference to the audit will be shared with the chairs of the Rotherham Research

Ethics Committee and Rotherham PCT Research Governance Committees to check that they agree with this understanding.
No patient identifiable data will be removed from the practice. For all practices other than SystmOne practices the practices' computer number will be used as the patient identifier – this number is only available within practices. For System One practices an audit number will be created the key to which will only be available within practices.

All Breathing Space Staff will be receive training on confidentially requirement at induction. No Breathing Space Staff or PCT Clinical Effectiveness staff will visit practices that they or their immediate family are registered with.

The audit results aim to create practice level information on performance against the criteria. The audit team are **not** attempting to provide a clinical commentary on individual patient's management. In the very unlikely event of the audit revealing a management problem that is an immediate risk to an individual patient the issue of whether the risk is real will be immediately checked with Breathing Space Specialist Respiratory nurse or if she is unavailable with the Public Health Consultant – the issue would then be discussed with the practice.

6. Breathing Space Primary Care Standards

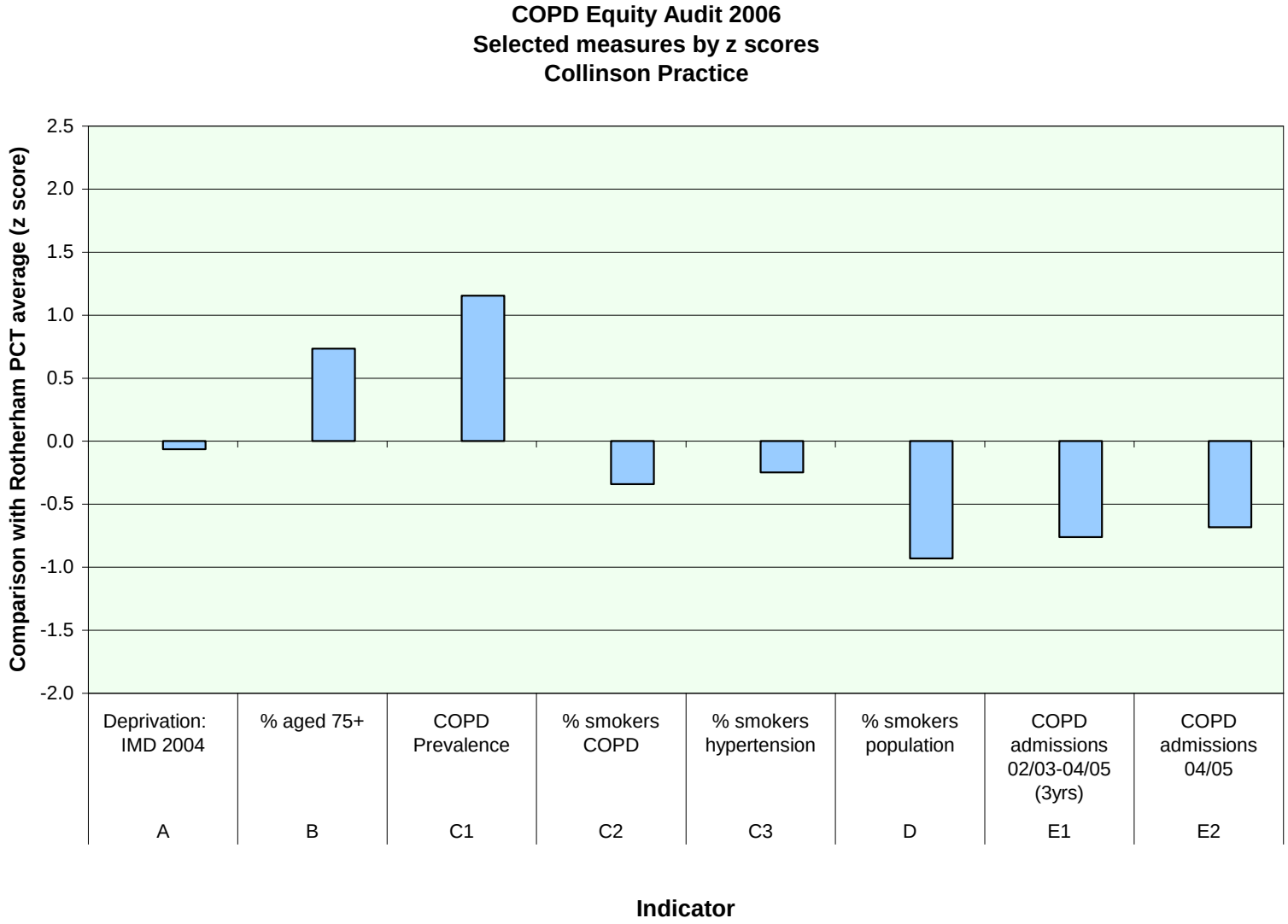
Below are 11 primary care standards that the Breathing Space Programme invites practices to work with us to achieve jointly. The standards are largely derived from the 2005 NICE Guidance together with data recording standards that are necessary if we are going to be able to prove that Breathing Space has made a positive difference to patients and carers with COPD in Rotherham.

By March 2009 we aim to achieve:

1. We will have maximised the number of patients with COPD in Rotherham who have been accurately diagnosed by the active use of spirometry
2. All patients diagnosed with COPD will be accurately categorised into the NICE definitions of mild, moderate and severe airways obstruction.
3. There will be a continuing reduction in the number of COPD patients who smoke.
4. Pulmonary rehabilitation, to the standard provided within the Breathing Space Programme, to be offered to all patients with COPD.
5. Information required for audit will be electronically recorded using standard COPD templates.
6. All exacerbations of COPD will be Read Coded.
7. All patients with COPD will have been given an individualised self-management plan
8. Self management plans for all patients with moderate and severe airways obstruction will include standby antibiotics and steroids.
9. Medicine usage will be appropriate to patient's NICE airways obstruction severity category.
10. All patients with moderate or severe airways obstruction and patients with 2 or more exacerbations in any year should be prescribed inhaled steroids
11. All patients with moderate or severe airways obstruction will have been assessed for oxygen using pulse oximetry.

7. Example of Equity audit data to be shared with practices

The practices QOF attainment for the 8 COPD measures will be discussed as well as the data overleaf



8. BREATHING SPACE COPD PRACTICE LEVEL AUDIT TOOL

Practice: (Main Partner) Branch:

Days of week most convenient for auditing: ..... Contact Person: .....

Will we need to access paper records at each branch for the patient audit? ☐ Yes ☐ No ☐ Practice computer log on codes requested.

A. SPIROMETRY			
1) Does the practice have a Spirometer machine?	☐ Yes	☐ No (G*o to Q5)*	
a) Is the Spirometer model hand held?	☐ Yes	☐ No	
b) What is the Spirometer model?	State:		
2) Is a Spirometer verification check undertaken before each session?	☐ Yes	☐ No *(Go to Q3)*	
a) If Yes, are quality control results of each session recorded in a log book?	☐ Yes	☐ No	
b) What type of verification check is carried out?	☐ Physiological	☐ Physical *(Go to Q3)*	
c) If Physiological, which syringe is used?	☐ 1 Litre	☐ 3 Litre	
d) Has the Syringe been serviced in last 12 months?	☐ Yes	☐ No	
e) What was the Syringe last service date?	Date:		
3) Do you clean the Spirometer after each session?	☐Yes	☐ No	
a) How do you clean the Spirometer:	☐ In Milton for 30 mins	☐ Other state:	
b) Which mouth pieces are used?	☐ Filtered	☐ Non-filtered	
4) Can a hard copy of results be printed on the Spirometer?	☐ Yes	☐ No	
5) Does the practice perform reversibility tests?	☐ Always	☐ Sometimes	☐ Never

NICE	
6) Does practice use NICE definition of mild, moderate or severe for airways obstruction test?	☐ Yes – based on NICE FEV1 ☐ Yes – based on signs and symptoms ☐ No Comments:
7) Does the practice use the MRC Dyspnoea Scale?	☐ Yes ☐ No
8) Does practice prepare the patient prior to spirometry?	☐ Yes ☐ No
TEMPLATES	
9) Does the practice use a COPD template?	☐ Yes ☐ No *(Go to Q10)*
a) If yes, Is it the Rotherham template? *(Show screen shot print)*	☐ Yes (*Go to Q10)* ☐ No
b) If No, would the practice consider changing to the Rotherham template?	☐ Yes ☐ No
SMOKING	
10) Does the practice record pack years?	☐ Yes ☐ No
OXIMETRY	
11) Does the practice have a Pulse Oximeter?	☐ Yes ☐ No
COPD LEADS	
12) Is there a Dr COPD lead for Breathing Space contacts?	☐ Yes ☐ No Name:
13) Is there a Nurse COPD lead for Breathing Space Contacts?	☐ Yes ☐ No Name:
14) Who is the Practice Manager?	Name:
15) Who will be the main contact for Breathing Space?	☐ DR COPD Lead ☐ Nurse COPD Lead ☐ Practice Manager

Practice: (Main Partner) Branch:

Staff Training

16) Please list all staff type that undertaken the following training: ☐ None

Staff type undertaking Spirometry	Training that staff have undertaken	Year training was undertaken	Year last update was undertaken	Training place
☐ GP	☐ Spirometry			☐ Education for Health/NRTC
☐ Practice Nurse	☐ Oximetry			☐ Liverpool/RERTC
☐ Support Worker	☐ COPD Diploma			☐ Liverpool/AMC
	☐ Asthma Diploma			☐ ARTP accredited centre
	☐ ARTP Course			☐ Other state:
	☐ Drug Company			
	☐ Manufacturer			
	☐ Education Health Spirometry Training – 2 days / 3 months			
	☐ Other state:			
	☐ No respiratory training			
☐ GP	☐ Spirometry			☐ Education for Health/NRTC
☐ Practice Nurse	☐ Oximetry			☐ Liverpool/RERTC
☐ Support Worker	☐ COPD Diploma			☐ Liverpool/AMC
	☐ Asthma Diploma			☐ ARTP accredited centre
	☐ ARTP Course			☐ Other state:
	☐ Drug Company			
	☐ Manufacturer			
	☐ Education Health Spirometry Training – 2 days / 3 months			
	☐ Other state:			
	☐ No respiratory training			
☐ GP	☐ Spirometry			☐ Education for Health/NRTC
☐ Practice Nurse	☐ Oximetry			☐ Liverpool/RERTC
☐ Support Worker	☐ COPD Diploma			☐ Liverpool/AMC
	☐ Asthma Diploma			☐ ARTP accredited centre
	☐ ARTP Course			☐ Other state:
	☐ Drug Company			
	☐ Manufacturer			
	☐ Education Health Spirometry Training – 2 days / 3 months			
	☐ Other state:			
	☐ No respiratory training			

If training could be offered, what would you require?

Other comments:

9. BREATHING SPACE COPD PATIENT LEVEL AUDIT TOOL

Practice: Branch:

Patient ID: ..... Age: ..... ☐ Male ☐ Female Date: .....

Is there a diagnosis of COPD? ☐ Yes ☐ No

THE FOLLOWING SECTIONS TO BE COMPLETED FOR ALL PATIENTS WHO ARE ON THE COPD REGISTER

SPIROMETRY	
17) Is there evidence that the patient has ever had Spirometry?	☐ Yes ☐ No *(Go to Q5)* ☐ Patient Exempted *(Go to Q5)*
18) When was the last Spirometry?	☐ ≤ 6 months ☐ ≤ 1 year ☐ ≤ 2 years ☐ > 2 years Date: ..... ☐ Never
19) Where was the Spirometry result recorded?	☐ Fully Computer Coded ☐ Mixed Paper & Computer ☐ Paper Only Including Scanned Graph ☐ Not recorded
a) Please indicate the most recent readings:	FEV1 % predicted ..... & FVC % predicted ..... & FEV1/FVC ..... OR FEV1/FVC% ..... OR FEV1% ..... OR FEV1/FVC Base *(reading off graph)* ..... FEV1 ..... FVC ..... ☐ No readings found
20) Has the Spirometry been recorded as normal?	☐ Yes ☐ No
NICE	
21) Has the COPD been recorded as?	☐ Mild ☐ Moderate ☐ Severe ☐ Not recorded *(Go to Q6)*
a) Where is it recorded?	☐ Computer ☐ GP Paper Record ☐ Hosp Letter
BREATHING SPACE TARGETS	
22) Is the patient a current smoker?	☐ Yes ☐ No *(Go to Q7)*
a) Have they been offered smoking cessation in the last year?	☐ Yes ☐ No

Comments:

THE FOLLOWING SECTIONS TO BE COMPLETED FOR A SAMPLE OF 1 IN 5 PATIENTS WHO ARE ON THE COPD REGISTER

SPIROMETRY	
23) Do the graph curves suggest there may be a problem with the Spirometry technique?	☐ Yes ☐ No ☐ No graph *(Go to Q7c)*
a) Do the records contain a graph which allows detailed verification of readings?	☐ Yes ☐ No *(Go to Q7c)*
b) If Yes to Q7a, are there 3 consistent graph readings?	☐ Yes ☐ No
c) If Yes to Q7b, are there 2 readings within 5%?	☐ Yes ☐ No
24) Has a reversibility test being undertaken?	☐ Yes ☐ No
NICE	
25) Is the recording of Mild, Moderate, Severe accurately categorised?	☐ Yes ☐ No *(Answer based on information collected in the audit)*
BREATHING SPACE TARGETS	
26) Does the patient have a self-management plan recorded:	☐ On computer ☐ In paper record ☐ Neither *(If no, go to Q11)*
a) Does the management plan include:	☐ Antibiotics ☐ Steroids ☐ Neither
EXACERBATION	
27) How many consultations, GP & PN, for all causes, has the patient had in the last 12 months?	State: .....
28) How many exacerbations in last 12 months:	State: .....
29) How many exacerbations in last 12 months were managed by GP / PN without admission?	State: .....
30) How many exacerbations in last 12 months are Read Coded as COPD exacerbation?	State: ..... Emiss/Vision: H3122 or H3y1. TPP: H3122 or Xa351 or H3y0 or X101i
31) How many respiratory related admissions in last 12 months?	State: .....
32) How many respiratory related admissions in the last 12 – 24 months?	State: .....
OXYGEN	
33) Has the patient been assessed using pulse oximetry?	☐ Yes ☐ No *(If no, go to Q18)*
a) If Yes, state result:	☐ ≤ 92% ☐ > 92%

Practice: Branch:

Patient ID: .....

Medicine Management

34) Is the patient on inhaled: ☐ SABA ☐ SA anticholinergic

	Name of Drug	Strength	Frequency	Device
a) If Yes:				

35) Is the patient on a combination Beta Agonist? ☐ Yes ☐ No

	Name of Drug	Strength	Frequency	
a) If Yes:				

36) Is the patient on : ☐ Inhaled steroid ☐ Combination steroid

	Name of Drug	Strength	Frequency	Device
a) If Yes:				

37) Is the patient on inhaled: ☐ LABA ☐ LA anticholinergic

	Name of Drug	Strength	Frequency	Device
b) If Yes:				

38) Is the patient prescribed any form of nebules? ☐ Yes ☐ No

	Name of Drug	Strength	Frequency	
a) If Yes:				

39) What medicines were prescribed for the last 2 exacerbations? ☐ Clinically N/A

	Name of Drug	Strength	Frequency	Date Initiated	No. of Days

40) Is the patient on maintenance Prednisolone? ☐ Yes ☐ No

Comments:

Suggested Actions:

10. QUEST AUDIT CRITERIA

1st Aim: To assist practices in identifying patients who are undiagnosed.

a) Number of people 35 and over.

b) Number of people 35 and over diagnosed with asthma, not diagnosed as COPD.

c) Number of people 35 and over diagnosed with asthma, not diagnosed as COPD with spirometry recorded in last 12 months.

d) Number of people 35 and over diagnosed with asthma, not diagnosed as COPD with no spirometry recorded in last 12 months.

e) Number of people diagnosed with asthma and COPD.

f) Number of people 35 and over not diagnosed as COPD recorded as current smoker.

g) Number of people 35 and over not diagnosed as COPD recorded as current smoker with spirometry recorded in last 12 months.

h) Number of people 35 and over not diagnosed as COPD recorded as current smoker with contraindication for spirometry recorded in last 12 months.

i) Number of people 35 and over not diagnosed as COPD recorded as current smoker with 2 or more chest infections/acute bronchitis/ in last 12 months.

j) Number of people 35 and over not diagnosed as COPD recorded as current smoker with 2 or more chest infections/acute bronchitis in last 12 months with no record of spirometry.

k) Number of people not diagnosed as COPD with spirometry recorded in last 12 months.

2nd Aim: To standardise data recording for patients with COPD

a) Practice population in 10 year age bands. (35 – 44, 45 - 54 etc)

b) Number of people diagnosed with COPD in 10 year age bands.

c) Number of people diagnosed with COPD.

d) Number of people diagnosed with COPD with no severity code.

e) Number of people diagnosed with COPD recorded as mild.

f) Number of people diagnosed with COPD recorded as moderate.

g) Number of people diagnosed with COPD recorded as severe.

h) Number of people who have COPD hospital admission in last 12 months.

i) Number of people who have COPD with no recorded exacerbation in last 12 months who have had hospital admission in last 12 months.

j) Number of people who have COPD with recorded exacerbation in last 12 months with no recorded hospital admission in last 12 months.

k) Number of people currently diagnosed with COPD who smoking status record on 01/05/2006 was current smoker.

l) Number of people currently diagnosed with COPD who smoking status record on 01/05/2006 was current smoker, whose latest smoking status record is current non-smoker\ex-smoker.

Protocol for Breathing Space Patient and Carer Interviews

Appendix 4a

Aim

To use the views of patients and carers to (1) inform the development of the Breathing Space programme and (2) evaluate its success.

Objectives

(1) To use interviews with patients and carers, conducted before Breathing Space becomes operational, to inform the development of the programme, and to provide a baseline assessment of patient and carer views on services for people with COPD in Rotherham.

(2) To use interviews with patients and carers, conducted after Breathing Space becomes operational, to inform the formal evaluation of the programme.

Background

Rotherham's "Breathing Space" programme aims to provide a comprehensive rehabilitation and respite service to people with Chronic Obstructive Pulmonary Disease (COPD) and a comprehensive programme of education for people with COPD, their carers and health professionals. It is hoped that the programme will not only benefit the patients and carers directly accessing the service, but also provide an impetus for system change in COPD care across the whole Rotherham Health Economy.

Approximately £11.7 million of funding has been secured for the construction of a new building and to provide up to two years revenue running costs. The planned opening date is 1st April 2007.

Patients and carers will be interviewed before and after Breathing Space becomes operational. These interviews will contribute both to the development of the programme and to its formal evaluation.

Initial interviews will record experiences of existing services and any perceived gaps prior to the opening of the Breathing Space Programme. A particular focus will be to explore potential barriers to access such as transport difficulties or perceived reluctance of smokers to attend a non-smoking building. The analysis of these data will be used formatively in the development of the programme.

A second sample of patients and carers will be interviewed in 2007 after Breathing Space has been up and running for a period of time in order to investigate the experiences of those who have used the service.

Identification of patients and carers

Protocol for Breathing Space Patient and Carer Interviews

A minimum of fifteen participants will be interviewed before the implantation of Breathing Space, and a minimum of 20 participants afterwards. It is assumed that this number of participants will provide data saturation. If this is not the case further participants will be selected.

The aim is to identify a group of patients and carers who are representative in terms of geographical location within Rotherham, the level of deprivation of the practice they attend, and severity of illness. It is intended that patients will make up approximately two thirds of the sample, and carers the remaining third. In order to ensure this purposive sampling will be used, with carers recruited through patients.

Five practices will be chosen to reflect geographical locations both near and distant from the urban centre of Rotherham. Practices will also be chosen to reflect the range of socioeconomic deprivation as defined by the practice attributed IMD2004 score. A letter will be sent to each practice asking for their consent for an investigator (Dr Hannah Jordan, Specialist Trainee in Public Health) to use the practice COPD register to identify patients for interview. In the event of a particular practice being unwilling to take part another similar practice in terms of geography and location will be selected.

The investigator will select patients from the COPD registers until the required sample is obtained. It is intended that roughly half the sample will have severe COPD and the other half moderate or mild. Once the required number and mix of patients are identified letters (see attached template) will be sent out. The investigator will keep a reserve list of patients to be contacted in those cases where consent for interview is not obtained.

Data collection

Interviews will be semi-structured and tape recorded, and will each last between one and two hours. The attached topic guide will be used for all interviews (see appendix 1).

Follow up interviews will take place with a second group of patients and carers. The decision on the timing of the follow up interviews will be made by January 2007. A second topic guide will be developed for the interviews with patients and carers that will take place after Breathing Space has been implemented. This topic guide will be informed by the results of the analysis of the initial interviews, and by circumstances at the time.

A service user or carer may it distressing to talk about their experience of COPD, or COPD services. Dr Jordan recognises this potential and will conduct all interviews with sensitivity. If in the course of an interview a service user or carer highlights a particular difficulty with a health care service they have used or are using, Dr Jordan will suggest they seek help from the Patient Advice Liaison Service, or the Primary Care or Hospital Public Patient Involvement Forum, as appropriate. The relevant contact details will be provided.

Analysis

All audio taped interviews will be transcribed verbatim. Data will be analysed using Framework Analysis[1]. Analysis will begin following the first interview and proceed iteratively until data saturation is reached. Transcripts will be read and re-read in order to explore and identify themes. The thematic framework will draw upon both an *a priori* conceptualisation of patient experience based on the Picker Institute's eight dimensions (see appendix 2), and any emergent themes from the interviews. Textual data will be coded by theme and entered onto a database. Analysis will also compare any differences in experience between patients and carers, and the extent to which age, sex, smoking status and area of residence influence participant's perceptions.

Resources required

Secretarial time for arranging interview dates and times and sending out letters: 60 hours (assuming 40 interviews, 1.5 hours per interview).

Secretarial time for transcribing interviews: 300 hours (assuming 60 hours of interview time).

Researcher time: 60 hours of interview time + 40 hours travel time + 240 hours analysis time.

Ethics

Patients and carers will be assigned a number and not be identified by name in the analysis or report. Data on age, sex, smoking status and area of residence in Rotherham will be the only demographic data linked to each participant. The report will be in a format similar to "*participant 1 (74 yr old male patient, non-smoker, Maltby) said <quote>*".

Written consent to take part in the evaluation will be obtained from each patient or carer. Before obtaining consent the interviewer will describe the purpose of the study, and the manner in which the data will be analysed and reported. Understanding will be checked and any questions answered.

Data handling

Interview tapes will be kept under lock and key until the end of the evaluation, at which point they will be wiped clean. Paper transcripts will be kept under lock and key until the end of the evaluation, at which point they will be destroyed. Individually identifiable data stored electronically will be password protected and deleted at the end of the evaluation process.

[1] Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In Bryman A, Burgess RG, eds. *Analyzing qualitative data*. London: Routledge, 1994:173-194.

Appendix 1

Topic guide for the before-implementation patient interviews

- **Illness history** (Prompts: "Could you tell me a little about your chest trouble, when did it start?" "How does it affect your life now?" "How does your illness affect your family and friends?")
- **Current services accessed** (Prompts: "Do you have any day to day help because of your illness?" "What's good about this help? – what's not so good?")
- **GP** (Prompts: "How does your GP help you with your chest?" "How do you find this help?" "Do you see a nurse at your GPs' because of your chest?" "How do you find this help?")
- **Outpatient attendance** (Prompts: "Do you see a doctor or nurse at the hospital with your chest?" "How do you find these appointments?")
- **Hospital admissions** (Prompts: "Could you tell me a bit about any stays in hospital because of your chest", "Thinking back to your last stay in hospital – what went well?, what was not so good?")
- **Respite care (**Prompts: "Have you ever used respite care?" "How did you find it?" "What was good about it? What was not so good about it?")
- **Gaps in current services** (Prompts: "Thinking back over what you've been telling me, what could we do better for people in Rotherham with chest problems?" "What is missing in Rotherham for people with chest problems?" "What do you think would help most?" "Why?")
- **[Discuss Breathing Space [*]]**
- **Access to Breathing Space:** (Prompts: "Do you think you would use Breathing Space?" "What sounds good about it for someone like you?" "What sounds not so good?" "What bits of breathing space might you use?" "What would help you to use the Breathing Space services?" "Is there anything that might put you off using a service like Breathing Space?" "How would you feel if the Breathing Space Centre was all non-smoking?")

Topic guide for the before-implementation carer interviews

- **Carer history** (Prompts: "How does caring for your wife's/husband's chest trouble affect your life now?" "How does the illness affect your family and friends?")
- **Support** (Prompts: "What sort of support do you get as a carer?" "Who supports you as a carer?")
- **Respite care** (Prompts: "Have you and the person you care for ever used respite care?" "How did you as a carer find it?" "What was good about it? What was not so good about it?")
- **GP** (Prompts: "How does your GP support you as a carer?" "How do you find this help?")
- **Outpatient attendance** (Prompts: "As a carer what is it like for you when the person you care for attends outpatients" "Why?")

- **Hospital admissions** (Prompts: "As a carer what is it like for you when the person you care for is admitted to hospital" "Why?")
- **Gaps in current services** (Prompts: "Thinking back over what you've been telling me, what could we do better for people in Rotherham with chest problems?" "What is missing in Rotherham for people with chest problems?" "What do you think would help most?" "Why?")
- **[Discuss Breathing Space [*]]**
- **Access to Breathing Space:** (Prompts: "Do you think you or the person you care for would use Breathing Space?" "What sounds good about it for someone like you?" "What sounds not so good?" "What bits of breathing space might you use?" "What would help you to use the Breathing Space services?" "Is there anything that might put you off using a service like Breathing Space?" "How would you feel if the Breathing Space Centre was all non-smoking?")

Discuss Breathing Space – covering each of the following points briefly

- What Breathing Space is: a new service for people with COPD, and their carers
- The purpose of Breathing Space: pulmonary rehabilitation / education for self management / improve the whole system of care for people with COPD
- Who BS will be for: people with COPD and their carers / relatives
- What services BS will provide: 24 hour helpline, respite care, pulmonary rehabilitation programmes, care management
- What pulmonary rehabilitation is
- Where BS will be located: Badsley Moor Lane

Appendix 2

Dimensions of Patient Experience

Adapted from www.pickereurope.org/index.php

- **access** (including time spent waiting)
- **respect** for patients' values, preferences, and expressed needs (including impact of illness and treatment on quality of life, involvement in decision making, dignity, needs and autonomy)
- **co-ordination** and integration of care (including clinical care, ancillary and support services, and 'front-line' care)
- **information** communication, and education (including clinical status, progress and prognosis, processes of care, facilitation of autonomy, self-care and health promotion)
- **physical comfort** (including symptom management, help with activities of daily living, surroundings and home environment)
- **emotional support** and alleviation of fear and anxiety (including clinical status, treatment and prognosis, impact of illness on self and family, financial impact of illness)
- **involvement of family and friends** (including social and emotional support, involvement in decision making, support for caregiving, impact on family dynamics and functioning)
- **transition and continuity** (including information about medication and danger signals to look out for, coordination and discharge planning, clinical, social, physical and financial support).

Protocol for Breathing Space Stakeholder Interviews

Appendix 4b

Aim

To use the views of key stakeholders to (1) inform the development of the Breathing Space programme and (2) evaluate its success.

Objectives

(1) To use interviews with key stakeholders, conducted before Breathing Space becomes operational, to inform the development of the programme.

(2) To use interviews with the same key stakeholders, conducted after Breathing Space becomes operational, to inform the formal evaluation of the programme.

Background

Rotherham's "Breathing Space" programme aims to provide a comprehensive rehabilitation and respite service to people with Chronic Obstructive Pulmonary Disease (COPD) and a comprehensive programme of education for people with COPD, their carers and health professionals. It is hoped that the programme will not only benefit the users and carers directly accessing the service, but also provide an impetus for system change in COPD care across the whole Rotherham Health Economy.

Approximately £11.7 million of funding has been secured for the construction of a new building and to provide up to two years revenue running costs. The planned opening date is 1st April 2007.

Key stakeholders will be interviewed before and after Breathing Space becomes operational. These interviews will contribute both to the development of the programme and to its formal evaluation.

Initial stakeholder interviews will record expectations, hopes and concerns in the months before Breathing Space becomes operational. The analysis of these data will be used formatively in the development of the programme. The same stakeholders will be re-interviewed after Breathing Space has been up and running for a period of time in order to elucidate how attitudes have changed and to describe successes, reasons for successes, problems and learning points.

Identification of stakeholders

Key stakeholders have already been identified by the evaluation team. At present these are roles, rather than individuals.

Chief executives will be asked to nominate a deputy if, for some reason they are unable or unwilling to take part in the evaluation.

Where there is more than one individual who fulfils a role (e.g. GP not directly involved in the project) then an individual will be randomly selected from the PCTs list of such individuals. If, once the individual is contacted, it is discovered that they are already involved in the Programme, or if they decline to be involved in the evaluation, then a second person will be randomly selected and invited, and so on.

Data collection

Initial interviews will be conducted by Dr Mark Strong, Clinical Lecturer in Public Health, with approximately 15 to 20 key stakeholders (see appendix 1). Interviews will be semi-structured and tape recorded, and will each last approximately 1 hour. The same topic guide will be used for all interviews (see appendix 2 for draft topic guide). The attached draft topic guide will be refined after an initial pilot stakeholder interview with Dr Robin Carlisle (Consultant in Public Health at Rotherham PCT with responsibility for the programme evaluation).

Follow up interviews will take place with as many of the stakeholders as possible. The decision on the timing of the follow up interviews will be made by January 2007. A second topic guide will be developed for the interviews with stakeholders that will take place after Breathing Space has been implemented. This topic guide will be informed by the results of the analysis of the initial interviews, and by circumstances at the time.

Analysis

All audio taped interviews will be transcribed verbatim. Data will be analysed using Framework Analysis[1]. Transcripts will be read and re-read in order to explore and identify the themes identified in the topic guide along with any emerging themes. Themes will be coded and entered onto a database. Analysis will compare themes between stakeholders, including the extent to which stakeholder affiliation influences the perception of the new service.

Resources required

Secretarial time for arranging interview dates and times and sending out letters: 40 hours (assuming 20 interviews before implementation and 20 after).

Secretarial time for transcribing interviews: 200 hours (assuming 40 hours of interview time).

Researcher time: 40 hours of interview time + 40 hours travel time + 160 hours analysis time.

Ethics

[1] Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In Bryman A, Burgess RG, eds. *Analyzing qualitative data*. London: Routledge, 1994:173-194.

Individual stakeholders will not be identified by name, but by role. However, given that some of the stakeholders are well known local individuals (e.g. hospital chief executive), their comments will clearly be attributable to them.

Written consent to take part in the evaluation will be obtained from each stakeholder. Before obtaining consent the interviewer will describe the purpose of the study, the manner in which the data will be analysed and reported, and the degree to which responses from individuals will or will not be anonymous.

Data handling

Interview tapes will be kept under lock and key until the end of the evaluation, at which point they will be wiped clean. Paper transcripts will be kept under lock and key for seven years to allow the researchers to reference the original data in the event of a query. After seven years they will be destroyed. Stakeholder identifiable data stored electronically will be password protected and deleted at the end of the evaluation process.

Protocol for Breathing Space Stakeholder Interviews

Appendix 1

List of Key Stakeholders

- Coalfields Regeneration Trust Chief Executive*
- Rotherham PCT Chief Executive
- Rotherham NHS FT Chief Executive
- Rotherham Local Authority Chief Executive
- Rotherham PCT Director of Public Health*
- Director of Rotherham Social Services
- Council Member for local Area Assembly*
- Expert Patient/ Breath Easy group member*
- GP not directly involved with the project
- RGH FT respiratory consultant not directly involved with the project
- Practice nurse not directly involved with the project
- Hospital physiotherapist
- PCT Smoking Cessation Service Manager
- Breathing Space Service Re-design Lead
- District nurse
- Fast response nurse
- Community physiotherapist (or other community based therapist)
- Chair of Professional Executive Committee of PCT

A small number of additional key stakeholders may be identified as a result of interviews with the individuals above.

* Member of Breathing Space Advisory Group

Appendix 2

Topic guide for the before-implementation stakeholder interviews

- What do you know about Breathing Space?
- What do you expect will be the main benefits for the people of Rotherham?
- What will be the most important benefits from your organisation/personal perspective?
- What do you think the main barriers to successful outcomes might be?
- Do you have any concerns about the impact of the programme from an organisational/personal perspective?
- How necessary do you think a building is in order to meet the programme's overall success criteria?
- Do you have any views on whether current NHS changes such as payment by results will impact on this programme?
- What effect do you think Breathing Space will have on equity of access to services for people with COPD?

Appendix 5

Final Protocol for Breathing Space Primary Care Patient Survey

November 2006

(Note this protocol describes the detail of the primary care element of the Breathing Space Evaluation – the background and overall context to the study are in the full protocol).

Research questions:
What is the quality of life of COPD patients in Rotherham and how does it vary with severity of disease.

Rationale:
This element of the evaluation seeks to determine the impact of COPD on the quality of life (QoL) of a random sample of Rotherham residents with mild, moderate and severe COPD. Together with the results of the primary care audit, which will allow us to estimate the number, age and sex distribution of COPD patients, this information can be used to estimate the overall Burden of Disease of COPD in Rotherham specifically in terms of reduced quality of life. This information will be used as a baseline for the cost-effectiveness modelling of the potential impact of Breathing Space interventions.

Information collected from patients who attend Breathing Space programmes will also include detailed information on the impact that their condition has on their quality of life and the severity of their condition. However it is likely that this population will include more of those whose condition is more severe but also those who are more motivated to participate in rehabilitation programmes than the population of Rotherham residents with COPD as a whole. The primary care patient survey is therefore needed to establish the quality of life of the COPD population as a whole. It will be possible to compare the QoL profile of all patients with COPD with the profile of Breathing Space attenders.

Methods:
Information on age, sex and clinical severity will be available from the primary care COPD audit. Permission will be sought from all GPs included in the audit to send a survey instrument to a sample of patients (Appendix 5a). A postal survey including the SF36 will be sent to a stratified sample of patients recorded as have mild, moderate or severe COPD according to the COPD audit (Appendix 5b).

Data collection:

Only the SF36 version 2 (a generic measure to estimate overall impact on quality of life) will be completed to allow overall assessment of the impact of COPD on quality of life.

Since it is likely that quality of life is different, and the impact of Breathing Space different, for individuals classified as having mild, moderate or severe COPD, the questionnaire will be sent by practices to a stratified sample of patients based on disease severity.

The patients with mild/moderate/severe COPD according to BTS criteria will be identified from the primary care audit and questionnaires will be sent out by the PCT (on behalf of practices) to ensure confidentiality is maintained. Practices will be

asked in advance if they are willing for the survey to go ahead and a list of patients who are being mailed will be sent to practices two weeks before the survey to allow practices to exclude any patients they feel would be unduly distressed by the survey (for example patients with terminal illness and families who are recently bereaved). A covering letter addressed from the practice to patients would explain that the purpose of the questionnaire is to understand how COPD/lung disease affects people's everyday life and how new services are best able to make a difference to this. The questionnaires will be coded by severity group (e.g. a different colour sent to patients with a different severity grade) and each will have a unique identifier. Responders will be asked to tick a box IF they are happy for their records to be consulted so that it is possible to match their clinical severity/treatment with their quality of life scores. The covering letter will also include a telephone number for any patient or carer to ring if they have any problems about filling in the form.

Sample size:
To have 80% power to detect an actual clinically significant difference in quality of life of 0.05 (on a 0 to 1 scale) with a p-value of 0.05, assuming a standard deviation of 0.15, would require 92 individuals. We would therefore aim for at least 100 completed questionnaires from patients with mild/moderate/severe COPD respectively. Assuming a response rate of around 30-50%, since this is a relatively elderly and unwell patient group, we would aim to send out a total of around 900 questionnaires, 300 to each severity group. Since there are approximately 5000 people with COPD, and around 350 (7%) of those classified as severe it may be that most practices would need to be asked to send questionnaires to all patients with severe disease, rather than a subset.

Data entry and analysis:
The anonymised questionnaires would be sent to ScHARR for data entry and analysis. Overall quality of life and quality of life for specific SF36 domains will be calculated for different severity categories. The results will be compared to scores obtained from Breathing Space programme attenders.

Use in modelling:
The overall SF36 scores will be used with the primary care audit data to estimate the baseline quality of life for people with COPD in Rotherham and subsequently used to generate a baseline burden of disease analysis.

Appendix 5a: Letter to general practices
Appendix 5b: Covering letter and questionnaire to be sent to COPD patients

Appendix 1: Letter to general practices

Letterhead of Rotherham PCT

Date

Dear Dr …….

Re: Breathing Space COPD Quality of Life Survey

As part of the evaluation of the new Breathing Space service, we are collecting information on the current impact of COPD on the lives of local people. We are doing this through a postal quality of life survey of a random sample of patients on COPD registers. Clinical information on these patients has already been collated for the on-going COPD audit and we are writing to ask for your permission to include a sample of your COPD patients in the survey sample.

The survey has been approved by Rotherham Research Ethics Committee. With your permission we would like to send out the enclosed questionnaire with a covering letter on your behalf. We will confirm the details of the patients in the sample before we mail them to check that we exclude anyone the practice feels it would be inappropriate to send a questionnaire to. Apart from this there will be no workload implications for the practice.

The survey will take place early in 2007. If you are happy with this please could you complete the reply slip?

If you have any questions please contact Julie Booker on ( ) ……..

Dr Robin Carlisle
Consultant in Public Health Medicine, Breathing Space Evaluation & Research Lead

Breathing Space COPD Quality of Life Survey

Practice Name……..

We agree to the inclusion of a random sample of our patients from our COPD register in the Breathing Space COPD Quality of Life Survey

Signed

…… (GP or practice manager, on behalf of practice)

Appendix 2: Covering letter and questionnaire to be sent to COPD patients

Dear ……..

Invitation to take part in the "Breathing Space" survey

Breathing Space is a major new service for people with lung disease in Rotherham opening in April 2007. Our practice is helping Breathing Space to do a survey to understand how people in Rotherham are affected by lung disease. The information from this survey will be used by researchers and health services in Rotherham to better understand the impact that lung conditions have on people's lives and to help us develop the support services that would be most useful to people.

You have been selected because, according to your GP's records, you have a lung condition that may be affecting your daily life.

Your personal details will be kept entirely confidential by the Breathing Space team and the research team will only be given anonymised information that cannot be linked to individuals.

If you have any questions about this survey or require any help filling in the form please contact Ian Baker, Clinical Audit Co-ordinator, Rotherham PCT, Oak House, Moorhead Way, Bramley, Rotherham S66 1YY (01709 302779).

The enclosed leaflet gives some information about plans for the new Breathing Space Programme. If you would like any more information please contact Ian. (A copy of the Breathing Space Programme leaflet will be sent with the questionaire).

Please return your questionnaire in the enclosed postage paid envelope. This does not need a stamp.

Many thanks for your help

(Name of GP if appropriate)

The following questions ask you about your health, how you feel and how well you are able to do your usual activities.

If you are unsure how to answer a question, please give the best answer you can.

OVERALL HEALTH

1. In general, would you say your health is:

(Please circle one number only)

Excellent 1
Very good..... 2
Good..... 3
Fair 4
Poor..... 5

2. Compared to one year ago, how would you rate your health in general now?

(Please circle one number only)

Much better now than one year ago 1
Somewhat better now than one year ago..... 2
About the same as one year ago..... 3
Somewhat worse now than one year ago..... 4
Much worse now than one year ago 5

Please turn the page and continue

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

(Please circle <u>one number on each line</u>)

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking **more than a mile**	1	2	3
h. Walking **several hundred yards**	1	2	3
i. Walking **one hundred yards**	1	2	3
j. Bathing or dressing yourself	1	2	3

Please turn the page and continue

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

(Please circle <u>one number on each line</u>)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the **amount of time** you spent on work or other activities	1	2	3	4	5
b. **Accomplished less** than you would like	1	2	3	4	5
c. Were limited in the **kind** of work or other activities	1	2	3	4	5
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

5. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

(Please circle <u>one number on each line</u>)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the **amount of time** you spent on work or other activities	1	2	3	4	5
b. **Accomplished less** than you would like	1	2	3	4	5
c. Did work or other activities **less carefully than usual**	1	2	3	4	5

6. During the <u>past 4 weeks</u>, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(Please circle <u>one</u> number)

Not at all 1
Slightly 2
Moderately 3
Quite a bit 4
Extremely 5

7. How much <u>bodily</u> pain have you had during <u>the past 4 weeks</u>?

(Please circle <u>one</u> number)

None 1
Very mild 2
Mild 3
Moderate 4
Severe 5
Very severe 6

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

(Please circle <u>one</u> number)

Not at all 1
A little bit 2
Moderately 3
Quite a bit 4
Extremely 5

Please turn the page and continue

YOUR FEELINGS

9. These questions are about how you feel and how things have been with you during the past 4 weeks. (For each question, please give the one answer that comes closest to the way you have been feeling.)

(Please circle one number on each line)

How much of the time during the past 4 weeks:	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt down-hearted and depressed?	1	2	3	4	5
g. Did you feel worn-out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
i. Did you feel tired?	1	2	3	4	5

Please turn the page and continue

HEALTH IN GENERAL

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional</u> problems interfered with your social activities (like visiting friends, relatives etc.)?

(Please circle <u>one</u> number)

All of the time 1
Most of the time..... 2
Some of the time 3
A little of the time..... 4
None of the time..... 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

(Please circle <u>one number on each line</u>)

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

We also wish to examine medical records for information on how severe your condition is and what treatment you are on. Please tick the box below if you are happy to have your medical record consulted.

I give permission to have my medical records consulted ☐

We would also like to interview a few people to gain more detailed information. Please tick this box if you would be happy to talk to a researcher in your home about your health and experience of local health services. We will be able to give you a £10 gift token as a partial compensation for you time if you are selected for this part of the study.

I would be happy to be interviewed by a researcher ☐

Please enter your telephone number if you are happy to be contacted by telephone

Please add any comments on this survey on the box below

THANK YOU!

Please return the questionnaire in the envelope provided – no stamp needed

Appendix 6 Final protocol for data linkage to inform modelling

November 2006

(Note this protocol describes the detail of the data linkage element of the Breathing Space Evaluation – the background and overall context to the study are in the full protocol)

Research Question
What is the current health service utilisation of patients with COPD in Rotherham and how will it change in the future?

Aim
To generate patient specific data on health service activity utilisation to use to predict future trends in health usage of people with COPD in Rotherham to model the cost effectiveness of the Breathing Space Programme.

Objectives
To link data from the 2006 and 2008 Breathing Space COPD audits with other health utilisation data to investigate the use of health services of patients with COPD before and after the Breathing Space Programme opens. The data will be used in anonymised form by ScHARR to generate a model of short and long term impacts of Breathing Space on the health service use by COPD patients.

Background
The 2006 Breathing Space COPD Audit will give a snap shot of the number of people in Rotherham identified with COPD in primary care, their airways obstruction severity category and some primary care activity information. If this audit data is linked with other data on community and secondary health care activity it will be possible to describe the current health service utilisation of people in Rotherham with COPD and model future trends. This will be used to evaluate the impact of Breathing Space but will also produce generalisable information for publication.

Monthly Breathing Space secondary care impact reports give aggregated information on secondary care admissions that are coded as COPD. However there are some doubts about whether these data give a complete picture of the impact of COPD on hospital activity as the data only reflect admissions for Health care Related Groups (HRGs) where COPD is considered the main cause for admission. It is possible that providing better out of hospital support for COPD patients will affect admission rates for episodes where COPD is not coded as the dominant HRG. In addition there are other community and secondary care activities where the reason for contact is not coded by underlying morbidity so it is not possible to describe how much activity is the result of COPD. These include for hospital activity: hospital outpatients, respiratory physiology sessions, hospital based pulmonary rehabilitation. For community activity CARATS and primary care out of hours activity.

It is proposed to perform a data linkage study to look at the total health service utilisation of the 5600 people in Rotherham on GP COPD registers. This will enable us to describe health service utilisation by COPD severity category. Modelling the impact of Breathing Space will be more accurate if the modelling can use individual patient data rather than aggregate data.

Given that data on severity category from the 2006 COPD will not be complete and there are substantial doubts about its accuracy we will perform a pilot study in 2007 on the cohort of patients identified in the 2006 COPD audit (the period of

investigation will be Jan 2006 to Dec 2006). The study will be repeated in 2008 using a cohort selected from the 2008 COPD re-audit. Health service usage for this cohort will be determined retrospectively for 2 years from April 2006 to March 2008 (i.e. the years before and after Breathing Space opens).

The modelling will estimate the total health service utilisation and activity by people with COPD in Rotherham in 2006/7 and 2007/8. This will include comparing the cohort identified by the pilot study with the repeat study to describe changes in activity levels resulting from changes in the numbers of people diagnosed with COPD.

Data to be collected

Numbers of contacts for the 5600 patients (who will be Rotherham responsible patients)

Secondary care

- Hospital admissions: total (all causes) then some sensible subdivisions e.g. Medical/ respiratory/COPD HRGS as defined in Adams reports)
- Bed days: total and some subdivisions
- Outpatients: total/ medical/ first contacts – follow up
- RFT Respiratory physiology contacts:
- RFT Pulmonary rehabilitation contacts:

Community care

- CARATS: total and subdivisions if possible
- GP OOH: to investigate whether this is possible
- Dynamic Case manager/ Community matron contacts

Time frame

2007 Pilot

Data collection on the 2006 COPD Audit will be complete by the end of 2006. The data collection on health service activity will take place in Jan 2007 and will include contacts between from Jan to Dec 2006. This data will be used mainly to pilot a more accurate study the following year but it will be informative to compare the total health service activity for this cohort of patients with the aggregate COPD activity data in Breathing Space monthly impact reports.

2008 data linkage

The 2008 COPD audit will be completed by June 2008. Data collection will be carried out in July 2008 and be a retrospective analysis of heath utilisation by severity category for 2 time periods April to March 2006/7 and 7/8. The main sampling frame for data linkage will be those patients and their severity category diagnosed with COPD in the 2007/8 audit. However the modelling will give a whole system impact and will take account of the health utilisation of people diagnosed with COPD in 2006/7 who have since moved away or died. The modelling work will be completed and a report written by December 2008. At that time it will be decided whether to repeat the data extraction in April 2008 to produce a third year of data for a final report in June 2009.

Who will handle what data?

COPD audit team

The PCT audit team with help form Breathing Space have carried out the COPD audit. The audit protocol has been approved by the PCT Professional Executive and

is subject to the PCTs normal information governance protocols. The data is stored at Oak House. Patients are identified by GP computer number which is only identifiable in practices. The audit team has a conversion file to enable the GP computer number to be linked to NHS number but this will only be used if this study is given ethical approval.

PCT FACT Team
If ethical approval is given the Clinical audit team will provide a list of approximately 5600 NHS numbers of COPD patients to the PCT FACT team who will extract data from data they have routine access to and possibly by asking RNHSFT to provide some data. The FACT team will give the data back to the Clinical Audit Team who will merge the data with data form the COPD audit and then take of the NHS number.

ScHARR
No data that is sent out of the PCT will be identifiable. ScHARR will receive files with COPD severity category, primary care activity, secondary care activity and smoking status. This will be used to construct a model of total health service activity for COPD describing the situation in 2006/7 and 2007/8 and predicting future trends.

Ethical considerations
The protocol has been approved in principle by the PCT Caldicott guardian. The protocol does not involve any staff having access to any data that is anymore sensitive than they have access to routinely (i.e. audit staff having data for audit purposes data, PCT information staff having patient data for contact payment purposes). Data that is handled by ScHARR outside the PCT for evaluation and research purposes will be fully anonymised.

There have been arguments that the secondary use of data that is collected for another purpose is unethical without prior consent of each individual to use the data for the additional purpose. However recent BMJ papers have pointed out that 'the data protection act, the human rights act and common law are not insurmountable obstacle to the secondary use of data without explicit consent'.[1]

In this study it is ethical to perform the data linkage and subsequent anonymous modelling because there is has a clear public health benefit (understanding the health impact of COPD in Rotherham and the impact of the Breathing Space Programme in a much more accurate way than can be achieved from using aggregate data), there are minimal risks of confidentially being breached and it is not practical to contact all 5600 patients for permission to use the data.

[1] Souhami R. BMJ 2006 333 315-6

Appendix 7:

List of key data items that should be collected from BS contacts (list from ScHARR 4 October 2006).

1. Information from initial referral - if from primary care it would be very useful if information included whether patient coded by practices as mild, moderate or severe COPD (is there a "diagnosis" field?). We could be criticised for assuming we can extrapolate from BS attendees to the population as a whole if we do not know how the patients seen relate to the COPD population as a whole. If it turns out that the primary care diagnosis is a reasonable predictor of the diagnosis made at baseline assessment, we can justify this, if not we can potentially adjust for GPs over/underestimating severity.

2. Information at baseline
Main priority is SF36 and clinical severity (mild/moderate/severe COPD) so can estimate how representative BS patients are.

Social care and home care over the previous 6 months (I suspect it is unreasonable to expect them to recall the previous 12 months which would be ideal otherwise because we then would not need to worry about seasonal variation in support needs ie greater in winter). Key items would be:
Nursing home admissions (number and duration) Residential home admissions (number and duration) Day care centre attendance (frequency) Routine home care (frequency of visits and who by - include nursing, personal care, social worker, meals on wheels, home help etc) Acute homecare (CARATS)

3. Followup data - it would be most helpful to know how SF36 changes over time post-rehabillitation and this could be self completion at eg post-rehab, 3 mths, 6 months and 12 months - or at minimum post-rehab and at 12 months.

4. Smoking status at first contact and follow up

Appendix 8: List of comparative data to be requested from Doncaster and Barnsley

- COPD standardised mortality
- 8 COPD QOF measures – which will include QOF COPD prevalence and the smoking rate in people with COPD
- All medical admission rates
- COPD HRG admission rates i.e. using all HRG D39 and D40 plus D99 where primary diagnosis is J40-44
- COPD HRG length of stay
- COPD HRG 14 and 28 day re-admission rates

These data to be requested for 2004/05, 2005/06.

We will subsequently ask for the same data for 2006/7 and 2007/8.