

**LOCAL ENHANCED SERVICE
for
Spirometry Testing**

(Cannock Chase Commissioning Consortium)

Service Level Agreement

Contents:

1. Introduction
2. Service Aims
3. Service Outline
4. Criteria
 1. Direct Service Delivery
 2. The development and maintenance of a register and records
 3. Liaison/Shared Care
 4. Education and Training
 5. Quality Assurance
 6. Review/Audit
5. Ongoing Measurement & Evaluation
6. Finance Details
7. Signature
8. Appendices:
 1. Professional Accreditation for Spirometry Testing
 2. Criteria for use of Spirometric Testing
 3. Maintenance and Calibration
 4. Spirometry Equipment

INTRODUCTION

All practices are expected to provide essential services and those additional services they are contracted to provide to all their patients. They are also encouraged to provide the Directed, National and Local Enhanced services to the populations they serve. The specification for this service is designed to cover the enhanced aspects of clinical care of the patient, which is beyond the scope of essential services.

This document outlines the Local Enhanced Service (LES) specification for primary care spirometry testing, for the care of patients registered with GPs within the Cannock Chase locality of the Primary Care Trust. It is intended to support Chronic Obstructive Pulmonary Disease (COPD) management and patient care and treatment in line with current national guidelines, British Thoracic Society (BTS) and National Institute of Clinical Excellence (NICE).

Procedures in this specification are generic to all staff involved in the care of patients requiring spirometry.

SPIROMETRY: Provides an objective measurement of lung function. Spirometry measures timed expired and inspired volumes from maximum inhalation to maximum exhalation, hence indicating how quickly and effectively the lungs can be emptied and filled. By using spirometry to assess lung function it is possible to diagnose COPD and asthma with greater confidence and accuracy. Spirometry is vital for assessing the severity of COPD.

SERVICE AIMS

This agreement is to cover the period commencing 1st April 2009 to the 31st March 2010.

This Local Enhanced Spirometry Service is designed to enable:

- (i) diagnosis
- (ii) monitoring of COPD and Asthma
- (iii) convenience for the patient
- (iv) consistency with the core GMS2 commitment of treating long term conditions in primary care
- (v) quality assurance

SERVICE OUTLINE

The spirometry service provided will meet the following criteria/standards:

- The patient should meet the defined criteria for spirometry testing as indicated in this proposal (Appendix 2)
- Spirometry equipment must be cleaned and calibrated in accordance with BTS guidelines
- Staff performing spirometry must be trained to recommended standards (Appendix 1)
- Staff interpreting Spirometry results must be accredited
- Practices should adhere to a minimum time standard for spirometry with reversibility of 30 minutes (GMS2 criteria) for diagnosis of COPD and 15 minutes for screening
- Be integral to the management of COPD and Asthma in compliance with national guidelines

CRITERIA

This Local Enhanced Service Specification details the following criteria. The following pages contain further guidance from the PCT on expected processes, outcomes and deliverables based on this process. On aspiring to this service practices are required to submit plans under each of these items to the PCT.

- 1 Direct Service Delivery
- 2 The development and maintenance of a register and records
- 3 Liaison/Shared Care
- 4 Education and training
- 5 Quality Assurance
- 6 Review/Audit

Criteria One: Direct Service Delivery

Details

- To ensure that an appropriate review of the patient's health is carried out including checks for potential complications, that the patient is safe to undergo the test, that there is nothing to erroneously affect results and prior to each test being carried out the patient is prepared
- Clear instructions must be forwarded to patients who will be attending for spirometry testing e.g. inhaler advice, clinically stable, loose clothing etc.
- To ensure that a technically acceptable test is achieved (Appendix 2)
- All tests must be interpreted by a competent clinician (Appendix 2)
- To ensure results of patients diagnosed with COPD are classified and recorded as mild moderate or severe
- Medication is prescribed and administered appropriately e.g. patient group direction
- To ensure that all clinical information related to the patient's spirometry test is recorded in feedback to the patient's own GP
- To ensure that an emergency procedure protocol is in place for patients who develop complications
- The service will provide patients requiring spirometry with reversibility testing or annual spirometry for monitoring of COPD patients

Criteria Two: The development and maintenance of a register and records

Details

- The development and maintenance of a register. Practices must be able to produce an up-to-date register of patients including:
 - patient demographics
 - the number of patients who have received spirometry testing, including reversibility if carried out
 - the number of tests undertaken
 - the number of tests undertaken for other GP practices
 - test results and outcomes
 - medication administered i.e. drug and dose
 - untoward incidents

The PCT may request to see the register.

- To ensure systematic call and recall of patients on the register for annual follow up of COPD patients
- Up to date records of cleaning, calibration and maintenance of equipment
- To provide full details to other practices when their registered patients are treated under this scheme.

Criteria Three: Liaison/Shared Care

Details

To work together with other professionals when appropriate

Criteria Four: Education and Training

Details

- Professionals undertaking this service should have undertaken **appropriate training**. (Appendix 1)
- Clinicians who have previously provided services similar to the proposed enhanced service and satisfy the PCT at appraisal and revalidation, that their continuing medical experience, training and competence enables them to contract for this LES will be deemed professionally qualified, provided they attend top up training for one day eg the National Respiratory Training Centre (NRTC) 1 Day Spirometry Workshop

Criteria Five: Quality Assurance

Details

- Professionals undertaking this service have responsibility to ensure that equipment standards are maintained, including calibration and regular cleaning according to manufacturers instructions and BTS Guidelines.
- Professionals should always record spirometry with the patient in the same position – sitting is safer (Appendix2)
- Staff involved in carrying out spirometry testing and interpretation of results should undertake a minimum of 50 per year in order to sustain competence
- A single disposal mouthpiece must be used for each patient. If a single disposal mouthpiece is fitted ensure that it has a one way valve

Criteria Six: Review/Audit

Details

- To carry out clinical audit of the standard of testing against the above criteria, including untoward incidents
- All practices involved in this service should perform an annual review to include:
 - number of patients on the spirometry register
 - number of tests performed
 - number of tests provided to other practices
 - information on patients tested
 - details on the arrangements for testing
 - details of training and education received by practitioners
 - details of the standards of calibration and maintenance of Spirometers
- The services delivered by this LES will be subject to monitoring. Monitoring will be carried out as part of the contract monitoring process.

ONGOING MEASUREMENT & EVALUATION

The ongoing measurement is outlined in the various criteria in the previous section. The services provided and scope of this LES will be reviewed with the practice as part of the half yearly contract monitoring process.

In addition the practice is required to agree with the PCT this service specification/plan at the start of the year.

This service level agreement will be reviewed annually as a minimum standard however alterations to the document may take place, to reflect new guidelines, respond to audit results or to comply with local needs, as and when required.

FINANCE

This agreement is to cover a 12 month period commencing 1st April 2008.

On agreeing a service plan with the PCT the practice will receive per patient per annum:

- Provision 1 Practice Based Spirometry for registered patient, **£12.18 per test**
- Provision 2 Practice Based Spirometry for registered patient including reversibility testing, **£25.38 per test**
- Provision 3 Practice Based Spirometry for non-registered patient, **£25.38 per test**
- Provision 4 Practice Based Spirometry for non-registered patient, including reversibility testing **£50.75 per test**

The fee is payable to the provider undertaking the spirometry test.

PAYMENT WILL ONLY BE MADE UPON RECEIPT OF THE PRACTICE SIGNATURE SHEET

SIGNATURE

The practice will need to sign a combined single signature sheet for all Enhanced Services provided. This will constitute the agreement between the practice and the PCT in respect of all Enhanced Service, as specified within each individual Service Level Agreement.

Appendix 1 – Professional Accreditation for use of Spirometry

Persons who perform spirometry will have completed an approved competency based training course in Spirometry and will select typical courses as below, dependent on current level of competence/training to date:

- ❑ Gold Standard ARTB/RB certificate in Spirometry 2 day course on COPD and Spirometry
- ❑ National Respiratory Training Centre (NRTC) 1 Day Spirometry Workshop
- ❑ NRTC Distance Learning Course
- ❑ Warwick Certificate in COPD - Distance Learning, examination, assignment (course attracts CPT points)
- ❑ Staffordshire University – Respiratory Disease Course (includes COPD and Spirometry training) – attracts CPT points

Ongoing quality assurance within practices

- ❑ Staff performing spirometry will be required to perform a minimum of 50 spirometric tests per year to ensure maintenance of skills in administration, interpretation and reporting
- ❑ Random assessment of spirometry administration, interpretation and reporting may be conducted. This will include checking of previous spirometry tracings and spirometry equipment

Appendix 2 – Criteria for Spirometry Testing

Who will Require Spirometry

The new GMS contract asks practices to screen people for COPD if they are:

- ❑ aged 35 or over
- ❑ have a history of/or currently smoke and have a cough
- ❑ are breathless

Spirometry should also be considered in patients with breathlessness of uncertain diagnosis or Chronic Bronchitis where significant numbers will go on to develop air flow limitation.

Aim

- ❑ For all spirometry to be performed safely and effectively
- ❑ Spirometry performed pre and post any reversibility tests
- ❑ Spirometry to be performed on initial assessment and then annually for COPD patients

Patient Safety

- ❑ All patients must be well and have no evidence of infection
- ❑ The patient should be clinically stable (ie at least four weeks should have elapsed since the last exacerbation)
- ❑ Verbal consent must be obtained
- ❑ Ensure the patient:
 - Has not had a bronchodilator (no beta-agonist or anticholinergic inhaler) for 6 hours prior to the test if reversibility test is to be carried out
 - Not had a large meal 2-3 hours prior to testing
 - Not had any alcohol
 - Is not wearing restrictive clothing
 - Remove any loose fitting dentures or chewing gum
 - Has had no eye or abdominal surgery within past 3 months
 - Has not had an MI, CVA or cardiovascular event within past 3 months
 - Has had no complaints of chest pain within last 48 hours
 - Ideally should not have smoked for 24 hours
- ❑ Proceed with test once patient safety is determined

Procedure

- ❑ Check patients height, weight and record with gender and ethnic origin
- ❑ Ensure patient is comfortable, and sitting in an upright position in a chair with arms (not standing, because there is a potential risk of feeling faint or dizzy, especially after repeated blows)
- ❑ Advise patient of what is expected – instruct not to lean forward
- ❑ Explain and demonstrate the technique to the patient
- ❑ Ensure new mouthpiece is used

- ❑ Record 2 relaxed vital capacity (RVC) measurements – should be done with patient pinching their nose to prevent air escaping
- ❑ Record at least 3 forced vital capacity (FVC) measurements ensuring a tight seal around mouthpiece instructing patient to blow out hard, as fast and as long as they can (with lots of encouragement)
- ❑ Ensure minimum 30 seconds between each blow
- ❑ Ensure variability between the FVC is +/- 5% or 0.1L (whichever is greater) - if not then further attempts can be made up to a maximum of 8
- ❑ Print and photocopy all recordings as thermal paper will fade in time
- ❑ Any variations should be documented on tracing and recorded in file (e.g. time of last inhaler/ cigarette/ reason test stopped)
- ❑ Patients should be warned that following testing they might experience some of the following side effects: headaches, palpitations, tachycardia and tremor

Errors in spirometric testing

- ❑ Poor seal around the mouthpiece
- ❑ Poor intake of breath
- ❑ Poor forced expiratory effort
- ❑ Coughing during procedure
- ❑ Incorrect data entered into spirometer prior to testing

Reversibility testing

CLINICAL USE

To make differential diagnosis between COPD and Asthma
To determine if airways disease is reversible

EXCLUDED PATIENTS

When pre-test results are not valid

Use of Short acting bronchodilator within past 4 hours

Those where spirometry is contraindicated

- ❑ MI or CVA within past 3 months
- ❑ Eye or abdominal surgery within past 3 months
- ❑ Evidence of infection

MEDICATION, DOSAGE AND ROUTE OF ADMINISTRATION

Salbutamol 400-600mcgs via metered dose inhaler and spacer device

Period of 15 minutes allowed before spirometry repeated

Emergency access to a telephone must be available prior to administration

Resuscitation equipment must be on site

DOCUMENTATION

Drug and dose administered, documented in notes

Date and time recorded and entry signed

Coding COPD patients air flow obstruction into, mild, moderate and severe as per NICE guidelines

Appendix 3 – Criteria for Maintenance & Calibration of Spirometry Equipment

A correctly calibrated spirometer is the only means of accurate, reliable and safe measurement. Failure to use appropriately calibrated, prepared equipment could possibly lead to incorrect diagnosis.

It is essential that individual manufacturers instructions are followed in accordance with NICE guidelines. The Micro-medical is used as an example of minimal cleaning.

MICROMEDICAL 3500

DAILY CLEANING

After each patient, the mouthpiece holder is cleaned using an alcohol wipe.

WEEKLY CLEANING

The turbine is removed and washed in warm soapy water, rinsed and left to air dry.

The turbine holder is gently cleansed with an alcohol wipe.

The keypad is gently cleaned using a damp cloth.

Quality Control

- Spirometer must be cleaned and maintained as per manufacturers instructions plus annual servicing
- Calibration (volume devices weekly and flow devices daily, with a 3 litre syringe)
- Should produce a hard copy which should be large enough to check values manually
- Volume/time plots are mandatory, flow/volume plots are optional
- Adequately trained staff are essential if inaccurate or misleading results are to be avoided
- Electronic devices without hard copy tracing may lead to underestimation of FEV1 and FVC because it is not possible to verify the reliability of the test (best achieved by looking at shape of graph)
- Verification of the equipment carried out monthly
- Cleaning and verification documented and records kept with equipment
- New mouthpiece for each patient
- Perform spirometry at room temperature (ideally 20-25°C)

General Maintenance

- Avoid exposure to direct sunlight during use

- A full service manual including parts list is available from the manufacturers on request

IN THE EVENT OF SUSPECTED TB EXPOSURE

Cease using all equipment

Use protective clothing – masks, gloves and apron

Place exposed equipment parts in “high risk” bags and label

After cleaning and checked for TB – take swabs of the equipment

Commence using the equipment only when all clear given in writing

Liaise with TB Nurse

Appendix 4 - Spirometry Equipment

Although not prescriptive the following information may be taken into consideration before purchasing new equipment.

All protocols should be based On the Guidelines for the Measurement of Respiratory Function (ARTP/BTS), Respiratory Medicine (1994) 88, 165 - 194
The contact details for the ARTP are www.artp.org.uk

The gold standard are the pneumotach devices such as the Alpha III and Vitalograph 2120.

The most widely used spirometers in primary care are: MicroMedical Microlab, Vitalograph Alpha and Vitalograph 2120. A new kid on the block is the KoKo legend.

Microlab is a nice compact spirometer with good software and relatively easy to use. Tests can be downloaded to a computer (software price extra) to give an A4 printout which you can type a report on this can be picked up by emist etc as a word document. Total price about £1,400.

Vitalograph, although the flow head is a very accurate device it drifts easily (because of moisture in the flow head). Software of the alpha is inflexible and the 2010 you cannot see what the attempt looks like until you print it out (a distinct disadvantage). Alpha £1,250, 2120 £2200 with base station. Or £1,430 without.

KoKo has a large colour screen, all attempts are shown on the screen and you can get rid of poor attempts (even after you have performed other attempts). It has a good flow head. It also has software that you can download. Cost £995 + £50 for software.

Others to consider are the MIR (they do a range but recommend spirometers where the attempt can be seen live on the screen) and Jaeger Flowscreen. There are many more at the price of around £1,000- £1,500 but none of them are perfect.

"turbine" method of measurement tend to overread.

A calibration syringe is needed despite what some of the manufacturers say.