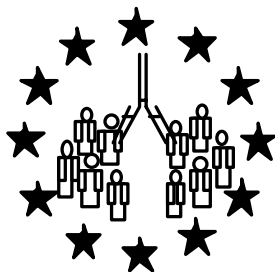


THE EUROPEAN COMMUNITY RESPIRATORY HEALTH SURVEY II



ECRHS II

LUNG FUNCTION PROTOCOL, DATA SHEETS AND LUNG FUNCTION QUESTIONNAIRE

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www.ecrhs.org



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LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

LUNG FUNCTION TESTS

CRITERIA FOR TESTING

Criteria for baseline spirometry

The purpose of baseline spirometry is to record an accurate Forced Expiratory Volume in one second (FEV₁) and Forced Vital Capacity (FVC) from every subject who attends the testing centre.

ACCEPTANCE CRITERIA:

Any subject who is able to attend the testing centre.

EXCLUSION CRITERIA:

If the subject smokes: Lung function testing should be carried out at least one hour after the last cigarette has been smoked.

If the subject has used an inhaler: Lung function testing should be carried out at least one hour after the use of any inhaler.

If the subject has used an inhaler that is not a beta-2-agonist or an anticholinergic inhaler in the last one to four hours: Lung function testing is carried out and the data recorded.

If the subject has used an inhaler that is a long acting Beta-2-agonist in the last 8 hours: If the subject is willing to come back at another time when they have not taken their long acting Beta-2-agonist, another appointment should be made. HOWEVER – this may be difficult for them to do, in which case, testing should proceed and medication used should be recorded.

If the subject has used an inhaler that is a beta-2-agonist or an anticholinergic inhaler in the last one to four hours: If the subject is willing to come back another time for lung function testing, another appointment should be made. If the subject is unable or reluctant to return another time, testing should proceed and the medication used should be recorded.

If the subject has taken an oral beta-2-agonist or an oral theophylline or an oral antimuscarinic within the last eight hours: If the subject is willing to come back another time for lung function testing, another appointment should be made. If the subject is unable or reluctant to return another time, testing should proceed and the medication used recorded.

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If the subject has had a respiratory tract infection in the last three weeks: Another appointment should be made unless the subject is unwilling to come back, in which case testing should continue. The number of days elapsed since the end of the respiratory infection should be recorded.

If, after a total of nine attempts, a subject is unable to produce a technically satisfactory manoeuvre, no FEV₁ or FVC will be recorded.

Predicted FEV₁ values

Normal FEV₁ values will be calculated using the following equations:

Males: $4.30 H - 0.029 A - 2.49$

Females: $3.95 H - 0.025 A - 2.60$

where

H = height in metres

A = age in years (range 25-44).

These equations are only valid for subjects over the age of 25. Subjects aged 20-24 should have their expected FEV₁ calculated as if their age is 25.

Criteria for methacholine challenge

The aim of methacholine challenge is for subjects to inhale increasing concentrations of methacholine solutions and to monitor any change in FEV₁ by repeated spirometric testing.

ACCEPTANCE CRITERIA: Any subject who fulfils all three of the following criteria is accepted:

- 1) has been able to perform at least 2 technically satisfactory manoeuvres during baseline spirometry
- 2) has signed a consent form for methacholine challenge,
- 3) is not in the categories for exclusion (see below).

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EXCLUSION CRITERIA: Any subject who fulfils any one of the following criteria is excluded from methacholine challenge:

- 1) has had a heart attack in the last three months,
- 2) has any heart disease for which he/she is taking medication,
- 3) has epilepsy for which he/she is taking medication,
- 4) is pregnant,
- 5) is breast feeding,
- 6) is taking a beta-blocker for any reason (including eye drops).

These criteria will be assessed by the Lung Function Questionnaire.

In addition, any subject who fulfils either of the following is excluded:

- 7) has an FEV₁ less than 70% of the predicted value,
- 8) has an FEV₁ less than 1.5 litres.

FEV₁ is the maximum assessed during the baseline spirometry.

Criteria for bronchodilator challenge

The FEV₁ and FVC will be measured following the administration of 400ug salbutamol by metered dose inhaler (MDI) via a Volumatic spacer.

ACCEPTANCE CRITERIA: Any subject who fulfils all of the following criteria is accepted:

- 1) has produced technically satisfactory FEV₁ and FVC manoeuvres,
- 2) refuses to undergo or is excluded from methacholine challenge,
- 3) has signed a consent form for bronchodilator challenge,
- 4) is not excluded by the following exclusion criteria.

EXCLUSION CRITERIA: Any subject who fulfils any one of the following criteria is excluded:

- 1) has had a heart attack in the last three months,
- 2) has any heart disease for which he/she is taking medication,
- 3) has epilepsy for which he/she is taking medication,
- 4) is pregnant,
- 5) is breast feeding,
- 6) is taking a beta-blocker for any reason (including eye drops).

These conditions will be assessed by the Lung Function Questionnaire.

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Making the appointment for testing

Ideally, lung function testing should be performed:

- 1) more than four hours after the use of a beta-2-agonist or anticholinergic inhaler,
- 2) more than eight hours after inhaled long acting beta-2-agonist, oral beta-2-agonist or theophylline or oral antimuscarinic.

When the appointment for lung function testing is made the fieldworker should determine if the subject is taking any of the following medications:

- 1) beta-2-agonist inhaler (short or long acting),
- 2) anticholinergic inhaler,
- 3) oral beta-2-agonist,
- 4) oral theophylline,
- 5) oral antimuscarinic.

If the subject is taking any of these medications (or any other inhaler) an appointment time should be agreed that will cause the least disruption to the subject's normal dosing schedule.

One simple way of ensuring compliance with these instructions is to:

- 1) avoid early morning appointments for those using inhalers,
- 2) fix a time for an appointment and then ask the subject to take their inhalers four hours before and oral medication eight hours before testing. Ask them to avoid taking their long acting beta-2-agonist if possible.

The fieldworker should ensure that the subject has not had a respiratory tract infection in the three weeks prior to testing and should advise the subject not to smoke for one hour prior to coming to the testing centre. A letter should be sent to the subject explaining this.

Subjects who have not followed guidelines

Those who have had a cigarette in the last hour should have the lung function test delayed until one hour has elapsed. (Most subjects will be in the centre for at least one hour.)

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Those who have had an inhaler in the last four hours or oral medication (or long acting beta-2-agonist) in the last eight hours may fall into one or more of the following categories:

- 1) misunderstood the instructions,
- 2) forgot the instructions,
- 3) ignored the instructions,
- 4) may have symptoms too severe to follow the instructions.

Lung function testing may still be carried out unless the subject is excluded for other reasons, and recent medication should be noted in the Lung Function Questionnaire.

THE FORCED EXPIRATORY MANOEUVRE

General guidelines

All forced expiratory manoeuvres will be performed:

- 1) sitting, legs uncrossed
- 2) with noseclip on,
- 3) using a plastic or cardboard mouthpiece without teethgrips,
- 4) tight clothing should be loosened.

Two types of forced expiratory manoeuvre will be used in this protocol:

- 1) During baseline spirometry and bronchodilator challenge FVC will be measured and all subjects must exhale fully.
- 2) During methacholine challenge only the FEV₁ needs to be recorded and the technician may interrupt the exhalation when this has been achieved.

A technically unsatisfactory manoeuvre (FEV₁ or FVC) is defined as:

- 1) an unsatisfactory start of expiration characterised by excessive hesitation or false start
- 2) coughing during the first second of the manoeuvre, thereby affecting the measured FEV₁ value, or any cough that interferes with the accurate measurement of FVC
- 3) Valsalva Manoeuvre (glottis closure)
- 4) A leak in the system or around the mouthpiece
- 5) An obstructed mouthpiece, e.g. the tongue in front of the mouthpiece.

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Manoeuvres which have these faults are technically unsatisfactory and are rejected as failed attempts.

Evidence of poor compliance is shown by:

- 1) greater than 200ml (NB in ERCHS I this was 5%, this has been changed in line with current ATS criteria) variation in FEV₁ between blows
- 2) greater than 150 mL or 5% FVC back-extrapolated volume
- 3) peak expiratory flow that is less than 85% of the best record
- 4) expiratory time that is less than six seconds

If these features are noted technicians should encourage the subject to produce a better reading but the blows should not be excluded as failed attempts on these criteria alone.

A manoeuvre may only be rejected as a failed attempt if it is 'technically unsatisfactory'. Manoeuvres with evidence of 'poor compliance' only should not be rejected.

The above protocol is consistent with current ATS guidelines (Am J Respir Crit Care Med 1995;152:1107-1136). These state that 'The only criterion for unacceptable performance is fewer than two acceptable curves. No spirogram should be rejected solely on the basis of its poor reproducibility.....elimination of data from subjects who fail to meet ATS reproducibility criteria may result in population bias by excluding subjects who have abnormal lung function'

Instructions to subjects

Some of the subjects will never have used any form of lung function testing equipment before and others will be very familiar with it.

Technicians should explain to the subject that the aim of the test is to find out how much air can be blown out of the lungs and how forcefully it can be blown out.

This can be done by asking the subject to follow these steps:

- 1) Take in as deep breath as possible when full-
- 2) Place the mouthpiece in his/her mouth.
- 3) Close his/her lips tightly around the mouthpiece.
- 4) Blast or blow through the mouthpiece into the spirometer, blowing air out as hard, fast, smoothly and completely as possible.

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The subject should continue to push out air actively for as long as possible (FVC manoeuvre) or until the technician tells him/her to stop (FEV₁ manoeuvre). During this time the technician must offer positive encouragement to push or squeeze out more air.

Baseline spirometry

- 1) Ensure that it is appropriate to perform lung function testing.
- 2) Demonstrate the manoeuvre to all subjects at least once (more often if he/she appears uncertain).
- 3) Ask the subject to carry out five FVC manoeuvres.
- 4) Record the FEV₁ and FVC and Peak Expiratory Flow (in litres per second) from at least two and up to five technically satisfactory manoeuvres.
- 5) If the subject has failed to produce two technically satisfactory manoeuvres after five attempts, the technician should show them again how to conduct the manoeuvre and allow them four more attempts.
- 6) Any subject who is unable to produce two technically satisfactory manoeuvres after nine attempts should not be tested further and no FEV₁ / FVC data should be recorded.
- 7) The number of rejected attempts should be recorded as appropriate on the Lung Function Data Collection Sheet.

Methacholine challenge

During methacholine challenge the subject may need to perform 30 or more expiratory manoeuvres and, to minimise exhaustion, the forced expiration will be abandoned each time after one second when the FEV₁ has been recorded.

- 1) Two minutes after inhalation from the dosimeter up to five attempts should be made to record an FEV₁
- 2) As soon as two technically satisfactory manoeuvres have been achieved these readings are recorded. The next dose can be given as soon as possible after the completion of these measurements.
- 3) Further testing should be abandoned if the subject is unable to produce two technically satisfactory manoeuvres within five attempts.

If a reversal of bronchoconstriction needs to be carried out then the procedure is the same as the bronchodilator challenge.

Bronchodilator challenge

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A bronchodilator challenge will be given to those who do not undergo methacholine challenge. Any subject who has more than a 10% fall in FEV₁ from baseline during the methacholine challenge test should have their bronchoconstriction reversed at the end of the test and before leaving the test centre, by the same method.

The salbutamol inhaler should be shaken and inserted into the volumatic. One puff should be activated and the subject asked to place their lips around the volumatic and to inhale and exhale five times. The salbutamol inhaler should be activated again and five inhalations/exhalations performed. This should be repeated two more times so that a total of 400ug of salbutamol has been delivered. Subjects who are known asthmatics and familiar with Volumatic usage can self-administer this dose.

The FEV₁ and FVC are measured 10 minutes after the administration of bronchodilator. During the bronchodilator challenge FVC manoeuvres will be used. Up to nine attempts may be made to obtain two technically satisfactory recordings after the inhalation of bronchodilator.

THE METHACHOLINE SOLUTIONS

Source and supply

Methacholine (Provocholine) will be obtained from Methapharm.

The Diluent

Saline buffered with phosphate to obtain physiological pH can be used as a diluent. Phenol must not be used as a preservative because of concerns regarding its safety. Citric acid/citrate buffer must not be used. Preservatives should be avoided.

Session number and order in session

Each time the nebulisers are filled with fresh methacholine solution a new session of testing is said to have started. Each session should be sequentially numbered. Each challenge within each testing session should also be sequentially numbered and recorded on the Lung Function Data Collection Sheet.

At the beginning of a session all nebulisers contain 3 mL methacholine. Six subjects are tested and their order in session is 1-6. After the 6th person has been tested the 12.5 mg/mL solution is discarded, the nebuliser is cleaned and dried, and 3 mL of fresh 12.5 mg/mL solution is added. Six more subjects are tested and they are numbered 7-12. After the 12th person has been tested all solutions are discarded and the nebulisers are cleaned. The next session begins when new solutions are added. A session may be extended over one night only by placing the nebulisers containing solutions upright in the fridge, covered with parafilm.

THE *MEFAR MB3* DOSIMETER

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Quality control of Mefar dosimeter nebuliser output

The methacholine challenge protocol has been written assuming that each single inhalation delivers approximately 0.01 mL solution to the mouth.

All Mefar nebulisers in the study will be calibrated in Melbourne prior to use in the study.

Pressure control Mefar

The driving pressure of the Mefar dosimeter should be checked before the study starts and every four weeks thereafter. The method for checking and adjusting the driving pressure is available at:

‘http://www.med.monash.edu.au/medicine/alfred/research/respiratory_medicine/newpage.htm.’

Pressure control forms should be returned to the co-ordinating centre at completion of the study.

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Each nebuliser should be colour coded for the solution it will contain as follows:

- 1) BLACK 12.5mg/mL
- 2) RED 6.25mg/mL
- 3) YELLOW 1.56mg/mL
- 4) BLUE 0.39mg/mL
- 5) WHITE Diluent

Setting up the Mefar dosimeter

3 mL of methacholine solution should be placed in the appropriate nebuliser. A dry sterile mouthpiece should be connected for each new subject.

The Mefar should be set at:

- 1) inhalation time: 1 second
- 2) pause time: 6 seconds

The standard inhalation

The sequence of inhalation is:

- 1) Slow expiration to functional residual capacity.
- 2) Place lips around mouthpiece to produce airtight seal.
- 3) Slow inspiration to total lung capacity.
- 4) Hold breath for at least three seconds.
- 5) Remove mouthpiece and exhale.

The procedure is repeated after six seconds until sufficient inhalations for the dose have been performed. Inhalations may be performed on consecutive breaths if desired. Spirometric testing is carried out two minutes after the dose. As soon as two FEV₁ manoeuvres have been recorded, the test is continued with the next dose.

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The end of the testing session

Solutions remaining in the nebulisers must be discarded and under no circumstances should they be returned to the storage containers. All nebulisers must be cleaned and dried. All mouthpieces must be cleaned, sterilised and thoroughly rinsed to ensure that there is no sterilising solution left on the surface.

THE METHACHOLINE PROTOCOL

Instructions for baseline spirometry

Perform full FVC manoeuvres as described previously for 'Baseline spirometry' (The forced expiratory manoeuvre). Record INITIAL FEV₁ and FVC. Calculate the BEST INITIAL FEV₁ as a percentage of the total predicted.

Measurement of control (post-diluent) FEV₁

The control FEV₁ is the FEV₁ measured following the inhalation of diluent. Four inhalations of diluent (WHITE nebuliser) are given, as described in 'The standard inhalation'.

Perform FEV₁ manoeuvres as described in 'Methacholine challenge' (The forced expiratory manoeuvre). Record CONTROL (POST-DILUENT) FEV₁. Calculate BEST CONTROL FEV₁ as a percentage of the BEST INITIAL FEV₁.

If the BEST CONTROL FEV₁ is less than 90% of the BEST INITIAL FEV₁ methacholine challenge is not carried out. Bronchoconstriction should be reversed by administering 400 µg salbutamol by MDI via a Volumatic and full FVC manoeuvres should be repeated.

If the BEST CONTROL FEV₁ is within 10% of the best initial FEV₁. Calculate 80% of the BEST CONTROL FEV₁. Calculate 90% of the BEST CONTROL FEV₁. Methacholine challenge may now be conducted following either the short or long protocol.

Dosing Schedule

In ECRHS I centres were able to decide whether to use one of two dosing schedules for methacholine challenge. In ECRHS II only one method shall be used (Method 2 from ECRHS I protocol).

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

Choice of long or short protocol

Each subject can be challenged on the short or long protocol. The long protocol will increase by doubling doses and the short by quadrupling doses. Subjects most likely to react to methacholine should be tested on the long protocol. Subjects who are unexpectedly reactive and have been allocated to the short protocol may switch to the long protocol during the challenge to avoid severe bronchoconstriction. The choice of protocol for each subject will be assessed by the Main Questionnaire. The questions to be used to direct subjects to the long protocol may be decided locally, but the following are recommended:

Subjects who answered 'YES' to any one of Questions 1, 2, 3, 5, 11 or 14 in the Main Questionnaire, that is any subject who has:

- 1) had wheezing or whistling in their chest in the last 12 months (Q1)
- 2) woken with tightness of chest in the last 12 months (Q2)
- 3) had an attack of shortness of breath during the day while at rest in the last 12 months (Q3)
- 4) been woken by an attack of shortness of breath in the last 12 months (Q4)
- 5) trouble with their breathing (Q11)
- 6) ever had asthma (Q14)

Methacholine challenge protocol

| CONC (mg/mL) | No of inhalations: | | CUMULATIVE DOSE (mg) | DOSE LEVEL (As per ECRHS I) |
|-----------------|--------------------|-------|-------------------------|--------------------------------|
| | LONG | SHORT | | |
| 0.39 | 2 | | 0.0078 | 3 |
| 0.39 | 2 | 4 | 0.0156 | 4 |
| 1.56 | 1 | | 0.0312 | 5 |
| 1.56 | 2 | 3 | 0.0625 | 6 |
| 6.25 | 1 | | 0.125 | 7 |
| 6.25 | 2 | 3 | 0.25 | 8 |
| 12.5 | 2 | | 0.5 | 9 |
| 12.5 | 4 | 6 | 1.0 | 10 |
| 12.5 | 8 | 8 | 2.0 | 11 |

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

Changing from Long to Short protocol

If, during the short protocol, the FEV₁ falls 10% or more from the best control FEV₁, the subject should change protocol and receive the next dose level on the long protocol.

For example: A subject following the short protocol shows a fall of 10% after Dose 4 (four inhalations of 0.39 mg/mL). They should inhale Dose 5 (one inhalation of 1.56 mg/mL) next.

Short protocol:

Change to long protocol if FEV₁ falls below 90% of the BEST CONTROL FEV₁. Go to next dose level on long protocol.

STOP challenge if FEV₁ falls below 80% of the BEST CONTROL FEV₁

Long protocol:

STOP challenge if FEV₁ falls below 80% of the BEST CONTROL FEV₁

Completion of test

The methacholine challenge is complete when a cumulative dose 2 mg of methacholine has been reached.

It is stopped sooner if:

- 1) there is greater than 10% fall in FEV₁ from the **BEST BASELINE FEV₁** following inhalation of diluent,
- 2) there is greater than 20% fall in FEV₁ from the **BEST CONTROL FEV₁** following inhalation of any concentration of methacholine solution,
- 3) the subject is not able to perform two technically satisfactory manoeuvres in five attempts following any dose level,
- 4) the subject does not wish to carry on.

Subjects may complain of mild chest tightness, coughing or wheezing but if lung function does not demonstrate a 20% fall in FEV₁ this is not an indication to stop the test.

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

Reversal of bronchoconstriction

Four hundred micrograms of salbutamol will be given via a volumatic (see above for bronchodilator challenge)
Perform full FVC manoeuvres as described in 'Methacholine challenge' 10 minutes after administration.

Record the POST-BRONCHODILATOR FEV₁ and FVC.

Calculate the BEST POST-BRONCHODILATOR FEV₁ as a PERCENTAGE of the BEST INITIAL FEV₁.

If the best post-bronchodilator FEV₁ is more than 90% of the best initial FEV₁ the test is over.

EACH CENTRE SHOULD PREPARE PROTOCOLS TO BE FOLLOWED IN THE EVENT OF A SUBJECT NOT RETURNING TO WITHIN 10% OF THE BASELINE.

BRONCHODILATOR CHALLENGE PROTOCOL

Four hundred micrograms of salbutamol are administered by MDI as described in 'Bronchodilator challenge'.
Perform full FVC manoeuvres as described in 'Baseline spirometry'. Record the POST-BRONCHODILATOR FEV₁
AND FVC.

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

Area Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

Personal Number

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

Sample

| |
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|--|

Date

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| | |
|--|--|

DAY

MONTH

YEAR

BEFORE STARTING THIS QUESTIONNAIRE PLEASE ASK THE FOLLOWING QUESTIONS

Have you had a cigarette in the last **hour**?

| | |
|--------------------------|--------------------------|
| YES | NO |
| <input type="checkbox"/> | <input type="checkbox"/> |

Have you used an inhaler (puffer) in the last **hour**?

| | |
|--------------------------|--------------------------|
| YES | NO |
| <input type="checkbox"/> | <input type="checkbox"/> |

IF 'YES' DELAY LUNG FUNCTION TESTS UNTIL ONE HOUR AFTER THE LAST CIGARETTE OR INHALER USE (RESPONSES DO NOT HAVE TO BE INCLUDED IN DATA RECORDER)

1. How many times have you been woken at night with shortness of breath in the last *two weeks*? NUMBER

2. During the last *two weeks*, has your breathing been

| | | |
|------------------------|----------|--------------------------|
| (a) worse than usual? | TICK ONE | <input type="checkbox"/> |
| (b) same as usual? | BOX ONLY | <input type="checkbox"/> |
| (c) better than usual? | 1 | <input type="checkbox"/> |
| | 2 | <input type="checkbox"/> |
| | 3 | <input type="checkbox"/> |

3. Have you had wheezing or whistling in your chest in the last 3 days? NO YES

4. Have you woken up with a feeling of tightness in your chest in the last 3 days?

5. Have you been woken by an attack of shortness of breath in the last 3 days?

6. Have you been woken by an attack of coughing in the last 3 days?

7. Have you had an attack of asthma in the last 3 days?

8. Have you taken any medicine (including inhalers, aerosols or tablets) For asthma in the last 3 days?

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9. Have you had any symptoms of hay fever or nasal allergy in the **last 3 days?**

| | |
|----|-----|
| NO | YES |
| | |
10. have you had a respiratory infection in the **last 3 weeks?**

| | |
|--|--|
| | |
|--|--|

IF 'NO' GO TO QUESTION 11

IF 'YES' AND THE SUBJECT IS WILLING TO COME BACK, STOP AND MAKE A NEW APPOINTMENT. IF NOT, PROCEED WITH QUESTION 10.1

- 10.1 How many days ago did it end?

| DAYS | |
|------|--|
| | |

11. Have you used an inhaler in the last **24 hours?**

| | |
|----|-----|
| NO | YES |
| | |

IF 'NO' GO TO QUESTION 12, IF 'YES' - :

- 11.1 What inhaler(s) did you use and for how many hours did you use it?

| | DRUG | | HOURS | |
|-------|------|--|-------|--|
| _____ | | | | |
| _____ | | | | |
| _____ | | | | |
| _____ | | | | |

IF THE SUBJECT HAS USED A BETA-2-AGONIST INHALER OR AN ANTI-MUSCARINIC INHALER IN THE LAST FOUR HOURS, CONSIDER: -

- a) WAITING UNTIL FOUR HOURS SINCE LAST USE HAS ELAPSED**
- b) RESCHEDULING FOR ANOTHER DAY IF THE SUBJECT IS WILLING, IF NEITHER OF THESE IS POSSIBLE, PROCEED.**

12. Have you used any other medicine (including pills, capsules or suppositories) to help your breathing, or any oral anti-muscarinic in the **last 24 hours?**

| | |
|----|-----|
| NO | YES |
| | |

IF 'NO' GO TO QUESTION 13, IF YES: -

- 12.1 What medicine(s) did you take and how many hours ago did you take it?

| | DRUG | | HOURS | |
|-------|------|--|-------|--|
| _____ | | | | |
| _____ | | | | |
| _____ | | | | |
| _____ | | | | |

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

IF THE SUBJECT HAS TAKEN AN ORAL BETA-2-AGONIST, AN ORAL THEOPHYLLINE OR AN ORAL ANTI-MUSCARINIC, CONSIDER RESCHEDULING FOR ANOTHER DAY IF THE SUBJECT IS WILLING, IF THIS IS NOT POSSIBLE, PROCEED.

- | | NO | YES |
|--|--------------------------|--------------------------|
| 13. Have you had a heart attack in the last three months ? | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Are you currently taking any medicine(s) for your heart? | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Are you currently taking any medicines for epilepsy? | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Are you currently taking any medicine containing beta-blockers, including eye-drops ? | <input type="checkbox"/> | <input type="checkbox"/> |

IF 'YES' TO ANY QUESTIONS 13-16 MEASURE BASELINE SPIROMETRY ONLY, DO NOT CHALLENGE.

For women only:

- | | NO | YES |
|-----------------------------|--------------------------|--------------------------|
| 17. Are you pregnant? | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Are you breast feeding? | <input type="checkbox"/> | <input type="checkbox"/> |

IF 'YES' TO QUESTIONS 17 OR 18 MEASURE BASELINE SPIROMETRY ONLY, DO NOT CHALLENGE.

For all subjects:

- | | NO | YES |
|---|--------------------------|--------------------------|
| 19. Would you like us to notify your GP of the results of any test? | <input type="checkbox"/> | <input type="checkbox"/> |

END

FIELDWORKER NUMBER

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

Coding for lung function questionnaire

The same general rules apply as for the main questionnaire.

Questions with NO / YES

- 1 NO
- 2 YES

Questions with 'TICK ONE BOX ONLY' instruction:

The number of the box ticked is the code for that answer.

QUESTION 11.1 Inhalers in the last 24 hours

Drug grouping should be consistent with those used for main questionnaire.

- 1 Beta-2-against (short acting)
- 2 Beta-2-against (long acting)
- 3 Non-specific adrenoreceptor agonists
- 4 Anticholinergic inhalers
- 5 Inhaled steroids
- 6 Sodium cromoglycate
- 7 Nedocromil
- 8 Compound bronchodilators

- 98 Not coded
- 99 Not known

QUESTION 12.1 Oral medications

Drug grouping should be consistent with those used for main questionnaire.

- 1 Beta-2-against
- 2 Non-specific adrenoreceptor agonist
- 3 Oral anticholinergics/antimuscarinics
- 4 Oral methylxanthines
- 5 Oral steroids
- 6 Oral antihistamines
- 7 Oral compound bronchodilators
- 8 Oral-antileukotrienes

- 98 not coded
- 99 not known

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

Area Number

Personal Number

Sample

Date

| | | | | |
|--|--|--|--|--|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

DAY MONTH YEAR

DAY MONTH YEAR

METRES

1. Subject's Height

METRES

2. Subject's Weight

KILOGRAMS

3. Subject's Age

AGE

Male Female

4. Subjects sex

5. Time of Day

'24 hrs' HOURS MINUTES
 •

6. **PREDICTED FEV₁**

•

Each subject now has five attempts to produce a technically satisfactory manoeuvre. If after five attempts there have not produced at least two manoeuvres – four more attempts are allowed
MAXIMUM NUMBER OF ATTEMPTS ALLOWED IS NINE ATTEMPTS

7. **INITIAL FEV₁ and FVC**

| | FEV ₁ | FVC | PEFR (L/s) |
|---|----------------------|----------------------|----------------------|
| 1 | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 2 | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 3 | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 4 | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 5 | <input type="text"/> | <input type="text"/> | <input type="text"/> |

7.1 Number of rejected attempts

8. **Best INITIAL FEV₁ as % of predicted FEV₁**

IF BEST INITIAL FEV₁ IS a) less than 70% PREDICTED or
b) less than 1.5 LITRES

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

**GO TO BRONCHODILATOR CHALLENGE – DO NOT DO METHACHOLINE
CHALLENGE**

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

METHACHOLINE CHALLENGE

Give four inhalations of diluent. Two minutes later record FEV₁

9. **CONTROL FEV₁** following inhalation of diluent.

9.1 Record two technically satisfactory manoeuvres

| | | | | |
|---|----------------------|---|----------------------|----------------------|
| 1 | <input type="text"/> | • | <input type="text"/> | <input type="text"/> |
| 2 | <input type="text"/> | • | <input type="text"/> | <input type="text"/> |

9.2 Number of rejected attempts

10. **BEST CONTROL (post-diluent) FEV₁** as % of INITIAL FEV₁

%

**IF BEST CONTROL FEV₁ <90% OF BEST INITIAL FEV₁
STOP METHACHOLINE CHALLENGE AND GO TO REVERSAL OF
BRONCHOCONSTRICTION**

Choice of methacholine long or short protocol

NO YES

DID THE SUBJECT ANSWER 'YES' TO QUESTIONS 1,2,3,5,11 or 14
OF THE MAIN QUESTIONNAIRE?

**IF 'NO' GO TO SHORT PROTOCOL
IF 'YES' GO TO LONG PROTOCOL**

11. Will the subject follow the short or long protocol?

LONG SHORT

CODING: 1 LONG, 2 SHORT

SHORT PROTOCOL:

CHANGE TO LONG PROTOCOL if FEV₁ falls to < 90% of CONTROL FEV₁

STOP METHACHOLINE CHALLENGE if FEV₁ fall to < 80% of CONTROL FEV₁

90% of CONTROL FEV₁

•

LONG PROTOCOL:

STOP METHACHOLINE CHALLENGE if FEV₁ fall to <80% of CONTROL FEV₁

80% of CONTROL FEV₁

•

THESE DATA NOT REQUIRED BY CO-ORDINATING CENTRES

12. METHACHOLINE BATCH NUMBER

NUMBER OF SESSIONS

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

ORDER IN SESSIONS

| | |
|--|--|
| | |
|--|--|

| DOSE LEVEL | CUMULATIVE CUM DOSE (mg) | NEBULISER CONCEN | NO. INHALATIONS | | FEV ₁ | | FEV ₁ | | Rejected attempts |
|------------|--------------------------|------------------|-----------------|------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | | | SHORT | LONG | | | | | |
| 3 | 0.0078 | 0.39 | ... | 2 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4 | 0.0156 | 0.39 | 4 | 2 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5 | 0.0312 | 1.56 | ... | 1 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6 | 0.0625 | 1.56 | 3 | 2 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7 | 0.125 | 6.25 | | 1 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8 | 0.25 | 6.25 | 3 | 2 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9 | 0.5 | 12.5 | | 2 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10 | 1.0 | 12.5 | 6 | 4 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11 | 2.0 | 12.5 | 8 | 8 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

TICK ONE

BOX ONLY

13. Why was methacholine challenge stopped

- a) end of test reached (2mg inhaled)
- b) >20% fall in FEV₁ occurred
- c) two satisfactory manoeuvres not achieved
- d) subject asked to stop
- e) other _____

| | |
|---|--|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |

LUNG FUNCTION PROTOCOL, DATA SHEETS AND QUESTIONNAIRE

IF SUBJECTS FEV₁ HAS FALLEN BY MORE THAN 10%

Reversal of bronchoconstriction

GIVE 400 µG SALBUTOMAL VIA VOLUMATIC AND 10 MINUTES LATER RECORD FEV₁

14. FEV₁ and FVC

14.1 Record first two technically satisfactory manoeuvres
(up to five attempts)

| | | | |
|----------------------|---|----------------------|---|
| | FEV ₁ | | FVC |
| <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="text"/> |
| <input type="text"/> | <input type="text"/> <input type="text"/> | <input type="text"/> | <input type="text"/> <input type="text"/> |

14.2 Number of rejected attempts

15 **Best POST-BRONCHODILATOR FEV₁ as % of initial FEV₁**

16 Has the subject's FEV₁ returned to within 10% of **initial FEV₁**

| | |
|----------------------|----------------------|
| NO | YES |
| <input type="text"/> | <input type="text"/> |

**IF 'YES' THE SUBJECT MAY LEAVE THE CENTRE
IF 'NO' FURTHER ACTION MUST BE TAKEN TO RESTORE BASELINE LUNG
FUNCTION**

BRONCHODILATOR CHALLENGE ONLY

GIVE 400 µg SALBUTAMOL VIA VOLUMATIC AND 10 MINUTES LATER RECORD FEV₁

17. FEV₁ and FVC

17.1 Record first two technically satisfactory manoeuvres
up to 9 attempts)

| | | | |
|----------------------|---|----------------------|---|
| | FEV ₁ | | FVC |
| <input type="text"/> | • <input type="text"/> <input type="text"/> | <input type="text"/> | • <input type="text"/> <input type="text"/> |
| <input type="text"/> | • <input type="text"/> <input type="text"/> | <input type="text"/> | • <input type="text"/> <input type="text"/> |

17.2 Number of rejected attempts

END

FIELDWORKER NUMBER