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Training in Multiple Breath Washout testing for respiratory physiotherapists

O'Neill, K., Elborn, J. S., Tunney, M. M., O'Neill, P., Rowan, S., Martin, S., & Bradley, J. M. (2018). Training in Multiple Breath Washout testing for respiratory physiotherapists. *Physiotherapy*, 104(1), 61-66.
<https://doi.org/10.1016/j.physio.2017.04.003>

Published in:
Physiotherapy

Document Version:
Peer reviewed version

Queen's University Belfast - Research Portal:
[Link to publication record in Queen's University Belfast Research Portal](#)

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1 **Debate article**

2 Title: Training in Multiple Breath Washout testing for respiratory physiotherapists

3

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6

7 Acknowledgements: Thank you to Dr Alex Horsley for providing training and expertise on the
8 use the modified Innocor™ device. Thank you to Dr Nick Bell for his permission to use the
9 Simple Washout software. Thank you to Prof Jane Davies, Clare Saunders and Katie Bayfield
10 for their guidance on training programme structure and content.

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23 Word count: 2473/3000

24

25 **Debate article**

26 Title: Training in Multiple Breath Washout testing for respiratory physiotherapists

27

28 **Abstract: 146/200**

29 Introduction: The development of multiple breath washout (MBW) testing in respiratory
30 disease highlights the need for increased awareness amongst respiratory physiotherapists and
31 a potential opportunity for professional development in the use of an important outcome
32 measure for clinical trials.

33 Objectives: To rationalise how MBW may be a useful assessment tool for respiratory
34 physiotherapists and to describe a local MBW training and certification programme for
35 physiotherapists.

36 Results: The respiratory Multi-Disciplinary Team in the Belfast Health and Social Care Trust
37 (BHSCT) identified a need for MBW testing to be available to facilitate clinical research and
38 assessment. A 2 day training programme consisting of pre-reading preparation, self-directed
39 learning, theory presentations, practical demonstrations and hands-on practice was developed
40 and delivered. All participants underwent a certification process.

41 Conclusion: We have demonstrated the successful training and certification of clinical and
42 research physiotherapists and encourage other respiratory physiotherapists to consider MBW
43 test training.

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48 **Contribution of paper**

49 • This paper highlights the need for increased awareness amongst respiratory
50 physiotherapists and a potential opportunity for professional development in the use of
51 an important outcome measure for clinical trials.

52 • This paper demonstrates that respiratory physiotherapists can obtain training and
53 certification in MBW testing

54

55 **Keywords**

56 Respiratory physiotherapy; multiple breath washout testing; lung clearance index; training;
57 eLearning.

58

59 **Introduction**

60 In recent years, there has been a resurgence of interest in multiple breath washout (MBW)
61 testing in respiratory disease. This method has the advantage of improved sensitivity in the
62 detection of early airways disease compared to spirometry and has improved feasibility across
63 a wider age range, requiring only relaxed tidal breathing. Studies in Cystic Fibrosis (CF) have
64 shown that measures of MBW detect early lung disease, relate to measures of spirometry and
65 health related quality of life and are responsive to mucolytic therapies (1-7). Consequently,
66 parameters of MBW have been recommended as outcome measures in clinical trials in CF (8)
67 and have already been used in landmark CF trials (9,10). Research into MBW in other
68 respiratory conditions have also demonstrated that it could be a useful tool to detect disease
69 and measure treatment response (11-14). FEV₁ is a key outcome measure in CF and is currently

70 the only Food and Drug Administration (FDA) approved surrogate outcome measure for use
71 in clinical trials (15). It is also the most commonly used and reported measure of lung function
72 in other lung diseases such as COPD (16). However, FEV₁ has physiological limitations; it
73 primarily reflects the larger airways rather than the more peripheral, smaller airways which
74 make up the majority of the surface area of the lung and where early processes occur (17).
75 Furthermore in CF, the slow rate of decline in FEV₁ evident as a result of improved standards
76 of care (18), limit its sensitivity to detect change in clinical status and response to treatment.
77 Spirometry can only be reliably carried out in individuals aged >6 years as it requires ability to
78 take instruction and co-operation. There is a clear need for an alternative measurement of lung
79 function. As research has established that MBW is a valid and reliable measure of ventilation
80 distribution which correlates with lung disease severity (8), it has become established as a
81 secondary outcome in clinical trials and may also have a place in regular clinical monitoring in
82 CF. Moreover, MBW could potentially inform physiotherapy assessment and the evaluation of
83 new treatments.

84 Unlike spirometry, MBW is not part of undergraduate training programmes and there
85 are few training programmes outside specialist research centers. Therefore, in order to facilitate
86 the translation of MBW into clinical care there is a need for effective training. We propose
87 that training respiratory physiotherapists to perform MBW could be advantageous in the
88 management of respiratory patients.

89

90 **Objectives**

91 The objectives of this article are to

92 1. Rationalise how MBW may be a useful assessment tool for respiratory physiotherapists.

93 2. Describe a local MBW training and certification programme for physiotherapists.

94 3. Highlight available MBW training resources.

95

96 *MBW testing*

97 In respiratory disease, airway narrowing from mucus obstruction, inflammation and structural
98 airway damage can cause uneven ventilation distribution and the degree of disease severity can
99 be assessed using MBW. Lung Clearance Index (LCI) is the most commonly reported measure
100 of the MBW test and represents the number of functional residual capacity (FRC) volume
101 turnovers required to “washout” the tracer gas during testing. Individuals with uneven
102 ventilation distribution use a greater number of turnovers to washout the tracer gas and
103 therefore will have a higher (more abnormal) LCI. Although MBW tests have been available
104 for many years, research and clinical interest has increased recently due to the availability of
105 more sophisticated and user friendly equipment. The MBW test can be performed either with
106 inhalation of an inert tracer gas such as sulphur hexafluoride (SF₆) or helium (He), or by using
107 100% oxygen (O₂) to wash out resident nitrogen (N₂). When using SF₆ or He, the gas is first
108 washed into the lungs and then washed out. When using N₂ washout, 100% O₂ is delivered until
109 N₂ is washed out. The European Respiratory Society/American Thoracic Society (ERS/ATS)
110 consensus statement for inert gas washout measurements (19) provides evidence based
111 guidelines on equipment specifications, test performance and analysis of results and is a key
112 reference document for sites planning the set-up and delivery of MBW testing. Some key points
113 about MBW from the inert gas washout measurements consensus statement (19) and an
114 evidence review for LCI (8) are summarized in Table 1.

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118 Table 1: MBW key points

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- MBW tests assess the efficiency of ventilation distribution (19)
- LCI is the most commonly reported MBW index in current paediatric and adult literature (19)
- LCI is the number of functional residual capacity (FRC) lung volume turnovers required to reduce tracer gas concentration to a fraction of its starting concentration (19)
- End of washout is historically defined as 1/40th of the starting tracer gas concentration (19)
- MBW testing requires only tidal breathing and stability of resting lung volumes throughout the washout is critical (19)
- LCI is reported as the mean (SD) of 3 technically acceptable and repeatable washout tests (19)
- In a healthy person, upper limits of normal for LCI between 7.0 – 7.5 have been reported (2,30)
- A complete MBW testing session (3 tests) typically lasts between 20 - 40 minutes (2,31)
- The minimum clinically important difference in LCI has yet to be defined but treatment effects of 1.0-2.2 lung turnovers have been reported (3,9,32,33)
- LCI is dependent on body size and appropriate reference equations are essential for accurate interpretation of results (34)
- Results are specific to equipment and therefore are not comparable across different systems (e.g. system using SF₆ vs. system using N₂ as tracer gas)

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There are key areas where LCI demonstrates potential clinical utility. Firstly, LCI can detect early lung disease, potentially informing clinical decisions on treatment and management plans earlier in the disease trajectory. It has been shown to detect early lung disease in children and adults and is more sensitive than measures of spirometry (FEV₁) in both CF and bronchiectasis (2,5,11). Indices from the MBW test have also been shown to be sensitive to lung disease in asthma (13), COPD (14) and alpha-1-antitrypsin deficiency (20).

138 Importantly, LCI relates to other meaningful clinical endpoints and patient centered
139 outcomes, which confirms its validity as a useful measure. In CF, LCI has been shown to relate
140 to health related quality of life as measured by a validated questionnaire, and to predict
141 pulmonary exacerbations (4,21). In both CF and bronchiectasis, LCI relates to measures of
142 high resolution computed tomography (HRCT) chest imaging (11). LCI has been shown to be
143 responsive to the disease modulating therapy, ivacaftor, in CF (9). LCI, but not FEV₁%
144 predicted, was also responsive to mucoactive therapies including inhaled hypertonic saline (3)
145 and DNase in CF (7). The responsiveness of LCI highlights that it could have a potential role
146 in the assessment of therapies and in the long term monitoring in patients.

147 A small number of studies have been carried out to investigate the short term effect of
148 airways clearance interventions on LCI in both CF and bronchiectasis. In CF, one study
149 demonstrated a significant reduction (improvement) in LCI following treatment with Non-
150 Invasive Ventilation compared to Positive Expiratory Pressure mask in 32 patients with CF
151 (22). Measures of gas mixing efficiency from a single-breath gas washout test also improved
152 significantly after airway clearance in 25 children with CF (23). The majority of studies show
153 no change or a variable change (increase and decrease) in LCI (12,24-26). This highlights that
154 airways clearance techniques cause alterations in gas mixing which are greater than those who
155 do not undergo airway clearance. One theory suggested is that airway clearance may open up
156 previously “blocked off” areas caused by mucus plugging, or relieve areas of atelectasis,
157 opening up poorly ventilated areas, thereby causing a rise (worsening) in LCI. Further studies
158 of the medium to long-term effect of airways clearance techniques on LCI and other MBW test
159 outcomes would be beneficial in informing physiotherapists whether there is a place for MBW

160 testing in assessing airways clearance. The challenge with airways clearance trials remains that
161 there is no consensus on the best index to use to measure effect (27).

162 As MBW testing demonstrates utility across a range of respiratory diseases, both
163 clinical and clinical trial sites are exploring the acquisition of equipment and training in order
164 to embed this outcome measure in trials and to offer this test as part of their assessment. This
165 highlights a development opportunity for respiratory physiotherapists.

166

167 *The role of respiratory physiotherapists*

168 Respiratory physiotherapists are directly involved in conducting and interpreting lung function
169 tests and the key role of the physiotherapist in evaluating response to inhaled therapies, airways
170 clearance therapies and physical activity has been highlighted in CF (28). Physiotherapists are
171 ideally placed to build on their existing knowledge and expertise in acquiring the skill of MBW
172 testing, which could potentially be utilized as part of their patient's assessment. Respiratory
173 physiotherapists form an integral part of the multidisciplinary team and are involved in the
174 assessment of patients' respiratory status within the context of outpatient appointments, annual
175 assessments as well as inpatient admissions. MBW testing falls under the Chartered Society of
176 Physiotherapy (CSP) scope of practice of physiotherapy in the UK, defined as "any activity
177 undertaken by an individual physiotherapist that may be situated within the four pillars of
178 physiotherapy practice where the individual is educated, trained and competent to perform that
179 activity" (CSP, 2008) and therefore is covered under professional liability insurance. As MBW
180 testing has its roots in clinical research, conduct of the technique has historically been the remit
181 of the researcher. Implementing research practices into clinical practice is challenging and
182 requires the collaboration and commitment of the academic researchers, clinicians, managers

183 and patients. Increasing awareness and knowledge of new assessments, skills required and the
184 wider practical implications are recognised aspects of successful integration of change to
185 practice (29). A key feature of all clinical practice including physiotherapy practice, is the
186 capacity to respond and evolve to changes in healthcare. A focus on providing the training
187 opportunities to support physiotherapists to be competent at embedding new techniques within
188 their clinical practice will facilitate the translation of research into practice. To enable the
189 successful integration into clinical practice, appropriate training in the technical aspects of set
190 up, conducting the test, and interpretation and quality assurance of results is essential (19).
191 Through our experience of delivering a training programme, we have demonstrated how both
192 clinical and research physiotherapists can successfully complete training and certification in
193 this skill for use in research and clinical practice.

194

195 *Training programme*

196 The respiratory Multi-Disciplinary Team in Belfast Health and Social Care Trust (BHSCT)
197 identified a need for MBW testing to be available to facilitate clinical research and clinical
198 assessment. In response to this, a 2 day programme was developed and delivered by a Queen's
199 University Belfast PhD researcher (physiotherapist KON) trained in using the modified
200 Innocor™ device (by an external expert in the equipment, Dr Alex Horsley, University of
201 Manchester). The programme consisted of pre-reading preparation, self-directed learning, a
202 presentation on theory, practical demonstrations and practice. Thereafter to be certified,
203 participants completed 10 tests after the 2 day programme which were then assessed for
204 technical validity and repeatability. The trainer was available for trouble shooting on
205 calibration and testing during the certification process. Table 2 details the programme content

206 and layout and the certification procedure. Appendix 1 details the programme in full. All
 207 content was based on the device Standard Operators Procedure (used with permission)
 208 “Multiple breath washout test using modified Innocor™ device SOP; UK Cystic Fibrosis Gene
 209 Therapy Consortium; September 2010, Dr. Nick Bell” and on guidance from external expert
 210 Dr Alex Horsley, University of Manchester. A knowledge (6 multiple choice questions) and
 211 confidence (Likert visual analogue scales rating setting up the equipment, conducting and
 212 interpreting the test) questionnaire was completed by participants before the programme and
 213 after submission of certification tests (appendix 2). Participants were also asked to make
 214 suggestions for improvement of the programme.

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216 Table 2: Programme content and layout

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| Preparation: Key references and protocols for pre-reading. |
| Day 1: Background to MBW. Overview of references and Standard Operating Procedure. Familiarisation with equipment components, on-screen menus and consumables. Overview and practice of calibrations. Patient preparation for testing. |
| Day 2: Explanation and demonstration of phases of testing: Washin phase, beginning of washout, washout phase. Practice testing with volunteer and quality control of readings. Log keeping, cleaning of equipment and infection control. Accessing and downloading tests. |
| Certification procedure: |

Trouble shooting on calibration and testing.

Collection of 10 tests.

9/10 technically acceptable tests required for certification.

If <9/10 tests valid, submission of additional 5 tests.

217

218 The programme was delivered on 2 occasions to a total of 10 participants (5 clinical researchers
219 [3 physiotherapists, 1 nurse, 1 clinical physiologist] and 5 clinical physiotherapists) based in
220 BH SCT. All 10 participants completed the 2 day programme. However 2/10 participants
221 (clinical physiotherapists) did not complete the certification procedure (no time due to clinical
222 caseload). The remaining 8 participants successfully completed the certification procedure. Six
223 participants completed the knowledge and confidence assessment before and after the
224 programme and certification (2 participants did not complete the certification and 2 completed
225 the programme before the knowledge and confidence questionnaire was introduced). For these
226 6 participants, knowledge improved from 61% at baseline to 100% post programme.
227 Confidence improved from 3% at baseline to 76% post programme; however 2 participants
228 highlighted that they still were not very confident in interpreting MBW results. Suggestions for
229 improvement included the development of eLearning material, the inclusion of content on N₂
230 washout devices and information on the interpretation and analysis of MBW results.

231 Experience from this programme demonstrates how both clinical and research
232 physiotherapists can successfully complete a training and certification programme in MBW
233 testing. As 2 clinical staff members were unable to complete certification due to time
234 constraints it highlights that agreement and ongoing support from management is required to
235 ring fence time to organise and complete certification readings.

236 *Resources for MBW training*

237 For those wishing to pursue training in MBW testing, the ERS/ATS inert gas washout
238 consensus statement provides a comprehensive outline on all aspects of equipment
239 specifications, test performance and analysis (19). As MBW testing involves practical and
240 technical skills, face-to-face training for “hands-on” experience is considered optimal. During
241 the equipment installation process manufacturers usually provide training according to their
242 standard operating procedure. Additional training is required to obtain certification to a
243 research quality standard and there are UK sites who provide training, certification and an over-
244 reading service (quality checking and final result verification of MBW data) as well as a point
245 of contact for re-fresher training and troubleshooting. (Royal Brompton and Harefield Hospital,
246 London and BHSCT).

247 MBW testing is a developing area and is technically challenging to perform. Therefore,
248 regular practice with quality control checks is essential to ensure that confidence and
249 competence with use of the equipment is maintained. Re-fresher training is important if time
250 has elapsed since original training or last use. As MBW is primarily a research tool at present,
251 it is possible that the operator may become deskilled if using the method infrequently or only
252 during a specific clinical trial. eLearning tools are one method that reinforce face-to-face
253 learning and support re-fresher training remotely. Some eLearning resources have been
254 developed by commercial companies using MBW testing, however access is restricted to sites
255 participating in the clinical trial. An eLearning tool developed at Queen’s University Belfast
256 (www.MBWtraining.com), is open access and provides comprehensive information on MBW
257 testing using a variety of learning mediums including slideshow presentations, animations and
258 a step by step library of videos demonstrating set-up and testing. The tool also includes a self-

259 assessment component, a social networking interface and teaching team contact details for on-
260 going support. In addition to reinforcement of face-to-face learning, this eLearning tool aims
261 to facilitate ongoing and re-fresher training and act as a point of contact for troubleshooting
262 and quality assurance issues. This blended learning approach (face-to-face programme
263 supported by eLearning) aims to provide an effective and accessible form of MBW training to
264 sites.

265

266 **Conclusions**

267 MBW to measure LCI is emerging as a promising outcome measure with potential for
268 integration into routine clinical management of patients with CF and growing potential for use
269 in bronchiectasis, asthma and COPD. In order for integration into clinical practice to be
270 successful, training of the appropriate personnel in the technical aspects of set up, conducting
271 the test, interpretation and quality assurance of results is essential. We propose that respiratory
272 physiotherapists are ideally placed to undergo such training and become qualified to perform
273 the MBW technique in response to expansions in service delivery. We have demonstrated the
274 successful training and certification of clinical and research physiotherapists and encourage
275 other respiratory physiotherapists to explore the area of MBW test training.

276

277 Ethical approval: n/a

278 Funding: The training programme described in this article was carried out as part of a US-
279 Ireland Partnership Grant funded by the Health and Social Care Research and Development
280 Division, Public Health Agency, Northern Ireland and the Medical Research Council. The

281 eLearning tool described in this article was funded through a Knowledge Exchange Award
282 from the Health & Social Care Research & Development Division of the Public Health Agency
283 (HSC R&D Division).

284 Conflict of interest: The authors have no conflicts of interest to disclose.

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402

Appendix 1: Training Programme: Multiple Breath Washout Test using Modified Innocor™ device: Queen's University Belfast & Belfast Health and Social Care Trust

PROGRAMME

Multiple Breath Washout (MBW) Test using Modified Innocor™ device: Queen's University Belfast & Belfast Health and Social Care Trust

Author: **Katherine O'Neill, Prof. Judy Bradley, Prof. Stuart Elborn.**

INSTRUCTIONAL GOALS

At the end of this course, you will:

- Understand the principals underpinning MBW testing.
- Be able to independently prepare the Innocor™ device and the testing room for procedure.
- Be able to independently set up device and perform all calibration procedures as per SOP
- Be able to maintain the set up to standard as per infection control guidelines in the SOP.
- Know how to complete and maintain the Innocor™ Usage log and the MBW Procedure and Analysis Washout Sheets.
- Know how to adequately explain and prepare patient for procedure.
- Be able to successfully conduct MBW test on adults as per SOP.
- Be able to recognize technically inadequate tests that may warrant an additional test.
- Be able to export the test tracings from the Innocor™ device in preparation for analysis.

NEEDS AND RESOURCES

Required Background

To successfully complete this course, you must;

- Read the key references
 - Robinson, P.D., Goldman, M.D. & Gustafsson, P.M. 2009, "Inert gas washout: theoretical background and clinical utility in respiratory disease", *Respiration*, vol. 78, no. 3, pp. 339-355.
 - Horsley, A. 2009, "Lung clearance index in the assessment of airways disease", *Respiratory medicine*, vol. 103, no. 6, pp. 793-799
- Read the SOP
 - Multiple breath washout test using modified Innocor™ device SOP; Nick Bell; Clinical Research Fellow; UK Cystic Fibrosis Gene Therapy Consortium; 20th September 2010.

Required Equipment

To commence and successfully complete this course, you will need

- Innocor™ in place with adaptations made as per SOP (see page appendix C SOP)
- Supply of SF₆ gas (NB: Wall bracket or cylinder trolley for size L cylinder required; flow head/regulator for size L cylinder required (ordered through BOC part number 850820) (see page 5 SOP)

- Room set up for procedure (see page 5 SOP)
- Flow past circuit and patient interface consumables in stock (see page 19 SOP)

Required Materials

To successfully complete this course, you will need;

- Multiple breath washout test using modified Innocor™ device SOP; Nick Bell; Clinical Research Fellow; UK Cystic Fibrosis Gene Therapy Consortium; 20th September 2010.
- MBW Procedure and Analysis Washout Sheets
- Multiple Breath Washout Test using the Modified Innocor™ device ; LCI operator Qualification Assessment Form; Oct 2011
- Innocor™ Instructions for Use Manual

COURSE CONTENT

TRAINING ITEMS

1. Overview of references and SOP.
2. Checklist of all equipment and consumables in place
3. Set up room, equipment and patient interface

4. Familiarisation with equipment
 - a) Innocor™
 - b) Innocor™ menus
 - c) Patient interface
 - d) Flow past circuit
 - e) Gas cylinder
 - f) Room set up

5. Practice with set up and calibration
 - a) Flow meter linearization
 - b) Flow meter calibration
 - c) Flow gas delay calibration

6. Preparing and explaining procedure to patients
7. Concepts of washin; disconnection and washout (as per SOP).
8. Observe a test *Volunteer needed*
9. Supervised practice with patients / volunteers *Volunteer(s) needed*

- a) Including keeping the log and note keeping during the test.
- b) Troubleshooting: Awareness of reasons for invalid tests (technician related and patient related) and how to avoid.

10. Infection control procedures

- a) Patient interface
- b) Room

11. Accessing and downloading tracings; sending tracings to analyzer.

12. Information obtained post analysis.

Certification procedure (completed independent post programme)

Trouble shooting on calibration and testing.

Collection of 10 tests.

9/10 technically acceptable tests required for certification.

If <9/10 tests valid, submission of additional 5 tests

Appendix 2: Knowledge and Confidence Assessment Questionnaire_ Multiple Breath Washout
Test using Modified InnocorTM device_ Queen's University Belfast & Belfast Health and Social
Care Trust_ Katherine O'Neill_ March 2013

Knowledge assessment questionnaire

Multiple choice questions- Please choose one

1. LCI is derived from

- a) Single breath washout test
- b) Multiple breath washout test
- c) Body plethysmography test
- d) Diffusion capacity test

2. LCI is a measure of

- a) Airflow
- b) Perfusion
- c) Inflammation
- d) Gas mixing efficiency

3. The upper limit of normal for LCI is

- a) 10
- b) 5.5
- c) 7.5
- d) 15.5

4. LCI is calculated as

- a) The number of lung turnovers required to washout a tracer gas
- b) The concentration of tracer gas at functional residual capacity

- c) The mean concentration of CO₂ at end tidal volume
- d) The number of lung regions ventilated

5. LCI is a measure most sensitive to

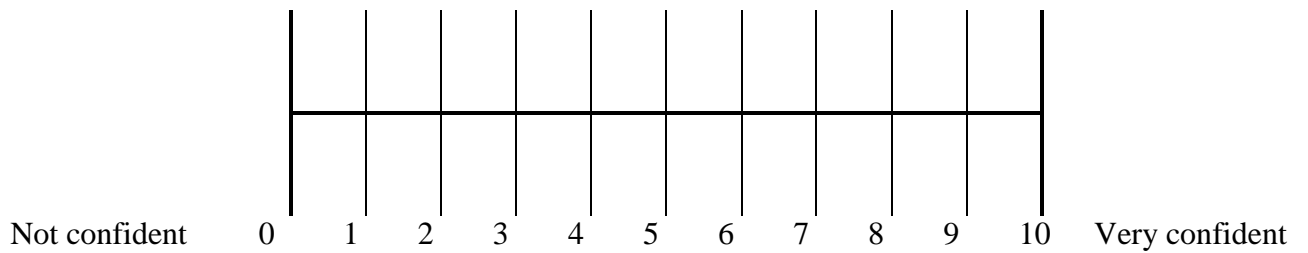
- a) Large airways dysfunction
- b) Small airways dysfunction
- c) SpO₂ levels
- d) Airways inflammation

6. LCI is a measure which is most informative in

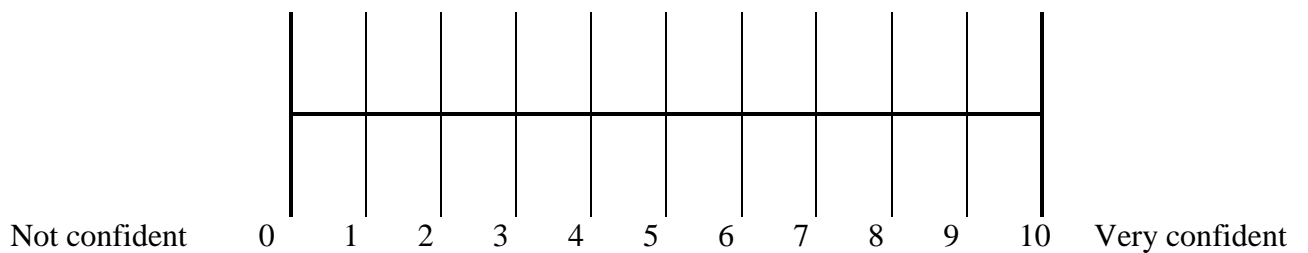
- a) Patients with advanced disease
- b) Patients awaiting transplant
- c) Healthy individuals
- d) Children and patients with mild disease

Please answer the following questions which relate to your confidence in MBW procedure to obtain LCI

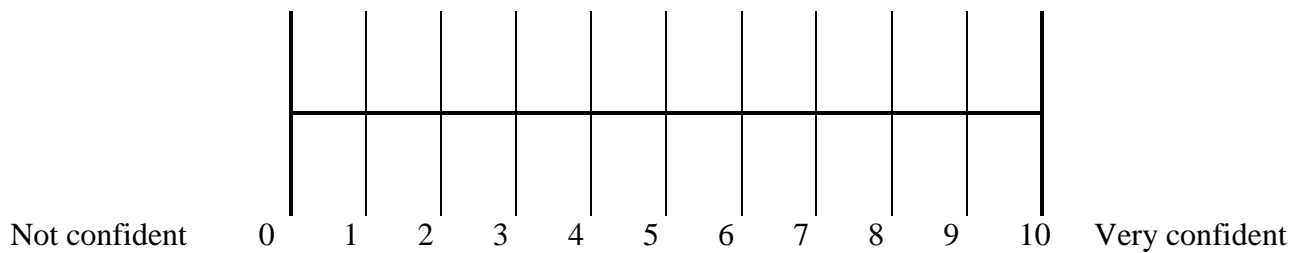
Rate your confidence performing **calibration procedures for MBW testing** before starting the training programme



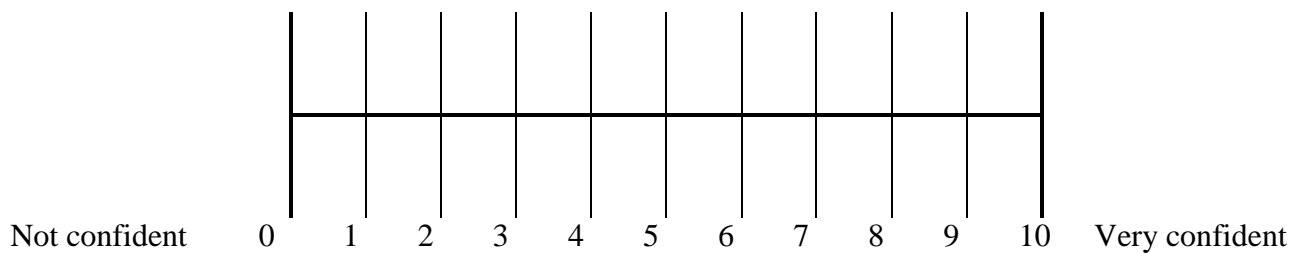
Rate your confidence performing **calibration procedures for MBW testing** on completion of the training programme



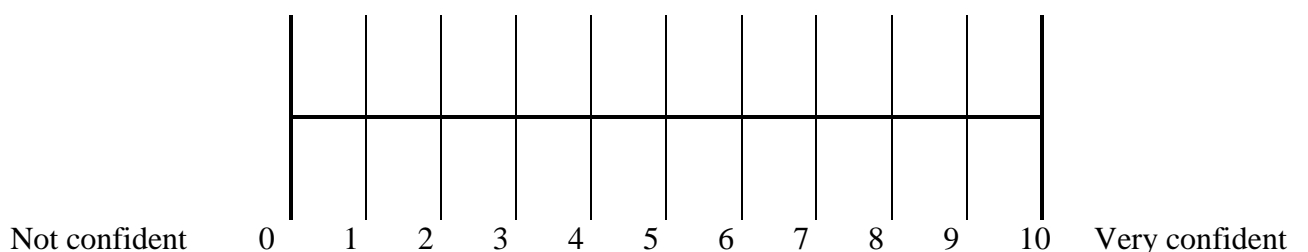
Rate your confidence using **equipment to perform MBW test** before starting the training programme



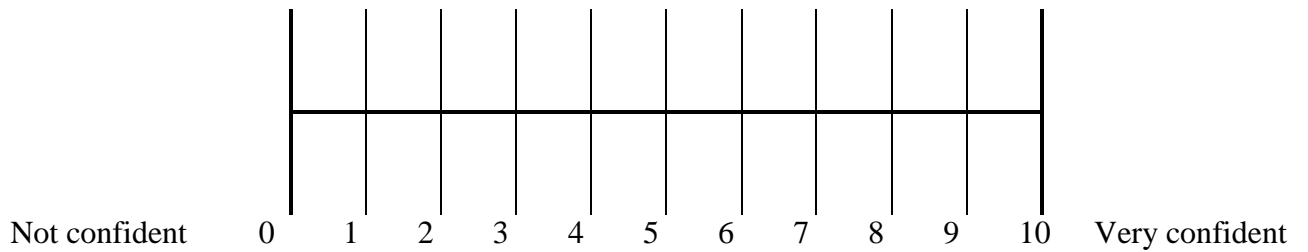
Rate your confidence using **equipment to perform MBW test** on completion of the training programme



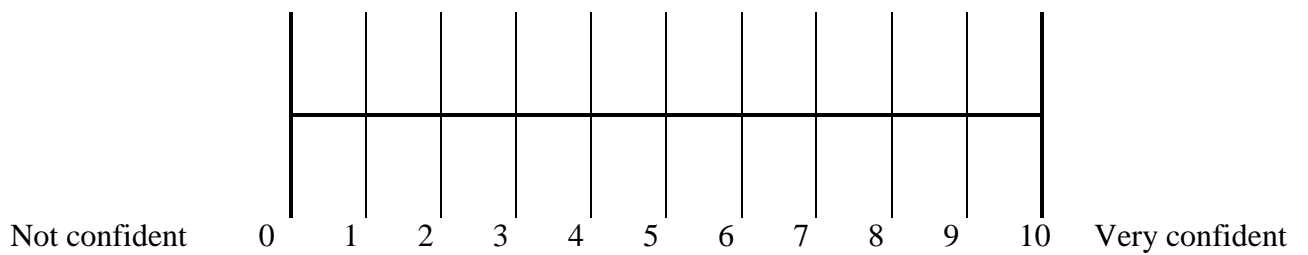
Rate your confidence on **interpreting the LCI result from the results sheet** before starting the training programme



Rate your confidence **interpreting the LCI result from the results sheet** on completion of the training programme



Rate your confidence on **maintenance of the MBW equipment** before starting the training programme



Rate your confidence **maintenance of the MBW equipment** on completion of the training programme

