A MANUAL FOR PULMONARY REHABILITATION IN AUSTRALIA

EVIDENCE BASE AND STANDARDS

Peter Frith
Professor and Head of Southern Respiratory Services
Flinders University and Southern Adelaide Health Service
(Repatriation General Hospital and Flinders Medical Centre)
South Australia
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Executive Summary

This “Manual for Pulmonary Rehabilitation In Australia: Evidence Base and Standards” provides a comprehensive review of evidence relevant to pulmonary rehabilitation as a support for pulmonary rehabilitation practice and management in Australia. A Pulmonary Rehabilitation Toolkit has been developed to assist new practitioners and administrators, and to enable continuous quality improvement for established programs. The Australian Lung Foundation (ALF) with the Thoracic Society of Australia and New Zealand (TSANZ) and Australian Physiotherapy Association (APA) helped in the development and implementation of the suite of tools supporting management of chronic obstructive pulmonary disease (COPD), which currently includes evidence-based practice guidelines for COPD (known as ‘COPD-X’), a diagnostic algorithm, a COPD-Checklist, COPD Action Plans, the Pulmonary Rehabilitation Toolkit, and this Manual.

Description of Pulmonary Rehabilitation (PR)

Pulmonary rehabilitation (PR) is a system of care that includes education, exercise training and psychosocial support delivered by an interdisciplinary team of therapists. It was originally designed for people with moderate to severe COPD, but those with other respiratory disorders who have disabling breathlessness can also benefit. Although it does not alter traditional lung function parameters [Level II], PR can help people achieve and maintain a maximum level of independence and functioning in the community [Level I]. It has favourable interactions with other interventions [Level II], particularly nutritional and pharmacotherapeutic, and can be delivered in a range of settings. Single modality treatments also have benefit.

Evidence Statements

Comprehensive Integrated Rehabilitation

Each component of PR is beneficial, but comprehensive integrated programs have greater efficacy. Effective PR requires close liaison among care providers and a philosophy of support for informal caregivers as well as the patient. Patient-specific goal-setting within a biopsychosocial paradigm, communicated to all care providers, should be reviewed regularly. As benefits wane after six to twelve months, continuing exercise should be encouraged, knowledge should be updated regularly, and social support structures should be optimised.

Meta-analyses and randomised controlled trials show that comprehensive Pulmonary Rehabilitation enhances health-related quality of life and self-efficacy, improves exercise performance and mental health, reduces breathlessness, and reduces health care utilisation (and associated costs) more effectively than each component. [Level I]

Exercise training

Exercise training includes aerobic training of upper and lower limbs and trunk muscles, flexibility and muscle strength, guiding efficient energy expenditure, and teaching breathing control during

exertion. Supervision helps build patient confidence, maximises skeletal muscle training, teaches breathing techniques, optimises cardiovascular fitness, and encourages exercise maintenance.

**Large randomised controlled trials and meta-analyses of exercise training alone in COPD have shown improvements in cardiovascular fitness, exercise tolerance, breathlessness, muscle strength, functioning, self-efficacy, mood and health-related quality of life. Training of multiple muscle groups is more beneficial than confining exercise to upper or lower limbs or to inspiratory muscles alone. [Level I]**

**Education**

Education improves the patient’s knowledge about breathing and the various treatments to control breathlessness. Of primary importance is assisting smokers to quit and sustain quitting. Patients should be trained to optimise activities and nutrition, gain control over anxiety, panic or depression, and use appropriate medications and therapeutic devices effectively. A background of respiratory anatomy and physiology is traditionally given, to assist with problem solving and building the patient's capacity to co-manage their condition.

**Small randomised trials of education alone show better self-efficacy, mood and health-related quality of life, above usual medical care, though the evidence for education alone is less robust than for exercise. [Level II]**

**Psychosocial support**

Depression, anxiety and panic are frequent complications of chronic disabling breathlessness, with dependency and social isolation being common consequences. General support, specific behavioural training and use of appropriate antidepressant medications where needed may enhance quality of life for the patient and the family caregiver.

**Small randomised controlled trials show better exercise tolerance, mood, self-efficacy and health-related quality of life from cognitive behaviour therapy alone in COPD. There is limited evidence that anxiolytics or antidepressant medications can help some people. [Level II]**
Roles and Responsibilities of Health Professionals

Health professionals involved in PR should have a high level of understanding about COPD and other chronic respiratory diseases, and the relevance of disability and handicap. They and their employers should recognise and respect the roles of all members of the care partnership, including the patient and family caregivers. They should have commitment to quality of care and continuous improvement. They should understand clinical indicators that reflect risk factors, and outcome measurements that reflect changes in impairment, disability and cost-effectiveness. They need to be timely, clear and relevant when communication with each patient’s health care providers. Above all, they must remember that PR represents an ideal opportunity to alter people’s lives for the better and that it should contribute to their patients’ lifetime care. [Level IV]

Patient Goals

Patients should be encouraged to explore their own needs and to plan their goals of treatment accordingly. After completing PR patients should be confident to monitor and manage their lung condition more effectively so they will have fewer sudden exacerbations and need for emergency treatment, and their dependency level is reduced. PR should enable patients to collaborate in an informed manner with their doctor and other care providers in planning their own care. [Level III-3] Their informal caregivers should also feel more confident and less restricted. [Level IV]

Levels of Evidence

Throughout all ALF documents a similar system for recording levels of evidence is used.

<table>
<thead>
<tr>
<th>Level</th>
<th>Sources of Evidence</th>
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<tbody>
<tr>
<td>I</td>
<td>systematic review of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>at least one properly designed randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>well-designed controlled studies without randomization</td>
</tr>
<tr>
<td>III-2</td>
<td>well-designed cohort or case-control studies preferably from more than one centre or group</td>
</tr>
<tr>
<td>III-3</td>
<td>multiple time series, including dramatic results in uncontrolled experiments</td>
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<tr>
<td>IV</td>
<td>opinions of respected authorities, case series, descriptive studies, or reports of expert committees</td>
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Strength of Recommendations

The strength of support for recommended management is graded in a standard way throughout all ALF documents.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Sources</th>
<th>Definition</th>
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<tbody>
<tr>
<td>A</td>
<td>Rich body of data</td>
<td>Randomised controlled trials</td>
<td>Evidence from well-designed RCTs with clear endpoints providing consistent patterns of outcomes, involving large numbers of studies with substantial numbers of participants systematically reviewed in meta-analysis. This implies very low risk of bias, high degree of consistency, and direct applicability to the target population.</td>
</tr>
<tr>
<td>B</td>
<td>Limited body of data</td>
<td>Randomised controlled trials</td>
<td>Evidence from intervention studies that include limited numbers of participants, sub-group analysis of RCTs, case control or cohort studies. This implies good quality evidence with low risk of confounding or bias, and good applicability to the target population.</td>
</tr>
<tr>
<td>C</td>
<td>Very limited data</td>
<td>Non-randomised trials. Observational studies.</td>
<td>Evidence from outcomes of uncontrolled or non-randomised trials or from observational studies, well conducted case control or cohort studies with low risk of confounding and moderate applicability to the target population.</td>
</tr>
<tr>
<td>D</td>
<td>Opinion</td>
<td>Panel consensus. Judgement.</td>
<td>Little direct evidence apart from case studies, case reports, or opinions of respected authorities, extrapolated from clinical experience, cohort studies with potential confounding bias, descriptive studies or reports of expert committees.</td>
</tr>
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Evidence-Based Recommendations

1. Comprehensive pulmonary rehabilitation should be an integral part of treatment for all people with moderate to severe COPD (A), as it provides extra benefits over standard medical care in terms of clinically and statistically significant improvements in:
   - Exercise capacity (A)
   - Health-related quality of life (A)
   - Psychosocial problems (B)
   - Dyspnoea (A)
   - Fatigue (A)
   - Functional status (A)
   - Mastery and self-efficacy (A)

2. Comprehensive pulmonary rehabilitation should be considered for people with other disabling lung conditions. The following in particular are recommended:
   - Training for correct use of and asthma medications and devices (A)
   - Training for ensuring adherence to asthma treatment plan (A)
   - Exercise conditioning for people with asthma (B)
   - Sputum clearance for people with bronchiectasis including Cystic Fibrosis (B)
   - Education, psychosocial support, relaxation and exercise training for people with Pulmonary Fibrosis (D)

3. Exercise training for people with COPD is more effective than standard medical care, in terms of:
   - Exercise capacity (B)
   - Health-related quality of life (B)
   - Fatigue (B)

4. Additional benefit from exercise training may be provided by
   - Breathing control (slower deeper breathing pattern) (B)
   - Oxygen supplementation – inconsistent evidence (B)
   - Helium-oxygen breathing (B)
   - Use of long-acting bronchodilator (tiotropium) (B)

5. Educational training alone for people with COPD appears more effective than standard medical care, in terms of:
   - Health-related quality of life (B)
   - Self-efficacy (B)
   - Mastery (B)
   - Dyspnoea (C)
   - Functional status (C)
   - Psychosocial problems (C)

6. Psychosocial support through pulmonary rehabilitation and/or support groups is recommended for people with disabling COPD, as it is effective for the patient in terms of:
   - Self-efficacy (B)
   - Mastery (C)
   - Depression (C)
   - Panic disorder (D)
Functional status (B)
Health-related quality of life (B)
Carer health (D)

7. **Pulmonary rehabilitation is effective in a variety of settings**, including hospital inpatients (A), hospital outpatients (A) and community settings (B).

8. **Core staff for pulmonary rehabilitation** should be health professionals who understand lung and exercise physiology, pharmacology, and psychosocial issues (D).

9. **The Program Director** should be a health professional with a high level of commitment to outcome evaluation, quality improvement and economic aspects (D). The appointment will depend on local requirements and staff limitations.

10. **A medical consultant should take a lead role** in program content, patient assessment and program safety supervision (D). Medical input into educational training is also recommended (D).

11. **A referral process should be agreed with consumers, administrators and professionals**, and adhered to (D), taking into account local needs and limitations. Referring professionals should be required to document all conditions and treatments applicable to the patient.

12. **All patients referred for pulmonary rehabilitation should undergo an initial clinical assessment (D)**, to include as a minimum:
    - Age, gender, racial or ethnic background, occupations, family respiratory history
    - Place of residence and presence of family caregiver, plus other important supports
    - Smoking status (past and present, quantity, readiness to quit if still smoking, level of nicotine dependence and other habit issues)
    - Nutritional status (current weight and body mass index, recent weight loss)
    - Functional status (mobility, causes of limitations)
    - Primary respiratory and secondary diagnoses (comorbidities & complications of the primary disease or treatment)
    - Pharmaceutical and other treatments (oxygen, physical, psychological, and complementary)
    - Patient perceived problems and their goals

13. **All patients enrolled in pulmonary rehabilitation should have documentation of clinical indicators (D)**, which should address
    - Nutritional measures (eg height, weight, body mass index, etc)
    - Symptoms and dyspnoea scoring (eg MRC Dyspnoea Grade, etc)
    - Respiratory impairment (eg spirometry, gas transfer, etc)
    - Mental health status (eg General Health Questionnaire, Hospital Anxiety and Depression Scale, etc)
    - Level of disability (eg 6-minute walk, shuttle walk, functional index, etc)
    - Level of handicap (eg functional / ADL assessment)
    - Health-related quality of life (eg St George Respiratory Questionnaire, SF-36, etc)
    - Current level of achievement of negotiated goals

14. **All patients completing pulmonary rehabilitation should have changes in outcome measures documented**, addressing the above clinical indicators (D)
15. **Timely feedback should be provided to health professionals involved in the care of each patient** (whether referring the patient or not) (D) about:
   - Initial assessments and recommendations relating to new findings
   - Post-program assessments and recommendations for ongoing care
   - Long-term assessments
1. INTRODUCTION

This Manual aims to provide comprehensive information for health workers and other providers, administrative boards, governments, insurers and other interested bodies relating to Pulmonary Rehabilitation and its application in Australia. Recommendations are based on current scientific evidence, guidelines from the USA\textsuperscript{1,2}, UK\textsuperscript{3} and Europe\textsuperscript{4}, systematic reviews, meta-analyses and careful literature review. American and European specialist societies have joined forces in a joint Statement more recently\textsuperscript{5}, and the AACP/AACVPR Clinical Practice Guidelines have also been updated\textsuperscript{6}. Data from ALF surveys of patients and professionals provide nationally relevant information about program availability, patient perceptions and an understanding of what constraints exist to providing or accessing this form of therapy in Australia.

The Manual should assist professionals and organisations wishing to develop programs that are relevant to the needs and demographics of the local community. It forms the evidence base for the Pulmonary Rehabilitation Toolkit, which provides direct assistance, through http://www.pulmonaryrehab.com.au, or http://www.lungnet.com.au/copd/PR_Toolkit.html

References are placed for immediate ease of access as footnotes on the same page. This should reduce the need for cross-referencing, and each section can be read independently. Key Points are emphasized throughout in shaded Boxes as helpful summaries. Submissions and special reports that form the basis for Australian application are available as a set of Appendices but are not published in this main document.

**History and Role of the Australian Lung Foundation in Research and Patient Care**

The Australian Lung Foundation (ALF) has had a charter since the late 1980's to improve the wellbeing of people with respiratory conditions and to promote lung health in Australia. It seeks to achieve these by:
- Raising funds in support of medical research into lung diseases
- Distributing research findings and knowledge
- Educating patients and the broader public on the prevention, early detection and effective treatment of lung diseases
- Fostering patient support activities
- Influencing public and corporate policy to ensure safe living and working environments and equitable access to quality health care

In 1995 the ALF convened a National Lung Research Summit to determine priorities, from which came the recommendation for the formation of multi-disciplinary condition-related Consultative Groups – aiming to develop priorities in respiratory health, and supporting holistic patient care and research. The Chronic Airflow Limitation Consultative Group was established in 1997 and later became the COPD Coordinating Group.

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\textsuperscript{1} AACVPR/ACCP Pulmonary Rehabilitation Guidelines Panel. Pulmonary Rehabilitation. Joint ACCP/AACVPR evidence-based guidelines. *Chest* 1997; 112:1363-1396

\textsuperscript{2} American Association of Cardiovascular and Pulmonary Rehabilitation. Guidelines for Pulmonary Rehabilitation Programs 2\textsuperscript{nd} edition. *Champaign IL: Human Kinetics 1998*

\textsuperscript{3} British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation. Pulmonary rehabilitation. *Thorax* 2001; 56:827-834

\textsuperscript{4} Donner CF, Muir JF. Selection criteria and programmes for pulmonary rehabilitation in COPD patients. *Eur Respir J* 1997; 10:744-757


Committee. LungNet, an information service and network of lung support groups was also created, informed by a Better Breathing Program to assess community-based groups that were set up to promote self-management and independent living skills in clients with breathing disorders. An informal ‘Pulmonary Rehabilitation Network’ of health professionals wishing to share information and knowledge was established, and in 2004 began the task of developing a PR Toolkit for those wishing to set up or enhance PR programs (in conjunction with Australian Physiotherapy Association – APA).

Close liaison between the ALF COPD Committee and the Thoracic Society of Australia and New Zealand (TSANZ) created a TSANZ/ALF COPD Guidelines Steering Group, charged with assembling, promulgating, implementing and evaluating evidence-based Guidelines for management of COPD (‘COPD-X’). The initial version was published in 2003 after considerable consultation and consensus. An independent ALF Evaluation Committee reviews evidence quarterly, and the COPD-X online version is updated. A formal Update was print-published in 2006. This PR Manual meshes with these Guidelines.

Given an expanding base of evidence, and a dearth of available programs in Australia, PR has been given very high priority by the ALF and TSANZ. In 2000 the ALF recommended to the TSANZ that there was a need for a set of Standards for PR, and a grant was offered under the ALF-Boehringer Ingelheim Award. The brief was to undertake wide collaboration and a careful search of scientific evidence, and to incorporate the resulting information into a document of Standards. Further products were to be a Toolkit, available in print and web-based version for people delivering PR and for those wanting to start a new program, as well as an evidence-based Manual. A submission has now been made to the Australian Commonwealth Government by ALF for active support of PR around Australia, and it has been piloting development of a rural and remote version of pulmonary rehabilitation in Aboriginal communities in Northern Territory and Western Australia.

Program of Evidence-Based Supports for Pulmonary Rehabilitation in Australia

Goal
To develop a series of resources for people and organisations wishing to set up, conduct, learn about or take part in pulmonary rehabilitation in Australia. The minimum resource will be a set of Standards for Pulmonary Rehabilitation in Australia, but other resources need to be planned:

- a Guidelines document (or ‘Manual’) based on best available evidence
- a consensus summary document for easy reference
- a toolkit of materials to support developing programs in a range of jurisdictions
- development of a Pulmonary Rehabilitation Database, with emphasis on outcomes

Resources
- ALF National Survey of Pulmonary Rehabilitation Programs (1999)
- ALF detailed survey of selected pulmonary rehabilitation sites (2000)
- AACVPR Guidelines for Pulmonary Rehabilitation Programs (third edition, 2005)
- ALF COPD Case Statement and COPD Economic Case Statement

• Guidelines of Management of COPD - TSANZ (‘COPD-X’ 2003 and 2006), BTS, NICE, ATS, ERS, ATS/ERS
• "Improving Cardiac Care and Outcomes. New South Wales Policy Standards for Cardiac Rehabilitation". NSW Health Department. State Health Publication No: (C)97 0120.
• “Best Practice Guidelines for Cardiac Rehabilitation and Secondary Prevention”. Heart Research Centre (AJ Goble and MUC Worcester), DHS Victoria (1999)

**Stages of Development**

- Search and critically review all available relevant scientific publications about pulmonary rehabilitation, its components and its links (including patient support).
- Evaluate systematic reviews, randomised controlled trials and other research about PR.
- Develop a package of minimum standards for each component of pulmonary rehabilitation and its components, documenting strength of supporting evidence, and continually updating them (‘A Manual for Pulmonary Rehabilitation in Australia’, an evidence base for a Pulmonary Rehabilitation Toolkit
  - Descriptions and analyses of community-based treatments
  - The place of different PR programs in COPD management
  - Outcome assessment tools
  - Health economics of PR and PSGs
  - Role of PR in other respiratory causes of dyspnoea
  - Staging of PR and linkages with other therapies
- Consult with people and organisations who have published high level research, and with Australian and New Zealand people and organisations currently undertaking such research.
- Review Australian and overseas models (notably home-based/community programs).
- Consult with groups providing PR (of various types), or with a particular stake in PR and its place in community care and disease management of chronic lung diseases.
  - Respiratory physicians
  - Physiotherapists
  - Nurses and asthma educators
  - Respiratory scientists
  - Exercise rehabilitation scientists
  - General practitioners
  - Clients, consumers and carers
  - Patient support groups
  - Other allied health professionals
  - Relevant Government and non-government agencies
- Provide updated ‘Summary of evidence-based recommendations’ for ALF web-site
- Assist with the development of a ‘Pulmonary Rehabilitation Toolkit’ by ALF.
- Circulate draft of ‘Manual’ to ALF COPD Coordinating Committee, ALF/APA Pulmonary Rehabilitation Toolkit Steering Committee, ALF COPD-X Evaluation Committee, TSANZ COPD SIG, TSANZ Executive and other relevant organisations and individuals for final critique
- Publish ‘A Manual for Pulmonary Rehabilitation in Australia’, and update according to emerging high level evidence at least triennially

**Acknowledgements**

The Australian Lung Foundation (ALF) has been a tireless and generous investor in the diagnosis and management of Chronic Obstructive Pulmonary Disease (COPD), and their support for the Pulmonary Rehabilitation Toolkit Program is applauded. The ALF National Council accepts the importance of patient support and the central role of pulmonary rehabilitation for people with chronic and complex respiratory diseases, and determined that its annual ALF-Boehringer Ingelheim Australia Award should be directed to the support of this project. The ALF COPD Coordinating Committee gave oversight. L Thompson, G Perl, W Darbishire, H Allen and D Marshall have been vital supporters.
Critical reviews of medical literature have been vital. P Walker, A Crockett and J Cranston provided invaluable assistance in its first and second iterations. P Cafarella and J Duffy have subsequently helped review psychological comorbidities and treatments. D Schembri has provided physiological contributions, and T Hunt has helped review trials of heliox supplementation. K Humphrys and G Cross have contributed expert nutritional advice and literature reviewing. Pulmonary rehabilitation programs around Australia, and data from the ALF Better Breathing initiative have also provided valuable information. In particular, J Allison, L Spencer and S Jenkins have been critical in early surveys and creation of the Pulmonary Rehabilitation Toolkit. Many individuals and organisations prepared superb expressions of interest, which are acknowledged. Ideas gathered from people with COPD and other chronic and complex respiratory conditions are too countless to mention. It would be unfair to single out individuals, but thanks to you all!

Medical staff in the Repatriation General Hospital (RGH) and Southern Respiratory Services (SRS) have been generous in backfilling time for this lengthy project, and with its literature searching and revision. B Hamilton, K Hendra and S Spry have helped with word processing advice and protecting my time.

I hope this Manual - the outcome of the energies and supports of many people - is a helpful reference work for ongoing enhancement of Pulmonary Rehabilitation in Australia. The ultimate acknowledgement must be to those who use this document and its associated Toolkit for the well-being of those many hundreds of thousands of Australians suffering from chronic respiratory diseases.

Peter Frith. July 2008
2. DEFINITIONS AND DESCRIPTIONS

2.1 Chronic Obstructive Pulmonary Disease (COPD)

The most widely recognised working definition of COPD is that adopted by the Global Initiative for Chronic Obstructive Lung Disease (GOLD):

"COPD is a disease state characterized by poorly reversible airflow limitation that is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases, particularly cigarette smoke. Symptoms, functional abnormalities, and complication of COPD can all be explained on the basis of this underlying inflammation and resulting pathology."9,10

The term COPD has globally superseded use of such terms as chronic airflow limitation (CAL), chronic obstructive airways (or lung) disease (COAD or COLD) and chronic airways obstruction (CAO).

COPD is an acquired inflammatory and degenerative condition of the lungs. The inflammatory nature of the condition, with its pulmonary and systemic ramifications, has been described11, with a recent update12. The effects of inflammation and the syndrome of COPD are unstable but ultimately progressive. The natural rate of decline of lung function (FEV1) after 25 years of age is 15 to 30 mL per year. In ‘susceptible’ smokers who continue to smoke, however, the decline averages 60 mL per year and may be as great as 200 mL per year.

Greater emphasis is now placed on the preventability and treatability of COPD - rather than earlier descriptions of it being incurable13,14 - as is the case with chronic heart failure, diabetes, depression, chronic renal disease and many other chronic conditions.

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Those who stop smoking during their 40’s still have a greater rate of functional decline than non-smokers, albeit slower than continuing smokers\textsuperscript{15,16,17}. Airway and systemic inflammation are associated with more rapid decline in lung function, as well as other poor outcomes, and are increased by exacerbations of the disease\textsuperscript{18}.

In essence COPD is more a syndrome than a specific disease, as there are different pathophysiology and clinical presentations. The typical phenotypes are \textit{emphysema} and \textit{chronic bronchitis}, though \textit{bronchiectasis} and \textit{chronic asthma} can also be identified in many patients. Chronic lung inflammation triggered by noxious inhalants appears to result from damage to the innate immune system in some individuals, with imbalances within protease-antiprotease and oxidative stress-antioxidant mechanisms, and ultimately leads to widespread pathological changes that represent COPD. The debate around whether these changes occur only in a proportion of ‘susceptible’ individuals is resolving\textsuperscript{19}. Central and peripheral airway inflammation, oedema, mucus hypersecretion, and ciliary dysfunction can lead to airway obstruction, airflow limitation, sputum production and dilatation and destruction of respiratory bronchioles and alveoli. Fixation of airflow limitation arises from remodelling of small airways and loss of elastic support of airway walls when there is emphysema. Despite the traditional view of irreversible airflow limitation being the physiological feature of COPD, it is increasingly recognised that there is a range of bronchodilator responsiveness, blurring the distinction between asthma and COPD\textsuperscript{20,21}.

The diagnosis of COPD relies on the identification of airflow limitation that is not reversible or at best only partially reversible following bronchodilator\textsuperscript{22,23}. A fixed ratio for FEV1/FVC of 0.70 is the cut-off value recommended, although arguments have been put that this underestimates COPD in younger people and overestimates in older people\textsuperscript{24}. It is recognised that FVC may be difficult for some untrained people to achieve, and the FEV6 (forced expired volume in six seconds) has been suggested as a replacement for the FVC, and hence the FEV1/FEV6 ratio has emerged\textsuperscript{25,26,27}. This has been tested in and Austrian population-based study (n=1,349), and its

\begin{itemize}
  \item \textsuperscript{15} Fletcher C, Peto R. The natural history of chronic airflow obstruction. \textit{Brit Med J} 1977; 1:1645-1648
  \item \textsuperscript{16} Anthonisen NR, Connnett JE, Kiley JP, Altose MD, et al. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1. The Lung Health Study. \textit{JAMA} 1994; 272:1497-1505
  \item \textsuperscript{17} Anthonisen NR, Connnett JE, Murray RP. Smoking and lung function of Lung Health Study participants after 11 years. \textit{Am J Respir Crit Care Med} 2002; 166:675-679
  \item \textsuperscript{19} Vestbo J, Hogg JC. Convergence of the epidemiology and pathology of COPD. \textit{Thorax} 2006; 61:86-88
  \item \textsuperscript{21} Soriano JB, Mannino DM. Reversing concepts on COPD reversibility. \textit{Eur Respir J} 2008; 31:695-696
  \item \textsuperscript{23} McKenzie DK, Frith PA, Burdon JG, Town GL. The COPDX Plan: Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease 2003. \textit{Med J Aust} 2003; 178(Suppl):S1-S40
  \item \textsuperscript{24} Celli BR, Halbert RJ, Isonaka S, Schau B. population impact of different definitions of airways obstruction. \textit{Eur Respir J} 2003; 22:268-273
  \item \textsuperscript{25} Vandevooorde J, Verbanck S, Schuermans D, et al. FEV1/FEV6 and FEV6 as an alternative for FEV1/FVC and FVC in the spirometric detection of airways obstruction and restriction. \textit{Chest} 2005; 127:1560-1564
  \item \textsuperscript{26} Hansen JE, Sun X-G, Wasserman K. Should forced expiratory volume in six seconds replace forced vital capacity to detect airways obstruction? \textit{Eur Respir J} 2006; 27:1244-1250
\end{itemize}
sensitivity for airflow limitation was high when a low FEV1 value was included in the algorithm\textsuperscript{28}.

There has been substantial discussion about the merits or otherwise of early diagnosis utilising spirometry in primary care\textsuperscript{29}. The FEV1/FEV6 ratio has a potential advantage of being measurable using inexpensive and simple equipment and this may lend itself to case-finding or screening for early diagnosis. On the other hand opinions are divided on whether it is useful and cost-effective to make earlier diagnoses. The findings from a survey in a working population in France (n=5,008) that even mild COPD is associated with significant dyspnoea and impairments in quality of life\textsuperscript{30} and, from other studies, that early identification of airflow limitation assisted with smoking cessation\textsuperscript{31,32} provide encouragement to diagnose COPD earlier in its trajectory.

Increasing use of spirometry in primary care is feasible\textsuperscript{33}. GP use of electronic spirometers in patients aged 35-70 (n=3,408) detected 126 new patients, of whom 42% would have been missed by a screening questionnaire\textsuperscript{34}. In a combined questionnaire and spirometry screening study in Belgian general practices there was a high new case detection rate\textsuperscript{35}. Open-access spirometry tests made available to a local area resulted in a new diagnosis of COPD for over 40% of those with full results, and they were considered to be under-treated before testing\textsuperscript{36}. Despite these positive findings, however, a number of problems associated with primary care spirometry have been identified. In Australia, for example (and similar trends have been seen in other countries), as many as three-quarters of GPs own an electronic spirometer but infrequently use them, and of those who do, low numbers perform high quality measurements or maintain their equipment adequately\textsuperscript{37}. Barriers to more widespread use relate to organisational and technical difficulties as well as poor understanding of interpretation of results and the clinical value of the test\textsuperscript{38}. Training

\textsuperscript{27} Akpinar-Elci M, Fedan KB, Enright PL. FEV6 as a surrogate for FVC in detecting airways obstruction and restriction in the workplace. \textit{Eur Respir J} 2006; 27:374-377
\textsuperscript{31} Clotet J, Gomez-Arbones X, Ciria C, Albalad JM. Spirometry is a good method for detecting and monitoring chronic obstructive pulmonary disease in high-risk smokers in primary health care. \textit{Arch Bronconeumol} 2004; 40:155-159
\textsuperscript{32} Bednarek M, Gorecka D, Wielgomas J, et al. Smokers with airway obstruction are more likely to quit smoking. \textit{Thorax} 2006; 61:869-873
\textsuperscript{34} Buffels J, Degryse J, Heyrman J, Decramer M. Office spirometry significantly improves early detection of COPD in general practice. The DIDASCOS Study. \textit{Chest} 2004; 125:1394-1399
The relative value and accuracy of using questionnaires or spirometry for case-finding has been discussed. Diagnostic questionnaires have been developed and validated, with somewhat disparate findings, using laboratory-based spirometry as the diagnostic reference point. FEV1/FEV6 using simple measurement tools has also been validated against high quality spirometry, and has very high validity and utility. In this same study, simple flow measurement was superior to the questionnaires for case finding.

Airflow limitation leads to static lung overinflation with increased work of breathing. During activities, the physical work leads to increased ventilation, and lung units with greatest airway narrowing are unable to empty at higher flow rates. This results in uneven ventilation and emptying which in turn lead to both increased mis-matching of ventilation and perfusion and also dynamic hyperinflation. The work of breathing therefore increases dramatically, and gas exchange inefficiency may also cause oxygen desaturation, either or both of which result in dyspnoea, the prime clinical characteristic of COPD.

Systemic manifestations, related to muscles, heart, body composition, and mental health must be accounted for in disease management.

Small vessel vasculitis is also often seen, and in combination with ventilation maldistribution, contributes to gas exchange abnormalities that result in hypoxaemia. This in turn can lead to further pulmonary vasoconstriction and ultimately pulmonary hypertension.

It needs to be emphasised that COPD is a largely preventable condition (cigarette smoke, occupational exposures, poor control of asthma, and indoor and outdoor air pollution are the leading aetiologic factors). Primary prevention needs to be promoted at all opportunities by PR.

practitioners, as well as secondary prevention, in order to reduce airway inflammation and its consequences. Therapies that reduce airway and systemic inflammation and their consequences, dilate and stabilise airways with the goal of deflating hyperinflated lungs, and enhance and maintain exercise capacity through good nutrition and exercise training are likely to improve overall health status, mood and carer health, and reduce exacerbations and mortality. The complex comorbidities of COPD need also to be taken into account when assessing and treating COPD, in line with evolving appreciation of chronic disease management. This Manual therefore provides substantial background material to help practitioners understand COPD and its implications elsewhere.

2.2 Clinical Indicators and Outcome Measures

Public accountability for clinical practice has challenged health professionals to be more systematic in documenting clinical outcomes, and the ability to assemble and analyse data has enabled professionals to turn this need into a science. As clinical practice has been more minutely examined, and clinical outcomes more readily measured, variations in both practice and outcomes have emerged. It has been stated, though, that “there are enough outcome measures and tests available to keep both the patient and the pulmonary rehabilitation staff busy for the entire rehabilitation time period!”\(^{49}\), and some rationality is needed.

The impacts of interventions are termed outcomes, so assessment of outcomes should be an integral part of good clinical practice. This Manual does not cover all possible measures, but most of those reported in trials of PR are addressed. Recommendations for using particular measures are based on evidence for their utility and validity. Recent publications have provided comprehensive discussion of a wide range of outcomes measures of potential use in trials of drug therapies\(^ {50}\), and a prospective study of what measures most effectively predict long term disease outcome is currently underway\(^ {51}\). These articles are recommended for careful consideration.

Health outcomes

Health outcomes may relate to impairments, disabilities, handicaps and costs. Outcome measures should be accurate, relevant to the intervention, reliable, and have undergone careful validation. For health outcomes to result in changes in clinical practice they should be overtly relevant to the clinical problem, and address consumer satisfaction, patient preferences and community needs.

It is useful to distinguish between effectiveness and efficacy of specific interventions.

- **Effectiveness** refers to benefits observed from an intervention in a real-life setting with unselected clinic patients, staff of average capability, and in facilities with real-life levels of funding.

\(^{49}\) ZuWallack RL. Outcome measures for pulmonary rehabilitation. *Eur Respir Monograph* 2000; 5:177-200


• **Efficacy** is determined in research trials, preferably randomised controlled trials, with carefully selected patients, usually highly qualified, specifically employed and motivated staff, in well-equipped research facilities.

### Health Economic Outcomes

It is increasingly acknowledged that economic issues are also important. Little work had been done before 1990 in either COPD or asthma, but analyses are increasingly applied in research trials, and certainly in evaluating clinical programs when sustainability issues arise. A useful review of health economics in COPD was recently published by Halpin.

- **Cost-benefit analysis** assesses which of two treatment programs is the more beneficial in terms of resources saved versus resources used. Both the costs and the benefits are expressed in dollar terms. Improvements in productivity may enhance the cost-benefit of a particular treatment. Such analysis does not account for the value placed by society or the individual on achieving certain outcomes at stated costs.

- **Incremental cost-benefits** provide an understanding of the marginal cost of adding one type of intervention to another (e.g. adding an education program to an exercise program in PR). If a treatment provides benefits that are delayed for a year or more after an immediate cost is incurred, a discount is applied to the delayed benefits, at an agreed rate (e.g. 5% per annum), so treatments with different time-frames can be compared.

- **Cost-effectiveness analysis** determines which of two alternative interventions offers the lowest cost per unit of benefit. It evaluates a ratio of total costs (numerator) to effectiveness (denominator). The costs are those related to the interventions studied minus savings accruing through prevention of events. The costs of two interventions (e.g. PR vs lung volume reduction surgery) may therefore be compared to their respective consequences. The outcomes need to be measured in the same units, and all resource implications (costs) are considered, including opportunity costs (related to spreading fixed funding between different programs and opportunities surrendered when one program is supported over another). Most commonly effectiveness is expressed as increased years of life, though it may be related to the number of lives saved or other outcomes. Cost-effectiveness is therefore expressed as a net cost per net outcome (cost-effectiveness ratio), and it indicates which intervention provides more value for money. A more expensive intervention may be more value than a less expensive one because its clinical effectiveness is substantially greater.

- **Cost-utility analysis** is a variant of cost-effectiveness analysis, in which outcomes as consequences of interventions are expressed in utilities (e.g. QALYs and DALYs) instead of natural units. The QALY (Quality-Adjusted Life Year) and DALY (Disability Adjusted Life Year) are the best-known measures of utility; they are based on a quantity of life scale adjusted for its quality.

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Indicators of Respiratory Impairment

Measures from Static Respiratory Tests
In each case, methodological details are addressed in Chapter 6. The tests have been developed and standardised over many years, and have value in describing respiratory impairment. There are ATS/ERS\textsuperscript{55} and TSANZ Standards that apply\textsuperscript{56} to testing and interpretation\textsuperscript{57}.

Spirometry requires maximum effort from the patient and standardised performance by the person supervising the test (Table 2.1). Some patients are unable to provide satisfactory results. However, results have major prognostic significance and are clinically meaningful. Moreover, spirometry results are a requirement for diagnosis and assessment of severity in COPD; the bronchodilator responsiveness of spirometry also helps in the differential diagnosis from asthma, and the patterns of results help to distinguish COPD from interstitial lung disorders.

Other tests of lung function not requiring forced expiratory effort have been developed, such as forced and impulse oscillometry\textsuperscript{58}. They may provide interesting research questions, but are not yet applicable to routine clinical assessment. Estimation of subdivisions of lung volumes (gas dilution or body plethysmography) helps document the work of breathing influenced by gas trapping and overinflation (Table 2.2). Gas transfer measurements, using carbon monoxide as the indicator gas, help in understanding the anatomic cause of dyspnoea (Table 2.3).

<table>
<thead>
<tr>
<th>TABLE 2.1. MEASURES FROM SPIROMETRY\textsuperscript{59,60,61,62}</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEV\textsubscript{1}</strong></td>
</tr>
<tr>
<td><strong>FEV\textsubscript{1}/FVC</strong></td>
</tr>
<tr>
<td><strong>FVC</strong></td>
</tr>
<tr>
<td><strong>SVC</strong></td>
</tr>
</tbody>
</table>

\textsuperscript{60} Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories (Crapo RO, Chairman). Standardization of spirometry; 1994 update. *Am J Respir Crit Care Med* 1995; 152:1107-1136
### Table 2.2. Measures from Body Plethysmography or Inert Gas Dilution

| **TLC** | Total lung capacity (litres). The overall volume of air within the lungs after a full inhalation. [TLC = RV + SVC, or TLC = FRC + IC]. Normal values are determined from race, gender, age and height. Values < 80% of predicted are abnormal. Low values indicate restriction (e.g. pulmonary fibrosis, lung resection, pleural disease, chest wall disease or obesity). Values > 120% of predicted are also abnormal, and indicate static hyperinflation. |
| **RV** | Residual volume (litres). The amount of air left within the lungs after a full expiration. Normal values are determined from race, gender, age and height. Values < 80% of predicted are abnormal. Low values occur with restriction (e.g. pulmonary fibrosis, lung resection, pleural disease, chest wall disease or obesity). Values > 120% of predicted are also abnormal, and occur with air-trapping (e.g. from persistent airway narrowing). |
| **RV/TLC** | Ratio of RV : TLC. Normal values depend mainly on age. Values over 120% of predicted are abnormal, and indicate distal air-trapping (e.g. from persistent airway narrowing). |
| **TV** | Tidal volume (litres). The volume of air breathed during normal resting breaths. |
| **IC and IC/TLC** | Inspiratory capacity (litres). The volume difference between FRC and TLC. IC/TLC is reduced where there is air-trapping. |

### Table 2.3. Measures from Carbon Monoxide Gas Transfer Test

| **DlCO or TlCO** | Gas transfer or transfer factor (mL CO per second per mmHg). The amount of carbon monoxide removed from a full inhalation of air containing trace quantities of carbon monoxide. Reflects gas transfer across the alveolar membranes from alveolar air to red cells haemoglobin. Normal values depend on race, gender, age, height, and haemoglobin level. Values < LLN (or < 80% of predicted), after correction for haemoglobin levels, are abnormal, and indicate abnormal gas exchange (e.g. from pulmonary fibrosis or other interstitial lung disease, emphysema, or pulmonary vascular disease). Values above the upper limit of normal (ULN), or > 120% of predicted may be abnormal, and occur where there is high circulating blood volume or intrapulmonary haemorrhage (e.g. Goodpasture's syndrome). |

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Measures from Functional Tests

Functional tests reflect a person’s ability to undertake activity of daily living. They are simple to conduct, though some training is required. A systematic overview suggested that the 6-minute walk is the test of choice as a functional test in both clinical and research settings\(^71\).

**TABLE 2.4. WALKING TESTS**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
<th>Measurements</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-minute walk test</td>
<td>Self-paced distance (metres) walked in 6 minutes, along a standard course, with standard encouragement(^72,73). Normal values relate to age and gender. Clinically significant changes are inferred from changes &gt; 49 m.</td>
<td>VE, HR, VO2, VCO2, W</td>
<td>ventilation (litres), heart rate (beats per min), oxygen uptake (mL/min), carbon dioxide uptake (mL/min), workload (watts)</td>
</tr>
<tr>
<td>Shuttle walk test</td>
<td>Distance (metres) walked in an incremental test to exhaustion, over a standard circuit, with standard encouragement(^74). Normal values relate to age and gender.</td>
<td>VE, HR, VO2, VCO2, W</td>
<td></td>
</tr>
<tr>
<td>Walking endurance tests</td>
<td>Time of walking at a set pace based on maximum walking capacity. May be done on a treadmill or a Shuttle test circuit(^75).</td>
<td>VE, HR, VO2, VCO2, W</td>
<td></td>
</tr>
</tbody>
</table>

Complex exercise tests have been more relevant to research as they require expensive equipment with highly skilled scientist involvement and physician interpretation, although with technological advances, they are emerging as useful clinical tools. They can assist in determining the cause of limitation, and therefore help target therapies more effectively. They can also provide valuable information about endurance, which in turn can help in prescribing exercise training loads. They can also provide a number of highly relevant outcome measures.

**TABLE 2.5. ERGOMETER TESTS\(^76\)**

<table>
<thead>
<tr>
<th>Type of test</th>
<th>Description of test</th>
<th>Measurements</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incremental ergometry</td>
<td>Performed on treadmill or cycle ergometer. Initial values at rest, then unloaded exercise, then increasing load to exhaustion (i.e. symptom-limited maximum test). Many others are calculated.</td>
<td>VE, HR, VO2, VCO2, W</td>
<td>Reasons for tests: Study cardiovascular and metabolic functions under load • a standard measure of endurance • a provocation for exercise-induced asthma(^77)</td>
</tr>
<tr>
<td>Steady-State tests</td>
<td>Exercise on cycle or treadmill ergometer at specific levels of work usually determined from incremental ergometry.</td>
<td>VE, HR, VO2, VCO2, W</td>
<td></td>
</tr>
</tbody>
</table>

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\(^71\) Solway S, Brooks D, Lacasse Y, Thomas S. A qualitative systematic overview of the measurement properties of functional walk tests used in the cardiorespiratory domain. Chest 2001; 119:256-270


**Indicators of Psychological Impairment**

There is increasing evidence supporting the importance of psychological impairments in chronic lung disease, though the epidemiology related to their prevalence and burden is inconsistent. Different interpretations may be driven most by the population under examination, with psychological distress being more prevalent in people with more severe disease. Further, confusion between psychological distress and mental health disorders exists, and needs to be clarified.

Apart from the population being investigated, another problem with estimating prevalence of mood disorders in people with COPD (and their carers) is the variety of measurement tools used. These vary from broad-based psychological health/distress questionnaires to specific anxiety or depression inventories and structured interviews for a codable psychiatric diagnosis. These issues are considered in more detail in the discussion of specific outcome measures.

**Indicators of Nutritional Impairment**

People with COPD develop an increasing potential for a variety of nutritional impairments and changes in body composition as the disease progresses. Weight loss, in particular, is seen in a third or more of those with moderate-to-severe COPD\textsuperscript{78-81}. Nutritional impairments may have significant effects on ability to function in everyday life. Those who are underweight have impaired exercise tolerance\textsuperscript{82,83} and there is a close association between nutritional depletion and quality of life\textsuperscript{84,85}. Moreover, worse nutritional status is associated with higher mortality.

\textsuperscript{78} Engelen MPKJ, Schols AMWJ, Baken WC, et al. Nutritional depletion in relation to respiratory and peripheral skeletal muscle function in outpatients with COPD. *Eur Respir J* 1994; 7:1793-1797
Body mass and body composition may have different implications. Body mass index (BMI) is a function simply of height and weight (weight in Kg / [height in metres]$^2$), and includes fat and fat-free mass; significant muscle wasting can occur in people with normal or even high BMI. BMI is a strong independent predictor of survival in COPD$^{91,92}$. BMI is an independent indicator of outcome, and has been included in a general impairment index, the BODE Index$^{93}$, which has even greater prognostic power in COPD.

Indicators that reflect muscle mass depletion have appeal over BMI as this appears to be the main component of body mass contributing to the associations with exercise limitation, quality of life and mortality. Both screening tools and direct measures of fat-free or muscle mass are available. Patients with COPD whose lean body mass (FFM) is depleted have the greatest impairment of HRQoL$^{94}$. Even in COPD patients with normal BMI, FFM was an independent predictor of mortality$^{95}$.

### Activities of Daily Living

The quality of life for people with moderate and severe COPD is impaired in most aspects of functioning, from basic self-care, home management, social interactions, to recreational and leisure activities. The activities of daily living (ADLs) should therefore be a focus of assessment and for management strategies in disabled patients with COPD. Assessment requires history taking (which allows appreciation of cognitive capability and interaction with spouse or carer, self confidence and motivation) and formal functional assessments, by questionnaire and task performance. Dyspnoea questionnaires, satisfaction with performance scales, and subjective rating scales are available. Technological advancements are increasingly being applied to the continuous monitoring of activity like pedometers, accelerometers and other related devices.

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While some of this testing is in the realm of exercise scientists and physiotherapists, full functional assessment and goal-setting is ideally undertaken by interaction between the physiotherapist and occupational therapist as well as the wider interdisciplinary team. The primary goal of the occupational therapist is to restore independence in performing ADLs. Minimising dyspnoea during activities by simplifying tasks may seem to be at odds with the desire to stimulate cardiovascular training through moderate and high intensity exercise. Balances and compromises are often needed, and collaboration between patient / carer and the physiotherapist, exercise scientist and occupational therapist is essential.

**Quality of Life**

The concept of quality of life (QoL) is complex, and the term is difficult to define, but in essence, quality of life is best understood as ‘happiness’. If the main aim of treatment is to reduce symptoms (dyspnoea, discomfort, pain, misery, and suffering) then standard methods that employ measurement of impairments may be less relevant to the individual than assessments that reflect or measure happiness.

A person's standing in relation to a series of core social concerns has been used by the OECD to define QoL96, with regard to community perceptions of health, education, employment, safety, justice, leisure time use, participation and social opportunity. Use of objective natural science indicators, where the patient is considered in isolation from the social milieu, is difficult and ineffective in evaluating QoL. Subjective QoL, which includes happiness, life satisfaction and well-being, humanistic characteristics that are critically dependent on stable positive relationships, is a more reliable measure of QoL97 in health terms.

**Health Status**

Quality of life is a personal attribute, while health status is a measurable attribute of a population group98. The most enduring, though crudest, measure of health status of a population is cause of death obtained from death certificates, but as increased survival rates from chronic diseases occur so disability assumes increasing importance99. The disability-adjusted life year (DALY) is a useful measure, as it represents the gap between a population's health status and that of an optimum reference population100. Just as individual QoL can be assessed from a careful clinical history, objective health status measures formalise similar questions that assess impacts of disease on groups of patients and changes following interventions. In turn they can guide history taking.

**Health-related quality of life (HRQoL)**

HRQoL refers to the physical, psychological and social domains of health unique to the individual101. Domains generally excluded from HRQoL are income, freedom and environment102. Tools to measure HRQoL are commonly used in research in chronic or terminal

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disease, but their application to routine clinical practice is small. Early instruments to measure HRQoL, particularly in cancer research, were uni-dimensional\textsuperscript{103}, but more recent models in chronic diseases have been multi-compartmental. Social and cultural contexts, physical and psychological illness, the amount of perceived freedom, achievement of ambitions, the matching of achievements to expectations, all impact on HRQoL.

The level of HRQoL in people with chronic illness is independently associated with risk of unplanned readmission to hospital\textsuperscript{104}, and with higher rates of depression\textsuperscript{105,106}. In chronic diseases like COPD, HRQoL measures aim to quantify the well-being of an individual and catalogue the contributing factors. The tools can be adapted for use in clinical care \textsuperscript{107}.

**Disease-specific measures**

These tools reflect the impact of a specific condition or organ-related abnormality on the individual. In general, they are more sensitive to change. Effects of an intervention on dimensions that are not included, however, may be missed in these more specific tools. In a recent UK study, disease-specific health status was worse in people with COPD than in an age-matched reference population\textsuperscript{108}, and declined progressively.

**Generic measures**

Generic tools allow us to compare the overall HRQoL of different chronic health conditions. They need to include a wide range of dimensions, which means their utility and responsiveness to change may be sacrificed because they need to be extensive or else their dimensions are addressed with such brevity. In the UK study referred to above, generic health status in people with COPD was barely different from age-matched controls\textsuperscript{109}, although a linear deterioration in generic health status over three years was demonstrated in those with COPD.

Disease-specific and generic measures have both recently been found in COPD to be related to health-care utilisation\textsuperscript{110}, and capable of predicting survival\textsuperscript{111}, and this inter-relationship becomes more significant in older individuals, those have higher levels of depression and those who are more symptomatic, regardless of gender\textsuperscript{112}. The possibility exists that the relationship between


\textsuperscript{104} Pearson S, Stewart S, Rubenach S. Is health-related quality of life among older, chronically ill patients associated with unplanned readmission to hospital? \textit{Aust NZ J Med} 1999; 29:701-706

\textsuperscript{105} Bosley CM, Corden ZM, Rees PJ, Cochrane GM. Psychological factors associated with the use of home nebulized therapy for COPD. \textit{Eur Respir J} 1996; 9:2346-2350

\textsuperscript{106} Cleland JA, Lee AJ, Hall S. Associations of depression and anxiety with gender, age, health-related quality of life and symptoms in primary care COPD patients. \textit{Family Practice} 2007; 24:217-223

\textsuperscript{107} Higginson JJ, Carr AJ. Using quality of life measures in the clinical setting. \textit{Brit Med J} 2001; 322:1297-1300

\textsuperscript{108} Spencer S, Calverley PMA, Burge PS, Jones PW. Health status deterioration in patients with chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2001; 163:122-128

\textsuperscript{109} Spencer S, Calverley PMA, Burge PS, Jones PW. \textit{ibid}

\textsuperscript{110} Desikan R, Mason HL, Rupp MT, Skehan M. Health-related quality of life and health care resource utilisation by COPD patients: a comparison of three instruments. \textit{Qual Life Res} 2002; 11:739-751


health care utilization and HRQOL may be in either direction\textsuperscript{113}. HRQoL may therefore provide a basis for staging COPD in functional terms\textsuperscript{114,115} to supplement lung function staging, as the two indicators may reflect different patient or disease characteristics\textsuperscript{116,117,118}, and HRQoL may better capture the systemic effects of COPD\textsuperscript{119}.


\textsuperscript{115} Hajiro T, Nishimure K, Tsukino M, et al. A comparison of the level of dyspnoea vs disease severity in indicating the health-related quality of life of patients with COPD. *Chest* 1999; 116:1632-1637

\textsuperscript{116} Hajiro T, Nishimure K, Tsukino M, et al. ibid


\textsuperscript{118} Mahler DA, Mackowiak JL. Evaluation of the short-form 36-item questionnaire to measure health-related quality of life in patients with COPD. *Chest* 1995; 107:1585-1589

QUALITY OF LIFE

KEY POINTS

1) Quality of life refers to an individual’s happiness.
2) Health status reflects the well-being of groups
3) Health-related quality of life can be measured with generic or disease-specific tools
4) Generic tools enable comparisons between different disease groups
5) Disease-specific tools are sensitive to respiratory disability and handicap, and sensitive to change

INDICATORS

KEY POINTS

1) Clinical indicator assessment should include impairments, disability, handicap and costs
2) Spirometry, lung volumes, and gas transfer reflect respiratory impairments
3) Exercise tests reflect respiratory impairment and disability
4) Psychological impairments include stable personality traits, mood states, emotions
5) Nutritional status is an independent prognostic indicator
6) Disability and handicap can be quantitated using quality of life measures

2.3 Disease Management

The philosophy of management of chronic complex diseases should incorporate patient-focussed evidence-based care through the disease continuum. ‘Chronic Disease Management’ (CDM) has emerged as a systematic approach to managing all aspects of a disease, from primary prevention,
through provision of cost-effective combinations of interventions aimed at optimising disease control, improving lifestyle factors influencing the disease, right to the end of life. It encourages holistic patient-centred care of people with chronic conditions and their family/informal caregivers within a care partnership, monitoring and constantly improving processes and clinical outcomes of interventions so that efficacy, effectiveness and cost-effectiveness are optimised.

Most chronic respiratory conditions have a progressive natural history that commences with minimal symptoms and mild impairment, and progresses to a systemic condition with severe handicap. Symptoms are generic – breathlessness with exertion, cough, and sputum production – and concurrent morbidities are common. These may be systemic manifestations of underlying inflammation, organ-based complications that result from the physiological or psychological stresses created by the severity of underlying disease, or in some cases adverse effects of treatments. Some may be present because they share either aetiology (smoking, pollution, etc) or age-related organ degeneration. All need attention in treating the respiratory disease.

**Systemic manifestations** of COPD include
- cor pulmonale and right heart failure
- polycythaemia
- loss of cardiovascular conditioning
- poor nutrition
- muscle weakness
- cognitive impairment
- mood disturbances

**Adverse effects of treatment** include
- osteoporosis, cataracts, proximal myopathy, systemic hypertension, psychoses, insomnia, peptic ulceration and diabetes associated with oral corticosteroids
- glaucoma and bladder outlet obstruction with anticholinergics
- cardiac arrhythmias and tremor with beta-receptor agonists or theophylline
- gastro-oesophageal reflux, peptic ulceration, nausea and seizures with theophylline
- candidiasis, skin fragility and bruising, and dysphonia from inhaled corticosteroids.

**Conditions that share aetiology or are age-related** include
- coronary artery disease
- cerebrovascular disease
- peripheral vascular disease
- lung and other cancers
- obstructive sleep apnoea (with obesity, hypertension, hypogonadism, etc)
- diabetes mellitus

**Consequences of the burden of disablement** are largely psychological and social:
- depression
- panic/anxiety
- social isolation
- dependency on spouses and family
- carer burden

A holistic approach to management of chronic complex respiratory conditions is likely to provide best outcomes. Providers of care should have expertise to identify and treat the concurrent morbidities, and support systems should cover the range of impairments, disabilities and
handicaps both of the primary disease and the concurrent conditions. CDM must encourage primary prevention and earlier detection of diseases, more equitable distribution of treatments, and better care for people with later stages of chronic complex diseases. It should give guidance for managing the continuously evolving nature of the conditions. Systems that support integrated self-management should aim to maintain better health for longer at the community level and reduce the need for crisis care. Integral to disease management in advanced respiratory disease are treatments for dyspnoea, palliative approaches, planning advanced directives and linking hospital management to community care guidelines.

Respiratory health professionals should be partners in initiatives that apply to the care continuum. Primary and secondary prevention involvement includes lifestyle, nutrition and quit-smoking projects (eg in schools, in general practice and in hospitals), and better identification of smokers at all ages. Providers (GPs, nurses and hospital doctors) should be trained to encourage behaviour change that leads to sustained quitting.

2.4 Impairment, Disability and Handicap

The World Health Organization (WHO) developed definitions in 1980\textsuperscript{120} that provided distinct albeit inter-related consequences of disease.

\textbf{Impairment} refers to an injury or abnormality occurring at the \textit{individual or organ system level} representing “any loss or abnormality of psychological, physiological, or anatomic structure or function”. Measurement of impairment typically focuses on severity of a deficit existing in the organ or system of interest, and usually requires disease- or organ-specific tools.

\textbf{Disability} may arise from an impairment or combination of impairments or diseases. Disability is primarily a social construct that occurs at the \textit{person level}, and represents “any restriction or lack (resulting from an impairment of ability to perform an activity in the manner or within the range considered normal for a human being”. Measurement of a disability is typically generic, and assesses the degree of independence with which an individual can perform activities of daily living.

\textbf{Handicap} arises from disabilities and impairments, and is the “disadvantage for a given individual that limits or prevents the fulfilment of a role that is normal (depending upon age, sex, social and cultural factors) for that individual”. Measurements of handicap address social roles, independence, mobility, social integration, productivity and economic self-sufficiency.

More recently the WHO has attempted to provide a classification of functioning and disability that covers any disturbance in terms of “functional states” associated with health conditions, organized according to three dimensions – body level, individual and society levels\textsuperscript{121}. It


addresses body functions, activities and social participation, treating all diseases on an equal footing for equitable comparison and combining them into a functionality framework.

2.5 Outreach and Home Care

The concept of providing care for people away from hospital is based on a desire to continue care for the aged and infirm at home for as long as possible. Hospitals and Community Health Centres have for many years employed health workers to provide community care and support. People prefer to avoid hospital care if they can, contagious diseases are issues in hospitals, and hospital funding is increasingly expensive and rationed. Visiting patients at home is a positive experience for patients, carers and health workers. It gives health workers a better insight into the difficulties patients and their carers have at home, provides patients and carers more confidence that the home environment is appropriate, and assists with personalising equipment and care needs.

Common examples of home-based and outreach care include wound care post-surgery, diabetes education and care, home-based rehabilitation after stroke or musculoskeletal surgery, and cardiac care post-myocardial infarction. In the field of respiratory diseases Respiratory Nurses from teaching hospitals typically visit patients with severe COPD or people with home oxygen to monitor progress or provide education about ongoing management. Nurses from Chest or TB Clinics screen and monitor contacts of people with tuberculosis. Hospital-At-Home professionals provide treatment of illnesses like pneumonia or post-operative wound care. Domiciliary Care or District Nursing Services workers (such as occupational therapists, nurses, physiotherapists, podiatrists, and carers) can provide health care services at home. GP surgeries are increasingly utilising specialist Practice Nurses to help people with COPD, diabetes, asthma and other conditions to understand their condition and its most effective management.

There is a paucity of strong evidence supporting use of home care for people with chronic respiratory diseases. A recent American Thoracic Society Statement pointed to the complexities of home care that need to be accounted for in determining costs and effectiveness122, and few of its recommendations had significant evidence base. This will be reviewed later in the Manual.

2.6 Pulmonary Rehabilitation (PR)

The definition of PR has undergone several evolutions since the development of the first programs in USA in the 1970's. Definitions from US professional bodies include:

"Pulmonary rehabilitation is a multi-dimensional continuum of services directed to persons with pulmonary disease and their families, usually by an interdisciplinary team of specialists, with the goal of achieving and maintaining the individual's maximum level of independence and functioning within the community."123

"Pulmonary rehabilitation may be defined as an art of medical practice wherein an individually tailored, multidisciplinary program is formulated which through

accurate diagnosis, therapy, emotional support, and education, stabilizes or reverses both the physio- and psychopathology of pulmonary diseases and attempts to return the patients to the highest possible functional capacity allowed by his pulmonary handicap and overall life situation.”

British\textsuperscript{125} and European\textsuperscript{126,127} guidelines reflect these definitions. The most recent Statement on PR from the American College of Chest Physicians (ACCP), the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), the American Thoracic Society (ATS) and European Respiratory Society (ERS) define PR as:

\textit{“..an evidence-based, multi-disciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease.”}\textsuperscript{128,129}

The concept emphasizes that practitioners of PR should have in mind a multidisciplinary approach to overall disease management that addresses physical and social function of the individual and give attention to early detection and both primary and secondary prevention.

Numerically by far the greatest experience in PR is for patients with COPD, though people with a very wide range of respiratory conditions actually attend programs. This Manual concentrates on COPD, with additional comments about other conditions where evidence exists, or where logic and consensus suggest either benefit or contraindications exist. The components of PR are detailed in the text.

The primary aim of pulmonary rehabilitation then is to reduce disability and handicap of persons with chronic lung diseases and support their carers, thereby restoring the patient to the highest possible level of independent functioning. It should be part of the integrated lifetime management of people with chronic respiratory disease.

\section*{2.7 Self-Management for Chronic Disease}

Traditional approaches to medical care have arisen from the need to "cure" acute disease. Greater longevity and the trend to unhealthy lifestyle habits in the past 100 years have contributed to the emergence of chronic degenerative diseases, for which "cure" is rarely possible, and acute care approaches are ineffective. Indeed, 30 years ago around 80\% of US health resources were already

\begin{footnotesize}
\begin{itemize}
\item\textsuperscript{124} AACVPR/ACCP Pulmonary Rehabilitation Guidelines Panel. Pulmonary Rehabilitation. Joint ACCP/AACVPR evidence-based guidelines. \textit{Chest} 1997; 112:1363-1396
\item\textsuperscript{125} British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation. Pulmonary rehabilitation. \textit{Thorax} 2001; 56:827-834
\item\textsuperscript{126} Donner CF, Muir JF. Selection criteria and programmes for pulmonary rehabilitation in COPD patients. \textit{Eur Respir J} 1997; 10:744-757
\item\textsuperscript{127} Donner CF, Decramer M. Pulmonary rehabilitation. \textit{Eur Resp Soc Monogr} 2000; 13
\item\textsuperscript{128} Nici L, Donner C, Wouters E, et al. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. \textit{Am J Respir Crit Care Med} 2006; 173:1390-1396
\end{itemize}
\end{footnotesize}
expended on the care of people with chronic conditions. Increasing longevity is further adding to the prevalence and burden of such conditions.

Patients with chronic health conditions experience variations in symptoms, which often result in disruptive and expensive hospitalisation. Yet they ought to be ideally placed to monitor and manage their own symptoms. A team approach to care that trades off this capacity of the patient and their doctor's scientific knowledge to interpret and respond to changes in symptoms offers scope for individualised rapid-response care. This requires adequate training for patients to respond with appropriate interventions under the guidance of medically agreed pathways.

Self-management refers to people with chronic diseases "engaging in activities that protect and promote health, monitoring and managing...symptoms and signs of illness, managing the impacts of illness on functioning and interpersonal relationships and adhering to treatment regimes". This approach requires health care providers and health care systems to support the central role of patients in managing their own chronic illness, and there is mounting evidence for its effectiveness. Perhaps the term “co-management” would be more applicable.

Again, as with home care, evidence relating to self-management approaches for people with chronic respiratory disease is lacking. This will be reviewed later in the Manual.

2.8 Support Groups

Support Groups (SG) for chronic lung disease aim to empower patients to take a more active role in their own health management and enable them to take charge of the physical and psychosocial impacts of their disease. They help patients and carers find enjoyment in a renewed quality of life through information, education, friendship, encouragement and shared experiences, and reduced social isolation.

The ALF has facilitated the development of over 120 groups around Australia, with over 11,000 members around the nation under the banner of LungNet. The LungNet encourages independence and self-motivation of groups, and advises them to meet regularly, have guest speakers with a range of interesting topics related to the health condition and its management, and address social issues. Member-to-member support, transport assistance, social outings and telephone contact, especially for the carer at times of hospitalisation, appear useful.

The benefits of SGs to people with COPD are as yet unproven, however. They have a demonstrable role in other chronic conditions, and it seems likely that similar benefits could be shown in chronic lung disease. It has been claimed that SGs facilitate the rehabilitation of people with COPD, and it has been included as an arm in disease management of COPD, despite the

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absence of substantiating data. Since the effects of a specific PR program package wane if exercise, education and psychosocial support are not maintained, SGs have the potential to promote continuation of activities and information.

135 Tiep BL. Disease management of COPD with pulmonary rehabilitation. *Chest 1997; 112:1630-1656*
3. EPIDEMIOLOGY AND BURDEN OF CHRONIC LUNG DISEASE

COPD is one of the five most important causes of death and disability world-wide. In white males living in developed nations the increasing prevalence and mortality have been slowing in recent years (unlike cardiovascular diseases, where rates have been declining). Rates in the developing world, and in women as well as black males in developed nations, continue to increase.\(^{136}\)

3.1 Prevalence and Incidence

The Australian Institute of Health and Welfare (AIHW) reported almost 300,000 Australians with COPD in 1996 (prevalence), with more than 20,000 new cases being diagnosed every year (incidence).\(^{137}\) A population based assessment model used by the WHO has been applied to the Australian population characteristics and estimates 558,000 people with moderate to severe COPD in the year 2000. The true incidence, prevalence, morbidity and mortality of COPD in Australia are uncertain, however. The Australian Institute for Health and Welfare (AIHW) admits recent estimates probably under-represent the magnitude of the problem.\(^{139}\) Prevalence estimates from a general population in Melbourne suggest 12% of people aged 45-69 years had symptomatic COPD.\(^{140}\) Results from the Burden of Obstructive Lung Disease (BOLD) are also pointing to rates of symptomatic disease around 10-12%.\(^{141}\)

The benchmark for diagnosis of COPD is spirometry, as it identifies airflow limitation, the major diagnostic criterion. Obtaining reliable prevalence data for COPD is complicated by how the condition is labelled (since chronic bronchitis, emphysema or COPD are coded differently). Prevalence can be based on patient self-report of symptoms, or by examining administrative databases (such as specified prescriptions in certain age-groups, or death records, or established diagnosis by doctors, or on presence of airflow limitation. Self-report provides an estimate (albeit poorly validated) of all Stages of symptomatic disease (including those at-risk), with prevalence rates reported at up to 24% in smokers and 6.5% in ex-smokers.\(^{142}\) COPD, however, is

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**Doctor diagnosis** is better validated for estimates of symptomatic and disabling COPD, and has been found in 6.4\% of the UK population based on general practitioner databases.\footnote{Soriano JR, Maier WC, Egger P, Visick G, et al. Recent trends in physician diagnosed COPD in women and men in the UK. Thorax 2000; 55:789-794} This study also found that doctor-diagnosed COPD had increased gradually over 1990 to 1997 in women in all ages (overall increase 68\%), with a plateau in prevalence in men. Prevalence, hospitalisation and mortality all increased markedly with age beyond 40 years in both men and women, and prevalence rates over age 65 were similar between the sexes. However, such diagnoses are infrequently based on objective findings from spirometry, and data using this approach can underestimate the prevalence. For example, providing open access to spirometry in a primary care area in UK was reported to have discovered 91 previously undiagnosed cases of COPD in 217 patients with complete records and spirometry results (42\% rate of non-diagnosis).\footnote{Walker PP, Mitchell P, Diamantea F, et al. Effect of primary-care spirometry on the diagnosis and management of COPD. Eur Respir J 2006; 28:945-952} \footnote{Soriano JR, Maier WC, Egger P, Visick G, et al. Recent trends in physician diagnosed COPD in women and men in the UK. Thorax 2000; 55:789-794} \footnote{Wilson DH, Tucker G, Frith P, et al. Trends in hospital admissions and mortality from asthma and chronic obstructive pulmonary disease in Australia, 1993-2003. Med J Aust 2007; 186:408-411} \footnote{Rabe KF, Hurd S, Anzueto A, et al. Global Strategy for the diagnosis, management, and prevention of COPD: GOLD executive summary. Am J Respir Crit Care Med 2007; 176:532-555} \footnote{Soriano JR, Maier WC, Egger P, Visick G, et al. Recent trends in physician diagnosed COPD in women and men in the UK. Thorax 2000; 55:789-794}

Examination of GP databases in the group referred to above (representing around 10\% of the England and Wales population) has since been carefully validated as an indicator of both disease incidence and prevalence.\footnote{Soriano JR, Maier WC, Egger P, Visick G, et al. Recent trends in physician diagnosed COPD in women and men in the UK. Thorax 2000; 55:789-794} An alternative administrative database has been used in Italy, consisting of repeated drug prescriptions of respiratory drugs, antibiotics and oral corticosteroids.\footnote{Anecchino C, Rossi E, Fanizza C, De Rosa M, et al. Prevalence of chronic obstructive pulmonary disease and patterns of comorbidities in a general population. Int J COPD 2007; 2:567-574} In the latter, the overall adult population prevalence of COPD was 3.6\%.


The objective measurement of **airflow limitation** in random population surveys shows prevalence rates of 14.2\% in male current smokers and 13.6\% in female current smokers, but 3.3\% in never-smoking males and 3.1\% in never-smoking females in USA. In UK opportunistic screening at the primary care level showed prevalence rates of 9\%.\footnote{Seamark DA, Williams S, Timon S, et al. Home or surgery based screening for chronic obstructive pulmonary disease (COPD)? Prim Care Resp J 2001; 10:30-33} A more
comprehensive screening was conducted among 22 GPs in Belgium over twelve weeks and uncovered new COPD in 18% of the symptomatic population and 4% of the asymptomatic patients. It has proven possible to screen high-risk populations using spirometry, such as the ‘Know The Age Of Your Lungs Project’ in Poland, where 110,355 people were tested over three years. Respiratory symptoms were reported by over half, and airflow limitation was found in 20.3%, more commonly in smokers and in rising numbers with increasing age. A random sample of 1,500 northern Swedish people from an earlier cohort of 6,610 was surveyed with interviews and lung function tests. COPD (airflow limitation post-bronchodilator) was diagnosed in 14.3%, increasing in older groups, and higher in those with greatest lifetime cigarette exposure, but only half had been previously diagnosed. A study conducted in Israel in 20 pack-year current and former smokers aged 45 and over (n=1,150) evaluated symptoms and spirometry abnormalities. Airflow limitation was found in 22%, and most had moderate stage COPD (with only 4% having a previous diagnosis of COPD). Based on such findings it is reasonable for the GOLD Workshop to have concluded that available prevalence and morbidity data are likely to underestimate the total burden of disease.

In a combined self-report and lung function study reported in 1996 from the UK, a respiratory symptoms questionnaire was sent to people over age 45 randomly selected from general practitioner patient lists. There was a high response rate of 92.3%, making the results reliable. Of the 723 subjects, 29.2% were smokers and 37.3% were ex-smokers. Respiratory symptoms were reported by 30.0%, of whom almost half were using inhaled medications. Of the responders to a full questionnaire 62.5% attended for lung function testing, and in 26.4% of these airflow limitation was identified. Only half the people with airflow limitation and respiratory symptoms had been diagnosed with respiratory disease by a doctor, so there was significant underdiagnosis, as well as misclassification as other conditions like asthma. A recent survey with a similar model conducted in general practices in Australia revealed similar findings, and this has been confirmed in a general population survey conducted prior to release of COPD-X. In adults aged 45-70 years, 3.5% had COPD and 3.6% had mixed asthma and COPD. Over 40% did not have a prior diagnosis of COPD, and almost half had received no prescribed respiratory medications.

159 Renwick DS, Connolly MJ. Prevalence and treatment of chronic airways obstruction in adults over the age of 45. Thorax 1996; 51:164-168
The ALF commissioned a review of data from the AIHW and New Zealand (NZ) Ministry of Health\textsuperscript{163}; an update is expected in late 2008. COPD is the third leading cause of ‘burden of disease’ in Australia\textsuperscript{164} behind Ischaemic Heart Disease and Stroke. COPD is the largest contributor to the burden of disease associated with all respiratory conditions (including asthma), three times the burden of acute respiratory infections and more than four times the burden of other chronic respiratory diseases\textsuperscript{165}. The burden of COPD is escalating worldwide. The 1996 Global Burden of Disease Study compared the leading causes of disability in 1990 and 2020 (projected). In 1990 COPD was globally ranked 12\textsuperscript{th}, but it is projected to rank 5\textsuperscript{th} in 2020, behind ischaemic heart disease, major depression, traffic accidents and cerebrovascular disease\textsuperscript{166}. A meta-analysis of studies evaluating population prevalence published in 2006\textsuperscript{167} included research reports that documented (a) total population or sex-specific estimates for COPD, Chronic Bronchitis and / or emphysema, and (b) detailed information on diagnostic criteria used. Of 5,464 articles screened 356 met inclusion criteria, and 67 articles were subjected to meta-analysis. Data were available for 28 countries. Spirometric-diagnosed COPD (26 estimates) provided a pooled prevalence of 9.2\% (95\% CI=7.7-11.0), while doctor-diagnosis gave pooled prevalence rates of 5.2\% for COPD and 5.3\% for Chronic Bronchitis.

Given the deficiencies in methodologies and data up to 2006, the Burden of Obstructive Lung Disease (BOLD) survey findings are keenly awaited. This global survey, being conducted in representative populations with questionnaire and lung function measures, should provide comprehensive data about COPD prevalence and burden. The current analyses suggest that adult population prevalence rates are in the range from 10 to 15\%\textsuperscript{168}.

**Incidence of COPD** is more difficult to document, as it relies on prospectively-collected data and accurate diagnosis. The European Community Respiratory Health Survey (ECRHS) began in 1991-1993 to examine a random sample of 14,252 young adults aged 20-44\textsuperscript{169}, with follow-up in 1999-2002\textsuperscript{170}. Valid lung function measurements were obtained in 5,002 of the 9,839 eligible subjects without initial airflow obstruction or asthma, and demonstrated an annual incidence of COPD of 2.8 cases/1,000/year (95\% CI=2.3-3.3)\textsuperscript{171}; the 10-year cumulative incidence of GOLD Stage II in male smokers in their fifties was around 25\%. In a smaller northern Swedish study, the

\textsuperscript{163} Crockett AJ, Cranston JM, Moss JR. Economic Case Statement. Chronic obstructive pulmonary disease (COPD). The Australian Lung Foundation; 2002

\textsuperscript{164} Mathers C, Vos T, Stevenson C. The burden of disease and injury in Australia. AIHW cat. no. PHE 17. Canberra: AIHW; 1999


\textsuperscript{170} European Community Respiratory Health Survey II Steering Committee. The European Community Respiratory Health Survey II. Eur Respir J 2002; 20:1071-1079.

cumulative 10-year incidence was 13.5% in a symptomatic cohort\textsuperscript{172}. A Finnish study of 40-64 year old male smokers found an annual incidence of 0.5%\textsuperscript{173}. Polish male smokers aged 41-60 had a mean annual incidence of COPD with FEV1 < 65% predicted of 1.2-1.6%\textsuperscript{174}. In a general practice setting in Netherlands, all males aged 40 to 65 years were screened, those without known lung disease were invited for spirometry, and those with normal initial spirometry or GOLD Stage I COPD were followed up with spirometry after another five years. The 5-year cumulative incidence of GOLD Stage II COPD was 8.3% (mean 1.6% per annum)\textsuperscript{175}.

### 3.2 Risk factors for COPD

Smoking is the major risk factor for developing COPD, though current understanding of risk cofactors is incomplete. Risk factors fall into two categories - host factors and environmental exposures. Some are known to cause COPD, while others, in combination, may increase an individual's risk and speed progression of COPD. One of the best-know host factors (Table 3.1) is the genetic linkage of deficiency of alpha-1-antrypsin (or antiproteinase)\textsuperscript{176}. The multi-centre randomized clinical trial comparing lung volume reduction surgery with medical management for severe COPD, the National Emphysema Treatment Trial (NETT), has identified polymorphisms in a range of genes associated with airflow abnormalities\textsuperscript{177}, and other COPD phenotypes and characteristics\textsuperscript{178}. A family history of respiratory disease may be an independent risk factor, although this is hard to separate from parental smoking.

\textsuperscript{173} Huhti E, Ikkala J. A follow-up study on respiratory symptoms and ventilatory function in a middle-aged rural population. \textit{Eur I Respir Dis} 1980; 61:33-45
\textsuperscript{175} Geijer RMM, Sachs APE, Verheij TJM, Salome PL, Lammers J-WJ, Hoes AW. Incidence and determinants of moderate COPD (GOLD II) in male smokers aged 40-65 years: 5-year follow up. \textit{Brit J Gen Pract} 2006; 56:656-661
TABLE 3.1. HOST-RELATED RISK FACTORS FOR COPD\textsuperscript{179,180}

<table>
<thead>
<tr>
<th>Host Factors</th>
<th>Relationship &amp; level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Causal (II)\textsuperscript{181,182}</td>
</tr>
<tr>
<td>Gender</td>
<td>Additive (III)\textsuperscript{183}</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>Additive (III)\textsuperscript{184,185}</td>
</tr>
<tr>
<td>Genes (e.g. deficiency of alpha-1-antitrypsin)</td>
<td>Causal (II)\textsuperscript{186}</td>
</tr>
<tr>
<td>Asthma</td>
<td>Causal (II)\textsuperscript{187,188,189} or Additive (II)\textsuperscript{190,191}</td>
</tr>
<tr>
<td>Airway hyper-responsiveness</td>
<td>Additive (III)\textsuperscript{192,193}</td>
</tr>
<tr>
<td>Familial (?genetic) clustering</td>
<td>Additive (II)\textsuperscript{194,195}</td>
</tr>
<tr>
<td>Lung growth</td>
<td>Causal (IV)\textsuperscript{196,197}</td>
</tr>
</tbody>
</table>


\textsuperscript{183} Prescott E, Bjerg AM, Andersen PK, et al. Gender difference in smoking effects on lung function and risk of hospitalization for COPD: results from a Danish longitudinal population study. \textit{Eur Respir J} 1997;10:822-7

\textsuperscript{184} Horne SL, Cockcroft DW. Ethnicity as a possible factor contributing to the development of chronic airflow limitation and asthma. \textit{Clin Invest Med 1990};13:333-338

\textsuperscript{185} Samet JM, Coultas DB, Howard CA, Skipper BJ. Respiratory disease and cigarette smoking in a Hispanic population in New Mexico. \textit{Am Rev Respir Dis 1988}; 137:815-9


\textsuperscript{187} Brown PJ, Greville HW, Finucane KE. Asthma and irreversible airflow obstruction. \textit{Thorax} 1984; 39:131-136

\textsuperscript{188} Silva GE, Sherrill DL, Guerra S, Barbee RA. Asthma as a risk factor for COPD in a longitudinal study. \textit{Chest} 2004; 126:59-65


\textsuperscript{192} Silva GE, Sherrill DL, Guerra S, Barbee RA. Asthma as a risk factor for COPD in a longitudinal study. \textit{Chest} 2004; 126:59-65


\textsuperscript{194} McCloskey SC, Patel BP, Hinchcliff SJ, Reid ED, et al. Siblings of patients with severe chronic obstructive pulmonary disease have a significant risk of airflow limitation. \textit{Am J Respir Crit Care Med} 2001; 164:1419-1424

\textsuperscript{195} DeMeo DL, Carey VJ, Chapman HA, et al. Familial aggregation of FEF25-75 and FEF25-75/FVC in families with severe, early onset COPD. \textit{Thorax} 2004; 59:396-400


TABLE 3.2. ENVIRONMENTAL RISK FACTORS FOR COPD\textsuperscript{198,199}

<table>
<thead>
<tr>
<th>Environmental Factors</th>
<th>Relationship &amp; level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarette smoking</td>
<td>Causal (II)\textsuperscript{200}</td>
</tr>
<tr>
<td>Environmental tobacco smoke (incl parental smoking)</td>
<td>Additive, or Causal if heavy (III)\textsuperscript{201,202,203,204}</td>
</tr>
<tr>
<td>Occupational dusts &amp; fumes</td>
<td>Causal if heavy (IV)\textsuperscript{205}</td>
</tr>
<tr>
<td>Indoor/Outdoor air pollution (notably burning of biomass fuels in poorly ventilated buildings)</td>
<td>Additive, or Causal if heavy (III)\textsuperscript{206,207}</td>
</tr>
<tr>
<td>Dietary lack of anti-oxidants</td>
<td>Additive (III)\textsuperscript{208}</td>
</tr>
<tr>
<td>Infections, and exacerbations</td>
<td>Additive (III)\textsuperscript{209}</td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td>Additive (IV)\textsuperscript{210}</td>
</tr>
</tbody>
</table>

Age

COPD is mainly a disease of the middle aged and the elderly. The peak prevalence of COPD has been observed in the 45-64 and 65-74 age brackets\textsuperscript{211}. Longitudinal data from the Tecumseh study identified risk factors for developing COPD in a large population sample. Ages ranged from 16-34 years at the start of the study to 30-80 years at follow up. The incidence of obstructive airways disease (including asthma and chronic bronchitis) ranged from 4% in the 35-44 year age group, to a peak of 16.3% in the 45-54 year age group in men. Men in the 55-64 year age group

\textsuperscript{205} Kauffmann F, Drouet D, Lellouch J, Brille D. Twelve years spirometric changes among Paris area workers. Int J Epidemiol 1979; 8:201-212
\textsuperscript{206} Samet JM, Marbury M, Spengler J. Health effects and sources of indoor pollution. Am Rev Respir Dis 1987; 136:1486-1508
\textsuperscript{207} Behera D, Jindal SK. Respiratory symptoms in Indian women using domestic cooking fuels. Chest 1991; 100:385-388
\textsuperscript{210} Prescott E, Lange P, Vestbo J. Socioeconomic status, lung function and admission to hospital for COPD: results from the Copenhagen City Heart Study. Eur Respir J 1999; 13:1109-1114
had an intermediate figure of 11.3%. In females there was less variation - 4.1% in the 35-44 year age group, 5.0% in the 45-54 year age group, and 5.1% in the 55-64 year age group. Data from Europe show trends similar to the United States with highest prevalence rates of COPD found in the older population. A study from the United Kingdom showed a prevalence of up to 16.4% in elderly populations. In the United Kingdom, annual consultation rates for COPD per 10,000 population are highest for people aged 75 to 84.

A review of the epidemiology of COPD (age- and gender-stratified prevalence rates in a population that consisted of smokers as well as non-smokers) documented prevalence rates based on physician confirmed diagnoses in males and females with FEV₁/FVC < 75%. The prevalence rates in men ranged from 2% in the 25-34 year age group to a peak of 24% in the 75+ age group. In females, the prevalence rates were 2.5% in the 25-34 year age group and 4% in the 75+ age group, with peak prevalence in females of 8.5% in the 55-65 year age group.

**Gender**

Prevalence of COPD is generally found to be higher in men than in women. This may be due to differences in smoking and occupational risks. With equivalent smoking, women may be at the same or greater risk of developing COPD than men. Data from the Beijing Respiratory Health Study suggest that adverse effects of smoking on pulmonary function were greater in women than in men, with similar rates of decline in lung function (and statistically different declines in FEV₁ compared to non-smokers). Data from two large population studies in Denmark also suggested that smoking had a greater effect on lung function decline in females compared to males, and, after adjusting for the level of smoking, females suffered a higher risk of hospital admission with COPD than men. In a Brazil 7-year prospective cohort study of people referred for long term oxygen therapy, females had a statistically significantly higher risk of early death than men (after accounting for age, nutrition and smoking).

**Race/Ethnicity**

In a study of Caucasian COPD patients in Canada, men of British origin were three times more likely to have airflow obstruction than those of other North Eastern European ancestry, after

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controlling for the effects of age and smoking\textsuperscript{220}. The frequency of COPD in USA has been unexpectedly low in African Americans, despite relatively high rates of smoking in this group, though the reasons remain unexplained\textsuperscript{221}; prevalence rates in this segment, though, are now increasing\textsuperscript{222}. Prevalence rates of COPD in Hispanic Americans living in New Mexico are significantly lower than in Caucasians\textsuperscript{223}, and after correcting for age and smoking exposure, the prevalence of COPD is lower among Japanese American males than white males\textsuperscript{224}. Asians have generally been thought to have a lower susceptibility to COPD from smoking, though there may be differences in type of tobacco used and the level of smoke inhaled, and allowing for these factors decline in lung function fails to show consistent differences across races\textsuperscript{225}.

**Asthma and Airway Hyper-responsiveness**

A Western Australian study was the first to present good data in 89 asthmatics, aged around 20, to suggest asthma alone, independent of smoking, could result in fixed airflow limitation\textsuperscript{226}. A follow—up of this same population after 17 years showed better asthma control than previously, with increased inhaled steroid use, but an even higher prevalence of chronic airflow limitation, independent of smoking history\textsuperscript{227}. There was a relatively high mortality rate (18 in 89 of these now young-to-middle-aged adults). Other Australian studies have shown increased rate of decline in FEV\textsubscript{1}\textsuperscript{228,229} and persistent airflow limitation post-bronchodilator\textsuperscript{230}. Several other studies support at least additive if not independently causative role for asthma in the development of COPD\textsuperscript{231,232,233,234}, and asthma and COPD may be comorbid or confounders of diagnosis\textsuperscript{235}.

\textsuperscript{220} Horne SL, Cockcroft DW. Ethnicity as a possible factor contributing to the development of chronic airflow limitation and asthma. Clin Invest Med 1990; 13:333-338
\textsuperscript{221} Coultas DB, Gong H, Grad R, et al. Respiratory Diseases in Minorities of the United States. Am J Respir Crit Care Med 1993; 149:S93-S131
\textsuperscript{223} Samet JM, Coultas DB, Howard CA, Skipper BJ. Respiratory disease and cigarette smoking in a Hispanic population in New Mexico. Am Rev Respir Dis 1988; 137:815-9
\textsuperscript{226} Brown PJ, Greville HW, Finucane KE. Asthma and irreversible airflow obstruction. Thorax 1984; 39:131-136
\textsuperscript{228} Peat JK, Woolcock AJ, Cullen K. Rate of decline of lung function in subjects with asthma. Eur J Respir Dis 1987; 70:171-179
\textsuperscript{231} Ulrik CS, Backer V, Dirksen A. A 10-year follow up of 180 adults with bronchial asthma: factors important for the decline in lung function. Thorax 1992; 47:14-18
Recent expert opinion from analysis of epidemiology and pathology suggests that a complex genetic background to airways reactions to environmental perturbations may lead to either or both asthma and COPD - altered innate immune responses cause progression of early airway damage by tobacco smoke (and other noxious fumes and gases) to more obvious, symptomatic and severe COPD through in turn inducing adaptive immune responses\textsuperscript{236}. The hypothesis links bronchial hyper-responsiveness with development of more severe stages of COPD.

**Smoking**

Most people with COPD have smoked over 20 pack-years (20 cigarettes per day or equivalent in other forms of tobacco for 20 years), and smoking is said to contribute about 85\% of the risk of developing COPD\textsuperscript{237}. However such data may be misleading, owing to the global misclassification problem with COPD, especially relating to death certification, where non-smoking status contributes to under-certification\textsuperscript{238}. This is discussed in other Sections. The large Copenhagen City Heart Study has indicated that after 25 years of smoking, at least 25\% of smokers without initial lung disease have clinically significant COPD, and 30-40\% have all forms of COPD; importantly early quitters did not develop COPD\textsuperscript{239}. Incidence studies that examined risk factors point to childhood smoking\textsuperscript{240,241,242}, and also to bronchitic symptoms\textsuperscript{243,244}. Parental smoking has also been found as an independent risk factor for incidence of GOLD Stage II COPD in some studies\textsuperscript{245,246}, though not in others\textsuperscript{247}. There is a clear demographic trend, with females as they age showing more rapid decline in lung function than males\textsuperscript{248}.


\textsuperscript{236} Vestbo J, Hogg JC. Convergence of the epidemiology and pathology of COPD. Thorax 2006; 61:86-88


\textsuperscript{242} Geijer RMM, Sachs APE, Verheij TJM, Salome PL, Lammers JWJ, Hoes AW. Incidence and determinants of moderate COPD (GOLD II) in male smokers aged 40-65 years: 5-year follow up. Brit J Gen Pract 2006; 56:656-661


\textsuperscript{244} Geijer RMM, Sachs APE, Verheij TJM, Salome PL, Lammers J-WJ, Hoes AW. Incidence and determinants of moderate COPD (GOLD II) in male smokers aged 40-65 years: 5-year follow up. Brit J Gen Pract 2006; 56:656-661


\textsuperscript{247} Geijer RMM, Sachs APE, Verheij TJM, Salome PL, Lammers J-WJ, Hoes AW. Incidence and determinants of moderate COPD (GOLD II) in male smokers aged 40-65 years: 5-year follow up. Brit J Gen Pract 2006; 56:656-661

\textsuperscript{248} Gan WQ, Man SFP, Postma DS, et al. Female smokers beyond the perimenopausal period are at increased risk of chronic obstructive pulmonary disease: a systematic review and meta-analysis. Respir Research 2006; 7:52-60
Biomass Smoke

The risk of developing chronic bronchitis is greater in populations exposed to indoor pollution and smoke resulting from the use of stoves and heaters that utilize wood and coal as fuel. This increase in risk is directly related to the length of the exposure to the smoke from the stoves. In individuals who on average spend four or more hours daily in rooms with indoor pollution due to heating or cooking with these stoves, the risk of developing chronic bronchitis is significantly higher. In general, combustion of biomass fuel, including wood, charcoal, or dried dung produces higher emission factors. This can lead to increased susceptibility to the development of COPD, as compared to combustion of fossil fuels, including kerosene and gas. The prevalence of indoor pollution from solid-fuel-fired cooking and heating stoves is widespread and this exposure is said to be present in more than half the world’s households. A number of studies from South Asia, including China, India, and Nepal, and a smaller number from Oceania, Latin America, and Africa, have shown high indoor concentration of particulate matters, carbon monoxide, and other pollutants which can cause decreased lung function. The prevalence of COPD was higher by 30 to 60 percent in coal using homes as compared to homes that used gas stoves. Women cooking more than three times per week, particularly if the frequency of heavy cooking fumes is higher in the kitchen, have been reported to have decreased lung function.

Occupational Exposure

Occupations involving a high exposure to airborne dusts during work have higher prevalence rates of obstructive lung disease. Exposure to asbestos, quartz, wood dust, metal gases, aluminium production and processing, and welding have been significantly associated with obstructive lung disease, with greater risk observed after adjusting for the effects of age and smoking.

Workers in mining are exposed to dusts that may affect their lung function. Coal miners develop bronchitis almost from the time of their entry into the mine, and the prevalence increases with cumulative dust exposure. Exposure to dust for workers in gold mining significantly increases their risk of developing COPD and emphysema. This has been observed in miners who smoke, as well as in those who do not smoke cigarettes. Significant declines in lung function have been observed in gold miners with exposure to smaller amounts of particulate matter in the

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252 Ng TP, Hui KP, Tan WC. Respiratory symptoms and lung function effects of domestic exposure to tobacco smoke and cooking by gas in non-smoking women in Singapore. *J Epidemiol Community Health, 1993;47(6):454-458*
dust, perhaps because of the increased silica content.\textsuperscript{257} Coke oven work in south-east China has also been found to interact with smoking to increase risk of COPD\textsuperscript{258}.

The prevalence of chronic bronchitis in workers exposed to dust from yarn and cement manufacturing has been reported to be double that of individuals not exposed to these dusts\textsuperscript{259,260}, though this has been disputed\textsuperscript{261}. A similar effect of more than doubled prevalence of chronic bronchitis and decline in lung function has been reported in workers in the textile dyeing industry.\textsuperscript{262} Workers in the Swedish paper manufacturing industry were found in a cross-sectional study to have dose-dependent upper respiratory tract symptoms, but no increase in cough or sputum production, but long-term heavy exposure did appear to be associated with lower lung function\textsuperscript{263}. Subsequent mortality study in this population confirmed higher prevalence rates of death from asthma and COPD\textsuperscript{264}.

In a study of over 10,000 farmers in Norway, it has been reported that full-time farming, livestock production and exposure to associated dusts can increase the risk of chronic bronchitis and significant decrease in lung function by 2 to 3 times. This risk can increase up to 6-fold if combined with smoking.\textsuperscript{265} In a study of over 1,600 subjects in New Zealand, working with vapours, gases, dust, or fumes was significantly associated with chronic bronchitis and airway obstruction and could increase the risk of this outcome by 3 times.\textsuperscript{266} In Canada there are powerful data supporting the risk of COPD from exposure to grain dust, especially among silo workers, where epidemiological evidence is supported by experimental data\textsuperscript{267}.

### Environment (Air Pollution)

According to conservative estimates, moderate air pollution is expected to increase the prevalence of chronic bronchitis by 25 percent.\textsuperscript{268} Moderate air pollution, defined in this Swiss study of approximately 10,000 individuals from areas in Switzerland, is a 10 mcg/m\textsuperscript{3} increase in annual mean particulate pollution (PM\textsubscript{10}). In a seminal Canadian series of studies where smoking rates

\begin{itemize}
\item \textsuperscript{258} Hu Y, Chen B, Yin Z, et al. Increased risk of chronic obstructive pulmonary disease in coke oven workers: interaction between occupational exposure and smoking. \textit{Thorax} 2006; 61:290-295
\item \textsuperscript{259} Arbons HL, Petersen MR, Sanderson WT, et al. Symptoms, ventilatory function, and environmental exposures in Portland cement workers. \textit{Brit J Indus Med} 1988; 45:368-375
\item \textsuperscript{261} Bernstein DM. Increased mortality in COPD among construction workers exposed to inorganic dust. Letter. \textit{Eur Respir J} 2004; 23:512
\item \textsuperscript{262} Zuskin E, Mustajbegovic J, Schacter N, Doko-Jelinic D. Respiratory function of textile workers employed in dyeing cotton and wool fibers. \textit{Am J Ind Med} 1997; 31:344-352
\item \textsuperscript{263} Ericsson J, Järhholm B, Norin F. Respiratory symptoms and lung function following exposure in workers exposed to soft paper tissue dust. \textit{Int Arch Environ Health} 1988; 60:341-345
\item \textsuperscript{265} Melbostad E, Eduard W, Magnus P. Chronic bronchitis in farmers. \textit{Scand J Work Environ Health} 1997;23(4):271-80
\item \textsuperscript{266} Fishwick D, Bradshaw LM, D’Souza W, et al. Chronic bronchitis, shortness of breath, and airway obstruction by occupation in New Zealand. \textit{Am J Respir Crit Care Med} 1997;156(5):1440-1446
\item \textsuperscript{267} Zejda JE, McDuffie HH, Dosman JA. Respiratory effects of exposure to grain dust. \textit{Semin Respir Med} 1993; 14:20-30
\end{itemize}
were standardised across the populations, a comparison of three cities found chronic bronchitis was positively associated with air pollution\textsuperscript{269}. In USA, a longitudinal study of never-smoking Los Angeles residents revealed worse lung function in those exposed to higher levels of photochemical oxidants, sulphates and particulates\textsuperscript{270}. In a review of the health effects of outdoor air pollution the American Thoracic Society attributed increased risk of development of COPD to exposures to high levels of ambient pollution during adulthood, citing acid aerosols, total suspended particulates and fine particulates (< 2.5 mcm)\textsuperscript{271}. Health professionals in PR should advocate for cleaner air to help their current clients and reduce the future impact of COPD\textsuperscript{272}.

**Socioeconomic Status**

In the first US National Health and Nutrition Examination Survey report (NHANES I), low income was a risk factor for COPD\textsuperscript{273}. Patterns of environmental exposures affecting the lung may differ depending on socioeconomic indicators such as housing characteristics, occupation and lifestyle. In developed countries an inverse relationship between income/education and prevalence of respiratory symptoms or disease can be shown\textsuperscript{274}, although in 1,217 women in Finland socioeconomic status was not related to the occurrence of respiratory disease\textsuperscript{275}.

**Nutrition**

Oxidant injury appears to be a significant contributor to the damage resulting from inhalation of toxic substances, and anti-oxidant intake might therefore modify initiation of COPD. Fresh fruit intake has been positively associated with lack of respiratory (asthma) symptoms\textsuperscript{276}, lung function\textsuperscript{277}, and lung function decline over time\textsuperscript{278}. The 1995 Scottish Health Survey had reliable results for all of: plasma levels of anti-oxidants, demographics, smoking history, dietary history, respiratory symptoms and FEV1 in 1,146 randomly selected adults, and confirmed a dose-response relationship between fresh fruit intake and pulmonary function, with vitamin E being protective for symptoms of sputum production and vitamin C being protective for lung function.


\textsuperscript{271} A Committee of the Environmental and Occupational Health Assembly of the American Thoracic Society. Health effects of outdoor pollution. *Am J Respir Crit Care Med* 1996; 153:3-50


\textsuperscript{273} McWhorter WP, Polis MA, Kaslow RA. Occurrence, predictors, and consequences of adult asthma in NHANESI and follow up survey. *Am Rev Respir Dis* 1989; 139:721-724

\textsuperscript{274} Lebowitz MD. The relationship of socio-environmental factors to the prevalence of obstructive lung diseases and other chronic conditions. *J Chronic Dis* 1977; 30:599-611


\textsuperscript{276} Butland B, Strachan D, Anderson H. Fresh fruit intake and asthma symptoms in young British adults: confounding or effect modification by smoking. *Eur Respir J* 1999; 13:744-750


\textsuperscript{278} Carey I, Strachan D, Cook D. Effects of changes in fresh fruit consumption on ventilatory function in healthy British adults. *Am J Respir Crit Care Med* 1998; 158:728-733
Smokers appear to have lower levels of serum anti-oxidants, and low anti-oxidant intake has been associated with lower FEV1 and more rapid decline of FEV1 with age. Conversely, French adults followed for 8 years had slower decline in FEV1 if they had higher β-carotene levels (and smoking plus low levels of β-carotene or vitamin E imposed the greatest risk of FEV1 decline). The Health Professionals Follow-up Study (HPFS) is a prospective cohort dietary, lifestyle and health study of US health professionals aged 40-75 that began in 1986. Its findings from 1986 to 1998 were recently published, and identified a diet rich in fruits, vegetables and fish reduces the onset of COPD while a diet rich in refined carbohydrates, cured meats, red meats, fried potatoes and desserts appeared to increase the risk of COPD. Separating out the influence of smoking and lifestyle from diet in developed populations may be difficult, but in spite of increasingly consistent findings, it is surprising that guidelines for management of COPD do not include discussion of dietary risk factors.

**Lung Growth**

Bronchopulmonary dysplasia is the most significant long-term consequence of premature parturition, with an increasing incidence of live births. It affects up to 35% of very low birth weight infants. Lung growth is affected through childhood, and persistent lung function abnormalities have been described. Recent data have shown that as these individuals reach adulthood they are at greater risk of abnormal computerised tomographic chest scan (CT) characterised by airspace dilation and destruction (emphysema), and of abnormal gas transfer, while over 68% of the cohort had features of airflow limitation — that is COPD appears to be common in such individuals, and further large-scale research of the incidence and prevalence of this occurrence, and examination of methods to intervene, are needed.

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COPD PREVENTION

KEY POINTS

The many environmental risk factors outlined indicate that COPD is one of the most preventable diseases.

Primary prevention

- smoking causes around 85% of the risk of COPD
- smoking is responsible for over 10% of global deaths (and is rising)
- preventing smoking initiation should be within the philosophical framework of each health professional who deals with COPD
- dietary anti-oxidants may be protective
- Western diet may increase risk of COPD

Secondary prevention

- quitting smoking in the 25-44 year age-group eliminates risk of COPD within the next 25 years
- smoking cessation is the only intervention shown to slow the natural progression of the airflow limitation and its consequences

3.3 Mortality

Population prevalence for COPD is less than for Asthma, but COPD causes more deaths. It is in fact the fourth leading attributable cause of mortality in Australia, being registered as the primary cause of death for 5,532 Australian in 1998, and 4,886 in 2005. COPD is the 4th most

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common cause of death in males and the 6th most common cause in females, with a steady or declining death rate in males, but an increasing death rate in females\textsuperscript{298,299}. In New Zealand COPD is the 3rd most common cause of death in males and 4th most common in females. Death rates in females were predicted to overtake those in men in around 2005\textsuperscript{300}, and this is close to being realized. A recent survey in the UK examined causes of death in patients with COPD from 1993 to 1999. COPD or asthma was listed in 312,664 death certificates (8.0% of total deaths), and was the attributable cause of death in 59.8% of these. The main other causes of death in COPD were acute myocardial infarction, non-infarct ischaemic heart disease and lung cancer, diseases that share tobacco smoking as major risk factors\textsuperscript{301}. It is likely that current population estimates substantially underestimate the real mortality from COPD, as under-reporting on death certificates is a major bias in such estimates\textsuperscript{302,303}. Recent re-modelling from existing data has been applied by the WHO Policy Cluster team, using three different sets of assumptions and “uncertainty ranges”\textsuperscript{304}. Total tobacco-attributable deaths are predicted to rise from 5.4 million in 2005 to 6.4 million in 2015 and 8.3 million in 2030, with COPD accounting for 27% of these. Respiratory diseases is likely to undergo a 0.3% per annum average increase in age-standardised death rates over that interval. Using these projections COPD will rise from 5th rank in causes of death worldwide in 2002 to 4th rank in 2030. COPD will be responsible for 4.1% of deaths in high income countries in 2030, 12.0% in middle income countries, and 5.5% in low income countries.

**Risk Factors for and Predictors of Mortality**

The progression of COPD is variable. Timed walking distance gradually deteriorated over three years after PR, and the 3-year survival of patients with moderate and severe COPD was 80\%\textsuperscript{305}, with a 6-years survival of 61\%\textsuperscript{306}. The risk factors for early mortality have been evaluated in a number of longitudinal and retrospective studies. Severity of airflow limitation and pulmonary hypertension\textsuperscript{307}, severity of lung volume restriction created by dynamic hyperinflation\textsuperscript{308,309}, rate

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\textsuperscript{303} Jensen HH, Godtfredsen NS, Lange P, Vestbo J. Potential misclassification of causes of death from COPD. Eur Respir J 2006; 28:781-785


\textsuperscript{305} Gerardi DA, Lovett L, Benoit-Connors ML, Reardon JZ, ZuWallack RL. Variables related to increased mortality following outpatient pulmonary rehabilitation. Eur Respir J 1996; 9:431-435


of decline in spirometry\textsuperscript{310}, level of hypoxaemia\textsuperscript{311}, development of hypercapnic respiratory failure\textsuperscript{312}, severity of functional limitation\textsuperscript{313}, continuing smoking\textsuperscript{314}, nutritional status\textsuperscript{315}, have all been identified as risk factors. In five Nordic countries a prospective study of people admitted to hospital for treatment of acute exacerbations of COPD identified 416 patients died in the 24 months of follow-up, with presence of diabetes being the risk factor with highest Hazard Risk ratio (2.42; 95\%CI=1.18-4.96) in addition to GOLD severity (HR 2.40), current smoking (HR=1.73), comorbid cardiovascular disease (HR=1.52), age (HR=1.45) and previous hospitalisations (HR=1.33)\textsuperscript{316}. Depression, low quality of life, high levels of symptoms, functional disability (low activity at home), and high exacerbation rates / hospitalization were good predictors of one-year mortality in a British study of 100 consecutive patients admitted with exacerbations\textsuperscript{317}. Smoking is a risk factor both independently and through its effects on decline rate of spirometry\textsuperscript{318,319} and on all-cause (especially cardiovascular) mortality. In-hospital mortality for people admitted for acute exacerbations of COPD was linked to age, severity of COPD, blood gas abnormalities, and complications arising during hospital stay\textsuperscript{320}. Even the presence of depression at admission for a hospitalisation for acute exacerbation of COPD has been shown to be associated with worse survival\textsuperscript{321}. Some of these factors have recently been drawn together after multifactorial analysis and subsequent prospective validation into a BODE Index, which emphasises body mass, spirometry, dyspnoea and exercise tolerance\textsuperscript{322}.

### 3.4 Morbidity and Burden of Illness

Burden of illness refers to the combined effects of mortality and morbidity from chronic health conditions. The WHO and World Bank have developed a summary measure of burden of illness.
due to premature death (years of life lost due to premature mortality – YLL) and disability (years of healthy life lost due to poor health or disability – YLD). Adding these, weighting for societal preferences for different health states, and applying an annual discount to account for the natural decline in activity, productivity and perceived health with age provides Disability Adjusted Life Years – DALYs\textsuperscript{323}. International and Australian data show that COPD ranks fourth in males for DALYs and sixth in females in most developed nations. Worldwide, COPD currently ranks twelfth for DALYs, though WHO projects that it will rank fifth in 2020, due largely to dramatic increases in use of tobacco in developing nations and improving life expectancy\textsuperscript{324}.

WHO has recently re-assessed the projections in mortality and morbidity through to 2030\textsuperscript{325}. DALY rankings predict COPD will rise from 11\textsuperscript{th} in 2002 to 7\textsuperscript{th} in 2030, and indicate it will be responsible for 2.5% of DALYs in high income countries at that time, 4.7% in middle income countries, and fewer than 2.5% in low income countries.

Other terms developed or suggested to account for inadequacies in QALYs and DALYs have not been well validated. One index specific to Australia is the Body Burden of Disease (BBD)\textsuperscript{326}, which refers to the number of body systems affected by the disease. The International Classification of Disease (ICD-9-CM) defines 23 body system (but not necessarily organ system) categories, and BBD can therefore range from 1 to 23 in any individual. Its utility was evaluated in a hospital population of 21,877 patients\textsuperscript{327}. BBD is one factor predicting hospital length of stay and death, though its contribution varied across major diagnostic categories. The usefulness of BBD based on the more recent ICD-10-AM, and in a broader context, needs further examination.

### 3.5 Costs

American Medicare beneficiaries with COPD have 2.5 times the expenditure of beneficiaries without COPD, with total costs for COPD care in 1993 for US being $US23.9 billion (61.5% direct costs, 18.8% due to mortality, and 19.7% due to morbidity\textsuperscript{328}). Studies in the UK using a “top-down” analysis of administrative costs\textsuperscript{329,330}, or “bottom-up” microcosting suggest total annual costs of £781-1,154 per patient (AUD 1,950-2,900)\textsuperscript{331}. The annual costs (direct + indirect) were £800-1,500 million, most attributed to care of patients with severe COPD.

There are other important though unquantified cost impacts that should not be overlooked. One is depression (between 30 and 96% of patients with COPD display anxiety, depression, panic,

\textsuperscript{324} Murray CJL, Lopez AD. Evidence-based health policy - lessons from the Global Burden of Disease Study. Science 1996; 274:740-743
\textsuperscript{327} Roe CJ, Kulinskaya E, Dodich N, Adam WR. \textit{ibid}
\textsuperscript{329} Guest JF. The annual cost of chronic obstructive pulmonary disease to the UK’s National Health Service. Dis Manage Health Outcomes 1999; 5:93-100
\textsuperscript{330} Sullivan SD, Ramsey SD, Lee TA. The economic burden of COPD. Chest 2000; 117:5S-9S
\textsuperscript{331} Britton M. The burden of COPD from the confronting COPD survey. Respir Med 2003; 97:S71-S79
confusion or neurosis). Another is the economic and emotional burden on carers. Third, as the disease progresses and impairments advance, other organ systems are threatened by complications and concurrent morbidities related to smoking and older age. None of these costs is accounted in costs of COPD. The ALF extrapolated from US statistics that the annual direct and indirect costs of COPD to the Australian community were almost AUD800 million\textsuperscript{332}.

**Direct Costs**

These are the financial costs of health care resources for diagnosing and treating the condition. As detailed by the AIHW\textsuperscript{333}, Respiratory Diseases are the sixth most costly disease group in Australia, accounting for $2.5 billion, or 8.0% of total health system costs. Each year in Australia, over 40,000 hospital separations have the principal diagnosis of COPD, with an average length of stay of 5.3 days. In 1993-1994 the direct health system costs in Australia for COPD were $300 million.

According to the US National Medical Expenditure Survey (1993) around 73% of direct expenditure in USA for COPD patient care was for 10% of the patients, and 72.8% of the costs of overall illness burden were for hospital admissions and emergency department presentations. Outpatient or clinic/office visits represented 15% and prescription drugs around 12\%\textsuperscript{334}. The health system in Australia places emphasis on a robust primary care sector, and the breakdowns may be different. Unlike asthma, where most of the costs are associated with pharmaceuticals to control the disease, in COPD over 35% of the direct costs are associated with hospitalisation (Table 3.3).

<table>
<thead>
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<tr>
<td>Hospital</td>
<td>$112 million</td>
<td>$188 million</td>
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<tr>
<td>Medical</td>
<td>$ 61 million</td>
<td>$102 million</td>
</tr>
<tr>
<td>Pharmaceuticals (prescribed &amp; OTC)</td>
<td>$ 66 million</td>
<td>$111 million</td>
</tr>
<tr>
<td>Other</td>
<td>$ 61 million</td>
<td>$102 million</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$300 million</strong></td>
<td><strong>$503 million</strong></td>
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**Indirect Costs**

These costs derive from missed schooling or employment by the patient or carer, premature death, and other costs related to disablement; social security payments are not usually included because these are intra-population transfers (from tax-payers to recipients of benefits)\textsuperscript{336}. Costs to the healthcare system therefore do not reflect the total cost of COPD to the community. COPD has other significant economic impacts, such as absenteeism, productivity losses and change of duties leading to early retirement. Within 7 to 8 years of initial diagnosis, most people with

\textsuperscript{332} Crockett AJ, Cranston JM, Moss JR. Economic Case Statement. Chronic obstructive pulmonary disease (COPD). The Australian Lung Foundation; 2002


\textsuperscript{334} Sullivan SD, Strassels SA, Smith DH. Characterization of the costs of chronic obstructive pulmonary disease (COPD) in the US. Eur Respir J 1996; 9 (Supp 23):421S

\textsuperscript{335} Crockett AJ, Cranston JM, Moss JR. Economic Case Statement. Chronic obstructive pulmonary disease (COPD). The Australian Lung Foundation; 2002

COPD are no longer capable of productive work. In the UK it has been estimated that 44% of people with COPD are within their working years, and these working patients lost on average almost two weeks’ work each year. AIHW figures do not reflect these indirect costs.

### COPD EPIDEMIOLOGY - KEY POINTS

1) The major risk factor for COPD is tobacco smoking
2) A quarter of all smokers have significant respiratory symptoms
3) COPD occurs in at least 12% of adults over 45
4) COPD ranks 4th as a leading cause of mortality in Australia
5) COPD ranks 3rd or 4th for burden of illness in developed nations
6) COPD will rank 5th globally for burden of illness by 2020
7) COPD increases in prevalence with age
8) COPD is increasing in women
9) Respiratory diseases account for 8% of Australia's health costs
10) COPD admissions in Australia cost over $AU300 million pa
11) Indirect costs for COPD are $AU500 million pa

### 3.6 Carer Burden

The bulk of long term care of people with many chronic conditions is undertaken by informal carers, who are usually family members. Recognition of this role has been made in conditions such as dementia and Alzheimer’s disease, depression, neurological disease including strokes, and in cancer. The psychosocial health of carers of people with dementia has been compared with that of older persons attending their general practitioners and of people with disabling arthritis and other conditions. The carers were as restricted in social and recreational activities as the arthritis sufferers, though not as much as dialysis patients. In an Australian study, full-time carers

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338 Britton M. The burden of COPD from the confronting COPD survey. Respir Med 2003; 97:S71-S79
of elderly people had more mental symptoms and worse life satisfaction than part-time carers. In particular, if the full-time carer felt controlled by the elderly person, carer distress was worse.340

While the burden of caring for people with chronic diseases has been acknowledged, and both physical and mental health problems have been ascribed to this role, measures of burden of disease, such as DALYs, do not include health and well-being of carers.

In non-respiratory populations, the psychological health of carers and patients are linked. No matter how intensive the caring role may be, carers suffer significant emotional distress in part due to the health of their patient and in part due to their inability to participate in their own activities and past-times.342 Levels of loneliness, social isolation and depression were similar among carers and their patients.343 The quality of care received by the patient from family carers is linked with health of the carer, and carer health status has been found to be associated with rates of health care utilisation by their patients.344 Caregivers and patients are often found to communicate their fears and anxieties ineffectively, and actually avoid conversations around their concerns about the rate of decline of their patient, often specifically to avoid psychological distress for them and their patient. Caregivers, though, actually prefer to have more communication about their patient’s illness, both with the physician and the patient.347 348 Education interventions and other supports may be useful in alleviating carer burden and improving the quality of patient care. Provision of guidelines to carers, formal teaching and specific family intervention have improved patient care, delayed nursing home placement, or reduced health care usage.349,350,351 Based on such observations, it has been suggested that a preventive approach with development of formal and informal supports for carers should be adopted, with training and education aimed at improving patient care and reducing carer burden.

344 Draper B, Luscombe G. Quantification of factors contributing to length of stay in an acute psychogeriatric ward. Internat J Geriatric Psychiatry 1998; 13:1-7
351 Mittleman MS, Ferris SH, Shulman E, Steinberg G, Levin B. A family intervention to delay nursing home placement of patients with Alzheimer’s disease. JAMA 1996; 276:1725-1731
Carers are critical to and are often bound up in care of respiratory patients, and this results in physical and emotional health problems. Parents of children with asthma, for example, are central carers for their child, yet in a prospective randomised partially blinded controlled trial provision of guided self-management principles to the parents yielded no significant benefits in health care utilisation, disability score of the children, or carers' quality of life. The carer burden for parents of children with severe asthma is likely to differ from that for spouses of patients with severe COPD. The former condition is usually more intermittent and attacks can be severe and highly emotionally charged. Carers of people with more chronic symptoms of schizophrenia, for example, use different coping styles, especially passivity, than carers of people with more episodic schizophrenia. Carers of children with asthma are younger than carers of people with COPD, and carer age, gender, health and cognitive function are significant predictors of carer stress.

Few formal studies about carers of COPD patients have been published, though Australian data from controlled studies suggested significant relationships in the psychological health status between patients with COPD and their carers, supporting the involvement of the care dyad in respiratory management planning. They also indicated that the handicap experienced by carers of patients with other chronic illnesses occurs in carers of patients with COPD, and that an improvement in patients’ self-management through completion of PR may reduce the handicap associated with the carer’s role and may also benefit the mental health of the carer. Carers themselves reported improved psychological health and social adjustment for their patients following PR, in line with what patients themselves report. In a recent US study, patients with COPD and their life partners had high levels of marital adjustment, associated with better quality of life for the patient and better physical functioning for the spouse. Those with poor marital adjustment responded more favourably to PR than did well-adjusted patients.

If education can help carers provide better care with reduced stress, it appears logical for sessions for carers to be included in PR programs. Carers should at least be encouraged to attend PR programs with their patient, and to become members of Support Groups (SG). However, there is no objective evidence to support (or refute) such recommendations.

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358 Cullen JS, Grayson DA, Jorm AF. Clinical diagnoses and disability of cognitively impaired older persons as predictors of stress in their carers. Internat J Geriatric Psychiatry 1997; 12:1019-1028
359 Cafarella P, Frith P. Psychological status of COPD patients and their carers are linked. Respirology 2001; 6(Suppl):A36
362 Ashmore JA, Emery CF, Hauck ER, MacIntyre NR. Marital adjustment among patients with chronic obstructive pulmonary disease who are participating in pulmonary rehabilitation. Heart Lung 2005; 34:270-278
3.7 Assessing COPD Severity

Guidelines of management of COPD have varying definitions of COPD severity, but by international agreement the GOLD Strategy developed a classification of stages of disease based originally on FEV1 alone. Recent modifications have included symptom severity and presence of complications or systemic consequences. Evidence supporting one or other classification of severity is at present lacking. The TSANZ guidelines (known as ‘COPD-X’) utilise several indexes relating to severity, from FEV1 levels to HRQoL impairment and severity of dyspnoea, because the degree of dyspnoea rating predicts exercise impairment, mood disturbance and health status (Table 3.4). The relevance of the COPD-X severity gradings to patient functionality has been challenged, however.
### TABLE 3.4. COPD-X CLASSIFICATION OF SEVERITY STAGES IN COPD

<table>
<thead>
<tr>
<th>Stage</th>
<th>Spirometry Criteria</th>
<th>Clinical Criteria</th>
<th>Other features</th>
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<tr>
<td>0: At Risk</td>
<td>Normal (FEV1/FVC&gt;0.7 and FEV1&gt;80% predicted)</td>
<td>Chronic symptoms of cough or sputum production</td>
<td>Presence of risk factors</td>
</tr>
<tr>
<td>I: Mild COPD</td>
<td>FEV1/FVC&lt;0.7 but FEV1&gt;80% predicted</td>
<td>Usually but not always chronic cough or sputum production</td>
<td>Chest Xray and complex lung function tests often normal</td>
</tr>
<tr>
<td>II: Moderate COPD</td>
<td>FEV1/FVC&lt;0.7 and FEV1 60% to 80% predicted</td>
<td>Chronic symptoms of cough, sputum production and shortness of breath on exertion</td>
<td>Patients start to seek medical attention with shortness of breath or exacerbations of disease. Chest Xray often shows hyperinflation, and DCO&lt;70% predicted</td>
</tr>
<tr>
<td>III: Severe COPD</td>
<td>FEV1/FVC&lt;0.7 and FEV1 40% to 60% predicted</td>
<td>Deteriorating quality of life with limitation of normal activities</td>
<td>As above</td>
</tr>
<tr>
<td>IV: Very severe COPD</td>
<td>FEV1/FVC&lt;0.7 and FEV1 below 40% predicted</td>
<td>Quality of life severely impaired with severe breathlessness, intractable coughing, and/or life-threatening exacerbations</td>
<td>Respiratory Failure (pO2&lt;60 mmHg and/or pCO2&gt;50 mmHg). Signs of right heart failure (raised JVP, ankle oedema).</td>
</tr>
</tbody>
</table>

### 3.8 Exacerbations of COPD

The term exacerbation has been difficult to define and to quantitate, but it is especially important to have an operational definition when research questions that relate to reducing exacerbations are being considered. Characteristics of exacerbations include a change in symptoms of cough, sputum or dyspnoea, change in overall health status, and a need for change in treatment. Variable elements of airway inflammation are usually (but not universally) evident.

Given the importance of exacerbations in the lives of people with COPD (and their carers) it has been useful to develop a standardised working definition of acute exacerbation of COPD: “an event in the natural course of COPD that is characterised by a sustained worsening in the patient’s condition of the stable state beyond normal day-to-day variations, such as dyspnoea, cough, or sputum, and necessitates a change in regular management.”

Exacerbations are more common in moderate and severe COPD. They are one of the most important contributors to worsening quality of life. In turn, worse quality of life was a

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more important predictor of hospital readmission for COPD than airway physiology\textsuperscript{377}. Exacerbations frequently result in critically altered ventilatory mechanics as a result of dynamic hyperinflation leading to the dyspnoea that triggers presentation to hospital, and onset of respiratory failure\textsuperscript{378}.

The airways of people with moderate and severe COPD are often colonised by \textit{Haemophilus influenzae}, \textit{Streptococcus pneumoniae}, \textit{Moraxella catarrhalis}, and other bacteria\textsuperscript{379,380,381}. Colonisation increases the rate of exacerbations\textsuperscript{382} but bacterial counts, changes in bacterial strains\textsuperscript{383} and greater airway inflammation\textsuperscript{384} correlate with each other during exacerbations. The other major triggers are viral\textsuperscript{385,386,387} (especially rhinovirus) with increased airway inflammation\textsuperscript{388}, and are associated with increased respiratory and all-cause mortality\textsuperscript{389}.

Increased rates of exacerbations are usually more common in winter months, though even in very cold regions, as long as adequate indoor heating and wearing of appropriate clothes are provided, this seasonal variation is surprisingly less evident\textsuperscript{390,391}. Indeed, in countries with warmer average

\footnotesize
\begin{itemize}
\item \textsuperscript{375} Wang Q, Bourbeau J. Outcomes and health-related quality of life following hospitalisation for and acute exacerbation of COPD. \textit{Respirology} 2005; 10:334-340
\item \textsuperscript{377} Osman IM, Godden DJ, Friend JA, et al. Quality of life and hospital re-admission in patients with chronic obstructive pulmonary disease. \textit{Thorax} 1997; 52:67-71
\item \textsuperscript{378} O'Donnell DE, Parker CM. COPD exacerbations. 3: Pathophysiology. \textit{Thorax} 2006; 61:354-361
\item \textsuperscript{381} Stockley RA, O’Brien C, Pye A, Hill SL. Relationship of sputum color to nature and outpatient management of acute exacerbations of COPD. \textit{Chest} 2000; 117:1638-1645
\item \textsuperscript{382} Sethi S, Maloney J, Grove L, et al. Airway inflammation and bronchial bacterial colonization in chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2006; 173:991-998
\item \textsuperscript{383} Chin CL, Manzel JJ, Lehman EE, Humliceke AL, et al. Haemophilus influenzae from COPD patients with exacerbation induce more inflammation than colonizers. \textit{Am J Respir Crit Care Med} 2005; 172:85-91
\item \textsuperscript{384} Wilkinson TM, Patel IS, Wilks M, et al. Airway bacterial load and FEV1 decline in patients with chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2003; 167:1090-1095
\item \textsuperscript{388} Bhowmik A, Seemungal TA, Sapsford RJ, Wedzicha JA. Relation of sputum inflammatory markers to symptoms and lung function changes in COPD exacerbations. \textit{Thorax} 2000; 55:114-120
\end{itemize}
temperatures, the mortality from winter cold-related exacerbations is greatest\textsuperscript{392}. It is logical to suggest that reduced exacerbations might be achievable through better heating for the aged and infirm during winter months, especially in more temperate climates.

Air pollution is a significant risk factor for exacerbations of COPD. Higher rates of mortality and/or hospitalisation (all-cause, cardiac and respiratory) are associated with higher levels of small particle, sulphur dioxide or nitrogen dioxide pollution\textsuperscript{393,394,395,396}, and pollution increases markers of airways inflammation. Diesel exhaust, for example, increases airway inflammatory markers\textsuperscript{397,398,399}.

Although there is increasing consensus on the definition of exacerbations of COPD (see above), the aetiologies, symptoms and treatments are heterogeneous. Additionally, the severity of an exacerbation may be hard to classify. Classifications and definitions that rely on symptoms may be unreliable, and this may impact on evaluation of treatments for exacerbations. Since inflammation is considered to be the root cause of exacerbated symptoms, there is logic in finding reliable markers of inflammation that might be used to detect and monitor exacerbations. To that end, a systematic research review was recently undertaken with meta-analysis\textsuperscript{400}. Among the 268 research reports (investigating 142,407 patients with COPD) the authors based their severity classification on simple ATS/ERS criteria (Level I – suitable for home management – Level II – requires hospitalisation – Level III – requires specialised care). Of the hundreds of measures examined in these studies, the most consistent markers correlating with severity rating were arterial pCO2 and respiration rate. If exacerbations can be prevented with appropriate therapies (see below) overall health status can be improved\textsuperscript{401}, and self-management of exacerbations should be part of patient education.

\textsuperscript{392} Eurowinter Group. Cold exposure and winter mortality from ischaemic heart disease, respiratory disease, and all causes in warm and cold regions of Europe. \textit{Lancet} 1997; 349:1341-1346
\textsuperscript{395} Garcia-Aymerich J, Tobias A, Anto JM, Sunyer J. Air pollution and mortality in a cohort of patients with chronic obstructive pulmonary disease: a time series analysis. \textit{J Epidemiol Community Health} 2000; 54:73-74
\textsuperscript{396} Sunyer J, Schwartz J, Tobias A, Macfarlane D, et al. Patients with chronic obstructive pulmonary disease are at increased risk of death associated with urban particle air pollution: a case-crossover analysis. \textit{Am J Epidemiol} 2000; 151:50-56
\textsuperscript{401} Spencer S, Calverley PM, Burge PS, Jones PW. Impact of preventing exacerbations on deterioration of health status in COPD. \textit{Eur Respir J} 2004; 23:698-702
3.9 Management of COPD

Management of COPD includes effective accurate diagnosis and treatment of COPD and its complications and comorbidities (Disease Management), then training the patient and carers to monitor and respond appropriately to changes in the condition (Chronic Disease Self Management). Aspects of management have been reviewed in the GOLD Guidelines\(^\text{402, 403}\), and COPD-X\(^\text{404,405}\) but are summarized below and in Table 3.5.

**TABLE 3.5. COPD-X MANAGEMENT PLAN FOR COPD\(^{406,407}\)**

<table>
<thead>
<tr>
<th>Management Principle</th>
<th>Broad Description of Management Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C</strong></td>
<td>Confirm diagnosis and severity (requires symptoms &amp; spirometry).&lt;br&gt;Check for complications and comorbidities.</td>
</tr>
<tr>
<td><strong>O</strong></td>
<td>Optimise patient function, with safe effective medications.&lt;br&gt;Encourage and assist activity &amp; good nutrition.&lt;br&gt;Provide oxygen if hypoxaemic.</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td>Prevent deterioration:&lt;br&gt;Stop smoking.&lt;br&gt;Pulmonary rehabilitation.</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>Develop shared-care Action Plan</td>
</tr>
<tr>
<td><strong>X</strong></td>
<td>Exacerbation treatment plan:&lt;br&gt;early diagnosis &amp; treatment&lt;br&gt;systemic corticosteroids&lt;br&gt;effective antibiotics if bacterial infection&lt;br&gt;oxygenate if hypoxaemic&lt;br&gt;ventilate if ventilatory failure</td>
</tr>
</tbody>
</table>

Only selected references are provided for important studies or meta-analyses. The pharmacotherapy aspects have been well-reviewed recently\(^\text{408}\), and overall management has also been reviewed\(^\text{409}\). Staging using GOLD (www.goldcopd.org), NICE (www.nice.org.uk) or COPD-X (www.copdx.org.au) guidelines can help to guide therapy (Table 3.6).

\(^{406}\) McKenzie DK, Frith PA, Burdon JG, Town GI. *ibid*
\(^{407}\) Abramson MJ, Crockett AJ, Frith PA, McDonald CF. *ibid*
\(^{409}\) Sin DD, McAlister FA, Man SF, Anthonisen NR. Contemporary management of chronic obstructive pulmonary disease: a scientific review. JAMA 2003; 290:2301-2312
### TABLE 3.6. COPD STAGES AS A GUIDE TO TREATMENT

<table>
<thead>
<tr>
<th>Stage</th>
<th>Recommended treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Add treatments (high levels of evidence of efficacy and safety)</strong></td>
</tr>
<tr>
<td>All stages</td>
<td>Avoid risk factors (especially smoking)</td>
</tr>
<tr>
<td><strong>I: Mild</strong></td>
<td>Symptom relief (as-needed bronchodilators)</td>
</tr>
<tr>
<td><strong>II: Moderate</strong></td>
<td>Regular long-acting anticholinergic and/or long acting beta agonist. Pulmonary rehabilitation</td>
</tr>
<tr>
<td><strong>III: Severe</strong></td>
<td>Inhaled corticosteroids</td>
</tr>
<tr>
<td><strong>IV: Very Severe</strong></td>
<td>Treat complications</td>
</tr>
</tbody>
</table>

Because of its many impacts on patients and their families, COPD can be considered a multi-system bio-psychosocial disorder, making a multidisciplinary approach to care entirely logical. Symptom control can to some extent be improved with **shorter-acting bronchodilators**. A systematic review found only four trials meeting Cochrane criteria, and confirmed efficacy in exacerbations of COPD, but found no difference between ipratropium and beta-agonist.\(^{410}\)

In people with severe airflow limitation reduction in exacerbations can be achieved, exercise capacity can be improved, and decline in quality of life can be slowed, without significant risk, by **long-acting beta-agonists**\(^{411,412}\) (LABA).

The long-acting anticholinergic drug, **tiotropium**, reduces hyperinflation, reduces exacerbations, increases exercise endurance, reduces dyspnoea, improves quality of life\(^{413}\), and enhances effects of pulmonary rehabilitation\(^{414,415,416,417,418,419}\). A meta-analysis has confirmed these findings\(^{420}\).

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\(^{419}\) Casaburi R, Kukafka D, Cooper CB, Witek TJ, Kesten S. Improvement in exercise tolerance with the combination of tiotropium and pulmonary rehabilitation in patients with COPD. *Chest* 2005; 127:809-817
There may be significant additional benefit from combining use of tiotropium and a LABA\textsuperscript{421,422,423}, although tiotropium may have better overall efficacy\textsuperscript{424}.

Despite its inflammatory nature, COPD has long been considered poorly responsive to inhaled corticosteroids (ICS). Recent research, however, has shown potential for ICS\textsuperscript{425}, especially in combination with LABA, not only to slow decline in quality of life and reduce exacerbations and hospitalisations but perhaps also reduce mortality\textsuperscript{426,427,428,429,430,431,432,433}. A systematic review found six relevant RCTs with 4,118 patients treated with ICS-LABA (pooling of both available combinations was used), and determined there were consistent benefits in quality of life, symptoms and rates of exacerbations in comparison with placebo, but little evidence relating to comparison with the mono-components\textsuperscript{434}. Post hoc analysis from the TORCH trial\textsuperscript{435}, and a nested case control study from a cohort of COPD patients (n=175,906)\textsuperscript{436} suggest an increased risk of pneumonia in people with COPD receiving inhaled corticosteroids (with or without

\textsuperscript{420}Barr RG, Bourbeau J, Camargo CA, Ram FSF. Tiotropium for stable chronic obstructive pulmonary disease: a meta-analysis. \textit{Thorax} 2006; ………………..


\textsuperscript{425}Burge PS, Calverley PMA, Jones PW, on behalf of the ISOLDE study investigators. Randomized, double blind, placebo controlled study of fluticasone propionate in patients with moderate to severe chronic obstructive pulmonary disease: the ISOLDE trial. \textit{Brit Med J} 2000; 320:1297-1303


\textsuperscript{427}Soriano JB, Kiri VA, Pride NB, Vestbo J. Inhaled corticosteroids with/without long-acting ß-agonists reduce risk of rehositalization and death in COPD patients. \textit{Am J Respir Crit Care Med} 2003; 2:67-74


\textsuperscript{433}Ernst P, Gonzalez AV, Brassard P, Suissa S. Inhaled corticosteroid use in chronic obstructive pulmonary disease and the risk of hospitalization for pneumonia. \textit{Am J Respir Crit Care Med} 2007; 176:162-166
additional drugs). Further definitive research addressing this possibility is indicated, but the findings warrant clinical monitoring of all patients treated with ICS who have severe COPD.

Additional benefits may be found from adding tiotropium to combined ICS-LABA in severe COPD (and deterioration after withdrawal of tiotropium)\(^{437}\), and a recent Canadian RCT has confirmed additional effects on exacerbation rates (but not on lung function, quality of life or exacerbation rates)\(^{438}\). Another small study (randomized, double blind double dummy three-way cross-over) in COPD patients aged 40-80 and with FEV1 averaging 47.1% predicted demonstrated greater lung function improvements, reduced hyperinflation and improved levels of dyspnoea from combined tiotropium and salmeterol+fluticasone than with tiotropium alone and the ICS-LABA\(^{439}\).

**Supplemental oxygen** in the home was found in two landmark controlled trials to improve survival of patients with COPD who are significantly hypoxaemic, especially if there was either polycythaemia or pulmonary hypertension\(^{440,441}\). The benefits were seen when the duration of treatment was longer than 15 hours a day (with greater benefit from longer hours of supplementation). Pulmonary haemodynamics have been shown to improve and stabilise in such settings\(^{442}\). More recent studies have not been so favourable when evaluating survival in those with mild hypoxaemia\(^{443,444}\), or in severely hypoxaemic patients with multiple comorbidities\(^{445}\). In prescribing home oxygen therapy, there are significant imperfections, however. Adherence to recommendations based on evidence by the physician is not infrequently poor\(^{446,447,448}\), and patients adhere to instructions poorly\(^{449,450}\). In particular smoking cessation is central, given the


\(^{439}\) Singh D, Brooks J, Hagan G, Cahn A, O’Connor BJ. Superiority of “triple” therapy with salmeterol/fluticasone propionate and tiotropium bromide versus individual components in moderate to severe COPD. *Thorax* 2008; 63:592-598


\(^{443}\) Fletcher EC, Donner CF, Midgren B, Zielinski J, et al. Survival in COPD patients with a daytime PaO2 > 60 mm Hg and without nocturnal oxyhaemoglobin desaturation. *Chest* 1992; 101:649-655


\(^{447}\) Oba Y, Salzman GA, Willies SK. Reevaluation of continuous oxygen therapy after initial prescription in patients with chronic obstructive pulmonary disease. *Respir Care* 2000; 45:401-406


counter-productivity of ongoing smoking (e.g., on survival, and the potential for adverse interaction between carbon monoxide and oxygen), as well as the ever-present danger of fires sustained in the presence of oxygen enrichment. PR professionals need to be alert to the fact that sometimes patients revert to old habits, despite warnings and even agreements about these dangers. Ongoing monitoring and reassessment are therefore warranted for people prescribed this therapy, and targeted education for them and their carers is recommended (though supported by limited direct evidence of efficacy for either approach)\textsuperscript{451,452}.

The question of ambulatory or intermittent oxygen therapy is at present unresolved. Even a recent systematic review\textsuperscript{453} has not answered the question, largely because they examined only RCTs, and discovered only two such studies. An early trial in twenty patients supported the benefits of ambulatory oxygen in COPD patients with secondary polycythaemia, in reducing the polycythaemia, without adverse effects or intolerability\textsuperscript{454}. Oxygen given for 5 minutes before or for 5 minutes after a 6MWT (double-blind, random order design study) to people with moderate to severe COPD who showed desaturation on a previous test of >4% had no appreciable benefit in walk distance or breathlessness scores, and there was no difference between pre- and post-exercise gas treatment\textsuperscript{455}. Exercise capacity may improve for mildly-hypoxaemic COPD patients using portable oxygen at rest and during exercise testing\textsuperscript{456}, activities\textsuperscript{457,458,459}, and with exercise training in PR\textsuperscript{460}, as it appears to decrease dynamic hyperinflation\textsuperscript{461}. A systematic review examining the role of oxygen supplementation during exercise training found five RCTs conducted in people with COPD without resting hypoxaemia\textsuperscript{462}. Results were heterogeneous, and no significant differences were found for functional exercise outcomes, maximal or sub-maximal exercise performance or HRQoL. In interstitial lung disease the operational arguments around

\textsuperscript{451} Pelletier-Fleury N, Lanoe JL, Fleury B, Fardeau M. Cost effectiveness of two types of structure delivering long term oxygen therapy at home. Rev D’Epidemiol Sante Publ 1997; 45:53-63
\textsuperscript{453} Ram FSF, Wedzicha JA. Ambulatory oxygen for chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2007, issue 4
oxygen supplementation are different. Patients with interstitial disease who desaturate from normoxia to hypoxaemia during exertion have shorter survivals. More research is warranted on the benefits (including survival, exercise endurance, and quality of life) and costs (both financial and personal inconvenience) of ambulatory oxygen therapy. Australian and New Zealand recommendations for domiciliary oxygen therapy have been updated in 2005, with acknowledgement that the evidence base needs strengthening.

**Oral corticosteroids** should be avoided in the long term because they are not effective and they have important deleterious adverse effects. However they are indicated in acute exacerbations as they speed recovery.

Recurrent inflammation from infections may be prevented by vaccinations, notably against influenza, but perhaps also against Pneumococcus. If antibiotics are used promptly for symptoms of bacterial infection of the lower respiratory tract recovery is quicker, and inflammatory damage is therefore probably reduced. Infections are the main cause of exacerbations of COPD, and these often lead to hospitalization, further reduce quality of life, increase mortality. All these aspects of medication use, and the equipments available to administer them, should feature in education of the patient and carers.

Weight loss arising from the catabolic state of advanced disease predicts rapid progression. Good nutrition should therefore be maintained before this stage is reached, and this can also maintain a sense of well-being and prevent loss of lean muscle mass. There is suggestive evidence that diet high in some flavonoids with anti-inflammatory and anti-oxidant effects reduces symptoms and protects against decline in lung function. Excessive weight increases work of breathing, and makes coexisting hypoventilation or upper airway obstruction during sleep more likely, so attainment and maintenance of ideal weight should be encouraged. This is more important when supporting people who are quitting smoking, as weight gain during the first year of cessation resulted in small but significant reductions in operating lung volumes in the US/Canadian Lung Health Study involving 5,346 individuals, especially deleterious in men.

**Sleep-disordered breathing** is relatively common, is related to excess weight, impairs ventilation during sleep, may contribute to poor control of cardiovascular disease, and needs treatment with assisted ventilation (CPAP).

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Moderate and severe COPD often result in a plethora of psychosocial difficulties, and these should be addressed in the management plan. Distinction between mood and psychopathological disease can be difficult. Dyspnoea is a distressing symptom, and inactivity leading to social withdrawal and loss of role can cause patients and carers to be disheartened. Depressive symptoms are common in chronic respiratory diseases (COPD and asthma)\(^ {472}\). Depression and anxiety with or without panic disorder are moderately frequent in COPD, and could potentially be helped by pharmacotherapy or cognitive behaviour therapy. A large Canadian random population health survey (n=36,984) used the World Mental Health Composite International Diagnostic Interview, a technique more likely to identify true psychiatric diagnoses than do mental health screening questionnaires; with a 77% response rate. Subjects were asked to select from an extensive list what chronic medical conditions had been diagnosed. This evaluation found 4,448 people reported one or more respiratory illnesses, and these people had high prevalence rates of major depression, panic disorder and substance dependence\(^ {473}\). The links are greater with more severe disease, and appear to be independent of therapies (including long-term oxygen therapy)\(^ {474}\). A systematic review in 1999\(^ {475}\) found only four case-control studies out of ten studies with otherwise satisfactory methodological design, and rates of depression varied widely, between 7% and 42%. Anxiety in COPD has been largely ignored, although the prevalence of anxiety in COPD may be between 8% and 67%\(^ {476,477,478}\), and it appears to contribute significant risk of hospitalisation for patients with COPD\(^ {479,480}\). The impact of comorbid depression on outcomes in COPD patients has been examined in a prospective cohort of 376 consecutive patients hospitalised for exacerbations of COPD, and depressive symptoms were independently associated with higher rates of re-hospitalisation, persistent smoking, worse symptoms, and higher mortality rates\(^ {481}\). In a later cross-sectional study of 109 oxygen-dependent patients with severe COPD, 57% had significant depressive symptoms, with 18% being severely clinically depressed\(^ {482}\). Other research suggests that depression is not uncommon in stable patients with


\(^{473}\) Patten SB, Williams JVA. Chronic obstructive lung disease and prevalence of mood, anxiety, and substance-abuse disorders in a large population sample. Psychosomatics 2007; 48:496-501

\(^{474}\) Lewis KE, Annandale JA, Sykes RN, et al. Prevalence of anxiety and depression in patients with severe COPD: Similar high levels with and without LTOT. COPD: J COPD 2007; 4:305-312


\(^{476}\) Rose c, Wallace l, Dickson R, Ayres J, et al. The most effective psychologically-based treatments to reduce anxiety and panic in patients with chronic obstructive pulmonary disease (COPD): a systematic review. Pat Educ Counsel 2002; 47:311-318

\(^{477}\) Brenes GA. Anxiety and chronic pulmonary disease: Prevalence, impact and treatment. Psychosom Med 2003; 65:963-970

\(^{478}\) Dowson CA, Kuijer RG, Mulder RT. Anxiety and self-management behaviour in chronic obstructive pulmonary disease: what has been learned? Chronic Respir Dis 2004; 1:213-220

\(^{479}\) Yohannes AM, Baldwin RC, Commolly MJ. Depression and anxiety in elderly outpatients with chronic obstructive pulmonary disease: prevalence and validation of the BASDEC screening questionnaire. Internat J Geriatric Psych 2000; 15:1090-1096


severe COPD\textsuperscript{483,484,485}, especially among smokers\textsuperscript{486}. In addition, depression and anxiety occurred with quite high frequency in New Zealand patients hospitalized with COPD\textsuperscript{487}. The overall interaction between mood disorders and COPD has also been reviewed\textsuperscript{488}.

Given these findings, use of anti-depressants or anxiolytics, or non-pharmacological treatments ought to be considered. The response rates in older depressed patients who are treated with antidepressants are thought to be as high as 50 to 60\%\textsuperscript{489}. A systematic review has found that antidepressants were more effective than placebo in older inpatients and outpatients with depression\textsuperscript{490}. Evidence for the benefit of antidepressant therapy for older COPD patients with depression is incomplete\textsuperscript{491,492}. Anxiety is often a significant problem in people with COPD and SSRIs are beneficial in reducing anxiety as well as depression\textsuperscript{493}. Weight gain may occur particularly with longer term therapy, and this may be a useful “adverse effect” in underweight COPD patients\textsuperscript{494}. Mirtazapine may also be considered for underweight patients with agitated depression, provided therapy is commenced at a low dose and the patient is monitored carefully for respiratory depression. Buspirone has been found clinically to be a useful anxiolytics without respiratory suppression\textsuperscript{495}.

**Cognitive behaviour therapy (CBT)** is a psychotherapeutic modality that aims to identify anxiety-provoking automatic thoughts and change both these negative thoughts and the underlying beliefs through behavioural tasks like diary-keeping, with validity-testing of beliefs between sessions and skills training in sessions\textsuperscript{496}. There is good evidence supporting CBT in a

\begin{thebibliography}{99}
\bibitem{486} Kostianev S, Mitrev I, Hodgev V, et al. ibid
\bibitem{489} Schneider LS, Olin TJ. Efficacy of acute treatment of geriatric depression. *Internat J Geriatric Psych* 1995; 7(Suppl 7):7-25
\bibitem{490} Wilson K, Mottram P, Sivananthan A, Nightingale A. Antidepressants versus placebo for the depressed elderly. *Cochrane Database Syst Rev* 2001; Issue 1
\bibitem{494} Masand PS, Gupta S. Long-term side effects of newer-generation antidepressants: SSRIs, venlafaxine, nefazodone, bupropion and mirtazapine. *Ann Clin Psych* 2002; 14:175-182
\bibitem{496} Hunot V, Churchill R, Silva de Lima M, Teixeira V. Psychological therapies for generalised anxiety disorder. *Cochrane Database Syst Rev* 2006; Issue 4
\end{thebibliography}
variety of syndromes and settings\textsuperscript{497,498,499}, but its utility in COPD has not been systematically studied.

Loss of exercise capacity with breathlessness can lead to fear of activity, panic, loss of confidence and depression. The consequent lack of activity can contribute to loss of muscle mass and strength. Encouragement therefore needs to be given to increase \textit{activities} and formal \textbf{exercise strength and endurance training} has strong evidence for its efficacy.

\begin{center}
\textbf{MANAGEMENT OF COPD}
\end{center}

\begin{center}
\textbf{KEY POINTS}
\end{center}

1) Stages of severity based on symptoms and lung function can be used to guide therapy.

2) Evidence-based management of COPD includes facilitating early diagnosis, rating severity, detecting complications, reducing risk factors, guiding drug therapy, maintaining activity, referring for rehabilitation, providing oxygenation, and support.

3) Smoking cessation slows COPD progression.

4) The progressive natural history of COPD and its multi-system effects require careful lifetime monitoring.

5) An ongoing disease management system is required, linking primary care and other care sectors, and involving a shared-care approach with the patient.

6) Support and education can be provided through Support Groups, Pulmonary Rehabilitation, and Outreach programs.

7) Attention should be given to palliative care and end-of-life issues in later Stages of the condition.


4. PULMONARY REHABILITATION

4.1 Introduction

Rehabilitation within Lung Disease Management

Evidence-based guidelines for management of COPD, and more specifically for Pulmonary Rehabilitation, first emerged in the 1990s. American Thoracic Society (ATS) Official Statement on “Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease” (1995)\(^\text{500}\), and British Thoracic Society (BTS) “BTS Guidelines for the Management of Chronic Obstructive Pulmonary Disease” (1997)\(^\text{501}\) emerged each with discussion on Pulmonary Rehabilitation (PR). Based on extensive references they concluded that PR should be an integral part of the management of patients with moderate to severe disability. By PR each Society was referring to a multi-disciplinary program aimed at patient wellbeing and functional status. The BTS did not give any detail of the components of PR, while the ATS Guidelines did.

Management of COPD

There has been a reasonably comprehensive cover of this topic in the previous Section. Many components of COPD management are integral parts of PR, however, and for this reason the topic is presented in summary format, and specific aspects that are of most relevance to PR are detailed below. Web-based documents are also available for more in-depth discussion.

International (‘GOLD’) COPD Guidelines were published after wide consultation and extensive literature searches\(^\text{502}\). They originally listed four components of management:

- Assess and monitor disease
- Reduce risk factors
- Manage stable COPD
- Manage exacerbations

In Australia and New Zealand the TSANZ and ALF co-developed COPD-X (see previous Section), a four-step management guideline\(^\text{503,504}\). New guidelines aimed at primary care have

\(^{500}\) American Thoracic Society Official Statement. Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease. Am J Respir Crit Care Med 1995; 152:S77-S120

\(^{501}\) COPD Guidelines Group, BTS. BTS Guidelines for the Management of Chronic Obstructive Pulmonary Disease. Thorax 1997; 52 (Suppl 5):S4-S27


also recently been published in the UK\textsuperscript{505}. Recommendations are thoroughly evidence based in both, covering diagnosis, preventative approaches, and managing stable patients, exacerbations and progression of disease through optimum treatment and self-management plans.

\textbf{Assess and Monitor Disease}

It is beyond the scope of this document to present further discussion on this aspect. It is, however, the responsibility of the physicians involved in PR programs to assess each patient in sufficient detail so that all respiratory diagnoses, complications of the disease and its treatment, and concurrent conditions are accurately diagnosed. PR physicians should initiate investigations and/or referrals for opinion if other conditions are suspected and treatment is found to be inadequate. In doing so, the physician should integrate actions with the relevant primary care doctor, and fully inform others involved in the patient’s care.

\textbf{Reduce Risk Factors}

There is a range of risk factors for the development and progression of COPD, as detailed previously. All pulmonary rehabilitation workers should be actively involved in promoting healthy living choices as part of their commitment to primary and secondary prevention, and helping their patients achieve a lifestyle that minimizes ongoing exposure to risk.

\textbf{Tobacco Smoking}

Smoking cessation is the leading risk reduction strategy, as it is the single most effective and cost-effective disease modifying treatment\textsuperscript{506}. As smoking is the major risk factor for development and progression of COPD, and a frequent trigger for asthma, intensive efforts in primary and secondary prevention are indicated. This implies a multi-facetted approach that includes patient education, overall review of lifestyle, pharmacological and behavioral support, and ongoing review. Several guidelines for smoking cessation have been published in recent years, including those from the US Public Health Service\textsuperscript{507,508}, the UK\textsuperscript{509}, and Australia\textsuperscript{510}, as well as many books, pamphlets and programs that provide support and information for people wanting to quit. Brief (e.g. 3 minutes) intervention by the physician can be effective\textsuperscript{511}. The “Five

\textsuperscript{507} The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives. A clinical practice guideline for treating tobacco use and dependence. JAMA 2000; 283:244-254
\textsuperscript{510} National Preventive & Community Medicine Committee of the Royal Australian College of General Practitioners. Putting Prevention into Practice. Guidelines for the implementation of prevention in the general practice setting. RACGP, Melbourne; 1998
A’s” are principles common to most interventions\(^{512}\) (see Box). The full evidence base has been reviewed for all recommendations in the UK guidelines, and in several other keynote publications\(^{513,514,515,516}\).

**THE FIVE A’s QUIT STRATEGY\(^{517}\)**

**ASK** – current and past smoking at each visit

**ASSESS** – nicotine addiction, habits, and readiness to quit

**ADVISE** – health effects, how to quit, withdrawal, supports

**ASSIST** – quit tools (drugs, counselling and support)

**ARRANGE** – regular follow-up to ensure abstinence

**BENEFITS OF SMOKING CESSATION**

Smoking cessation has many benefits. Some are outside the scope of this Manual, but include reduction of risk for development or progression of cardiovascular disease and peripheral arterial disease, and progressive reduction in risk for development of several cancers, especially those of the respiratory tract. The benefits related to respiratory disease are also multiple. These were the subject of a recent systematic review\(^{518}\). Spanish and Polish studies have shown that spirometry screening can result in increased uncovering of airflow limitation in symptomatic smokers, and that this discovery of early COPD can enable many smokers to quit\(^{519}\).

\(^{512}\) The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives. A clinical practice guideline for treating tobacco use and dependence. *JAMA* 2000; 283:244-254


\(^{517}\) The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives. A clinical practice guideline for treating tobacco use and dependence. *JAMA* 2000; 283:244-254


Respiratory symptoms are differentially responsive to smoking cessation. In cross-sectional studies, background cough, sputum production and wheezing are all lower in prevalence in ex-smokers than in current smokers. Prevalence of cough is reported in 5 to 21% of ex-smokers but 10 to 40% in current smokers. Sputum production is reported in 5 to 30% of ex-smokers and 10 to 40% of current smokers. The reported range for prevalence of wheezing is 1 to 19% in ex-smokers and between 7 and 32% in continuing smokers. However, the sensation of dyspnoea appears to be less responsive, with prevalence rates between 2 and 41% in both smoker and former smokers. Further, the prevalence rates of all these respiratory symptoms remain higher in ex-smokers than in people who have never smoked.

In longitudinal studies it has been shown that some symptoms are less likely to develop in people who quit smoking than in those who persist. Development of cough or sputum production, for example, was seen in 21% of smokers who quit compared to 29% of persisting smokers. Cough, sputum production and wheezing all decrease within a few months of smoking cessation. Indeed, the prevalence of cough and wheeze decreased to that in non-smokers. Sputum persisted, albeit at a reduced rate, and dyspnoea was not altered in this study. Dyspnoea may decrease slightly, or not at all. Alternatively weight gain following smoking cessation may contribute to an increase in dyspnoea with exertion, possibly related to restriction of operating lung volumes with the weight gain.

In people with established COPD, there are few longitudinal data relating to change in respiratory symptoms following smoking cessation. Development of symptoms is greater in continuing smokers than in those who persistently quit. A disappearance of chronic cough has been described, while the large Lung Health Study confirmed over 80% reduction in chronic cough, chronic sputum, day and night wheeze and dyspnoea after 5 years of smoking cessation, mostly in the first year of quitting. Sustained quitters were later found to have lower rates of lower respiratory tract infections than continuing smokers.

520 Krzyzanowski M, Robbins DR, Lebowitz MD. Smoking cessation and changes in respiratory symptoms in two populations followed for 13 years. *Int J Epidemiol* 1993; 22:666-673
521 Comstock GW, Brownlow WJ, Stone RW, Sartwell PE. Cigarette smoking and changes in respiratory findings. *Arch Environ Health* 1970; 21:50-57
527 Pride NB. Smoking cessation: effects on symptoms, spirometry and future trends in COPD. *Thorax* 2001; 56 (Suppl 2):117-110
528 Friedman GD, Siegal A. Changes after quitting cigarette smoking. *Circulation* 1980; 61:716-723
530 Kanner RE, Anthonisen NR, Connett JE for the Lung Health Study Research Group. Lower respiratory illnesses promote FEV1 decline in current smokers but not ex-smokers with mild chronic obstructive pulmonary disease. Results from the Lung Health Study. *Am J Respir Crit Care Med* 2001; 164:358-364
Several studies slower deterioration of lung function in people who successfully quit smoking compared with those who persist. Cross-sectional and longitudinal studies, including the Framingham Study and others, have confirmed the reduced rate of loss of lung function over time in successful quitters compared to those who continue to smoke, and some data have suggested that the rate of lung function decline reaches the normal rate by two years after quitting. Recent analysis from the Lung Health Study has demonstrated FEV1 decline rates averaging 27 mls per year in sustained quitters, while continuing smokers deteriorated by an average of 60 ml a year. At 11 years, FEV1 values had declined to less than 60% of predicted normal in 38% of continuing smokers and in 10% of sustained quitters.

In people with COPD the decline in lung function that accelerates with age and further increases with smoking, is faster in people with higher cumulative smoking consumption and with actual numbers smoked, and appears to be greater again in people with bronchial hyper-responsiveness. In the Lung Health Study, people who continued to smoke had higher rates of lower respiratory infections and a combination of lower respiratory infections and sustained smoking accelerated further the decline in lung function. Smoking is associated with an increase in airway responsiveness, generally thought to be due to the airway inflammation.

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induced by smoking, as well as an epi-phenomenon of altered airway geography (that is, reduced airway calibre). An interaction between airway reactivity and smoking has been described in the Lung Health Study, such that those with baseline increased methacholine reactivity had steeper declines in lung function than in smokers without hyperreactivity, and this was unrelated to baseline FEV1. The same benefits in lung function and symptoms as seen in normal smokers from quitting have been demonstrated in several cross-sectional and prospective studies of people with COPD (see Diagram 4.1).

**FIGURE 4.1  DECLINE IN LUNG FUNCTION**

![Diagram showing decline in lung function over time]

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549 Renkema TE, Kerstjens HA, Schouten JP, Vonk JM, et al. The importance of serum IgE for level and longitudinal change in airways hyperresponsiveness in COPD. *Clin Exper Allergy* 1998; 28:1210-1218
557 Anthonisen NR, Connett JE, Murray RP. Smoking and lung function of Lung Health Study participants after 11 years. *Am J Respir Crit Care Med* 2002; 166:675-679

76
Improvements in airway hyperresponsiveness have also been described in people with COPD who quit smoking. These improvements include tests of both direct and indirect hyperresponsiveness. Tests of direct specific receptor-activated smooth muscle constriction by inhaled histamine or methacholine deteriorated less in sustained quitters than in continuing smokers in the longitudinal Lung Health Study, though no such differences were seen in cross-sectional studies of smoking and ex-smoking populations. Tests of indirect smooth muscle effects of adenosine 5'-monophosphate (AMP) through activation of inflammatory cells and/or neural pathways have been shown to be less active in a cross-sectional study of ex-smokers than current smokers, and confirmed in an uncontrolled longitudinal study of 14 smokers with COPD who sustained quitting for one year. This latter study also showed reduced direct responsiveness, but showed no relationship between these changes and induced sputum markers of airway inflammation. The changes in symptoms and lung function with smoking, and their improvement after successful quitting, are not as consistently matched by pathological changes in the lungs. Goblet cell hyperplasia, even in non-COPD patients undergoing lung resection, is slightly less in ex-smokers than current smokers. This benefit is more marked in those with COPD. Some changes with smoking and after cessation, in COPD and without, have been described in expression of bronchial inflammatory mediators, and inflammatory markers in the blood and sputum appear lower in ex-smokers than in continuing smokers. That is, in people with COPD, although some airway inflammation appears to persist even after smoking cessation, reductions observed in alveolar, serum and sputum markers suggest the tissues effects ameliorate with time.

568 Skold CM, Blashke E, Eklund A. Transient increases in albumin and hyaluronan in bronchoalveolar lavage fluid after quitting smoking: possible signs of reparative mechanisms. Respir Med 1996; 90:523-529
Finally, analyses from the Lung Health Study Research Group have demonstrated increases in hospitalisation rates and higher 5-year mortality in continuing smokers than in sustained quitters. The Group has confirmed the reduction in all-cause mortality from quitting in the most recent 14.5-year follow-up analysis of the original 5,887 smoking cohort (aged 35-60 years at origin). A Finnish cohort study followed for 30 years (enrolling all eligible males aged 40-59 years in 1959) provides further powerful data, confirming the other studies. Lung function predicted all-cause mortality after adjustment for cardiovascular risk factors; smoking cessation improved mortality (mainly due to reduced cardiovascular deaths, seen within the first five years of quitting); deaths attributed to COPD or lung cancer did not decline, however, probably due to the lack of benefit from smoking cessation described in those with more severe COPD.

**Manage Stable COPD**

In managing stable disease, the elements of education, pharmacologic treatment, and non-pharmacologic treatments are defined within GOLD, COPD-X, and NICE guidelines for the management of COPD. In each case, education is considered important, though each paper acknowledges that studies of effectiveness for education alone in COPD are rare. Specific aspects of education are effective, including smoking cessation, explanation of optimum inhaled medications and apparatus, as well as oxygen use and self-management. Rehabilitation is the first aspect in non-pharmacologic treatment in these guidelines, and they all emphasise that careful evaluation has identified a range of clear benefits. The components of PR are addressed—

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specifically exercise training, nutrition counseling, and education. Depression, anxiety and panic are acknowledged as issues, but the GOLD document does not discuss this further, while the NICE document provides extensive analytical discussion.

**Manage Acute Exacerbations**

Through the PR program and in collaboration with the patient and primary care doctor, each patient should be trained to self-manage, by monitoring symptoms and signs, and to responding quickly with an agreed safe and effective treatment strategy if symptoms, signs or lung function worsen. Clear guidelines should be shared with and agreed by the health care team so consistent evidence-based but individualized treatments are given. The aim is to allow the patient to avoid whenever possible the need for life-disrupting admission to hospital.

Relevant recent systematic reviews relating to exacerbation management include non-invasive ventilation\(^{587}\), methylxanthines\(^{588}\), hospital at home care\(^{589}\), bronchodilator treatment\(^{590}\), and antibiotics\(^{591}\). The management of exacerbations is outlined in GOLD (www.goldcopd.org)\(^{592}\) and NICE (www.nice.org.uk)\(^{593}\), and is specifically presented in the COPD-X management guide (www.copdx.org.au)\(^{594,595}\). A useful summary of mechanisms and management for COPD exacerbations was published in 2003\(^{596}\).

**Goals of Pulmonary Rehabilitation**

- to improve adherence to recommended therapies
- to reduce frequency and severity of symptoms
- to improve mood and motivation
- to reduce dependency and increase involvement with friends and family

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• to enhance participation in therapeutic decisions by building self-management capacity
• to increase participation in and enjoyment of everyday activities
• to improve quality of life
• to reduce health care burden for patients, families and communities

**Figure 4.2** Enjoyment of everyday activities should be possible for most people with COPD

**Benefits of Pulmonary Rehabilitation**

In brief, benefits documented in randomised controlled trials and other research include:

- better exercise capacity and endurance
- better health-related quality of life / health status
- return to work
- reduced perceived level of breathlessness
- increased knowledge about respiratory disease and management
- reduced hospitalisation rate and days per admission
- reduced healthcare costs
- enhanced mood, reduced anxiety, reduced depression
- improved self-efficacy
- enhanced ability to perform activities of daily living
- improved strength
- extended survival
**Components of Pulmonary Rehabilitation**

British Thoracic Society Statement on Pulmonary Rehabilitation lists five components:
- Education
- Physical training
- Psychological support and behavioural intervention
- Physiotherapy and relaxation exercises with energy conservation
- Nutrition.

European, American and joint guidelines for pulmonary rehabilitation include similar categories, and add recommendations for four main outcome assessments:
- Dyspnoea
- Quality of life
- Health-care utilisation
- Survival

All these elements of PR programs and the evidence supporting their use are considered in detail in the following text.

### 4.2 Overviews of COPD and Rehabilitation

**Evidence review 1971-1994**

In thirty-one studies on COPD rehabilitation from the 1971-1994 medical literature systematically reviewed by P Frith and P Walker there were 1,536 subjects assessed. The range of sample sizes per study was 10 to 182. The average age was 59.8 years, though three studies did not report the ages of their subjects. The range of mean ages varied between 50 and 67, and most studies elected only to assess men. Average FEV1 ranged between 0.78L and 1.38L. This probably represents values between 20% and 55% of predicted for age and height, though only ten studies reported FEV1 as a percentage of the predicted value. Only 5 studies reported resting pO2 or gas transfer. We came to several conclusions at that time.

1. The utility of lung function tests to assess outcome from exercise training programs is limited. A range of laboratory measures of exercise performance is widely used to assess the degree of physical limitation (disablement) in COPD. One or more exercise evaluations were used in 12 studies. The most common combination was a maximal test of exercise capacity (usually incremental cycle ergometry) and a functional measure such as a six or twelve minute walk test. Of the studies that elected to only use one measure, incremental treadmill exercise performance was the most commonly used (five).

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598 Donner CF, Decramer M. Pulmonary rehabilitation. *Eur Resp Soc Monogr* 2000; 13
2. Eight of the 31 studies reviewed either did not measure any aspect of HRQoL, or did not use reliable and valid measuring instruments, or reported HRQoL without defining the instruments. The remaining studies used a variety of measures to assess HRQoL. Most used generic questionnaires to measure physical and emotional function. In only 3 studies reviewed in 1995 was a disease specific questionnaire used – the Chronic Respiratory Disease Questionnaire (CRDQ).

3. The nature of rehabilitation programs is highly variable. Seven of the studies published to 1994 were inpatient based, and ranged in duration (2 to 8 weeks) and exercise intensity (15 minutes once a day to 4 to 5 hours a day seven days a week). Programs offered different exercise regimens, from walking, stair climbing, swimming, and cycle ergometer to upper body conditioning. Some programs offered pulmonary education, while others did not. The remaining studies were outpatient based, and also ranged considerably in duration (4 weeks to 6 months), exercise intensity (5 minutes to 3 hours a day), and exercise type (upper body, inspiratory muscle training, stair climbing, cycle ergometry, upper body conditioning).

4. The timing of outcome measurements varies in the reviewed trials. Short-term outcome measures, within the first 3-4 months, were most usually taken, only evaluating subjects directly after the intervention programs. Only ten of the studies assessed longer-term outcomes greater than 5 months after program implementation and withdrawal.

5. The methods of patient selection, randomisation and control also vary. Fifteen of the 31 studies reviewed did not have a control group. Thirteen of these showed a statistically significant increase in some measure of exercise capacity. Curiously, neither of the remaining two used exercise testing to evaluate the outcome of an exercise program. The interpretations of outcomes from such uncontrolled studies must be treated with caution. Motivation, attentional influences, practice effect due to greater familiarity with test protocols, and familiarity with staff may alleviate anxiety and so may have contributed significantly to improvements in exercise performance and quality of life.

6. The specifics of rehabilitation components were also different. Eight of the 15 uncontrolled studies of exercise training incorporated other modalities of pulmonary rehabilitation (eg. breathing re-training, education) into their programs. Four did not assess any changes in HRQoL. Two alluded to subjective changes and two gave anecdotal accounts of improvements in quality of life. The remaining studies found reduced affective distress, sensation of dyspnoea, disability scores and fatigue, and improved well-being, self-efficacy and mastery.

Sixteen controlled studies were identified.

Nine of these used a control group that did not receive any form of intervention. The training programs in these 9 studies ranged in duration from 3 to 12 weeks, though the duration was not made clear in 2 studies. None of these 9 studies was able to demonstrate improvement in maximal exercise capacity when compared to the control group. Statistically significant (small) changes were seen in exercise endurance, shortness of breath and well-being compared to control groups. Three of the 9 controlled studies used well-validated health status questionnaires. Cockcroft found improvements in both groups’ affective states, although changes were not statistically significant. Both Goldstein and Wijkstra found improvements in experimental group’s mastery, dyspnoea and emotional function, but not fatigue (CRDQ).

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Seven studies used a treatment control group.

Lustig\(^{605}\) randomly allocated 45 adult patients with COPD to either an experimental group (which received 15 to 20 pulmonary rehabilitation treatments), or one of two control groups (which received either psychotherapy or no treatment). The outcome measure was Minnesota Multiphasic Personality Inventory (MMPI), and Mann-Whitney U tests were used for analysis (not appropriate for analysing change scores). The experimental group showed improvement compared to the no treatment group, but not compared to the psychotherapy group. This suggests a significant effect of therapy regardless of its modality, and may indicate an attentional effect.

Degre\(^{606}\) compared the effects of exercise training in 11 COPD subjects with a breathing exercise program in 5 COPD subjects (not randomly assigned). This study did not measure quality of life. Physiological data from pulmonary function tests and tests of exercise capacity were measured. No mention was made of the statistical procedures. The only significant change post-intervention was in resting partial oxygen tension in the exercise group, from 76mmHg to 82mmHg (of little clinical significance). No correction was made for the multiple comparisons of the data (30 in all), which, along with the small sample size, greatly reduces the power of the study.

Kaplan\(^{607}\) used three experimental groups: a behaviour modification group, a cognitive modification group, and a cognitive-behaviour modification group, compared to an attention control group (which spent six sessions completing psychological questionnaires and a variety of neuropsychological tasks, requiring little interaction). There was no placebo treatment for controls, and no treatment expectancy was induced. The paper gave no information regarding the number of subjects in each group or the dropout rates. The three experimental groups improved significantly compared to the control group in health status, exercise tolerance, exercise capacity, and self-efficacy, but there was no significant difference between the three experimental groups.

Jones\(^{608}\) randomly allocated severe COPD subjects to one of two training programs: a physical exercise (n=8) or a resistive training (n=7); or to placebo training (n=6). There were significant improvements in all three groups’ maximal exercise capacity and global mood but no significant changes in lung function, respiratory symptoms or 12MWD. The small sample size and multiple comparisons made using paired and un-paired t-tests limit the statistical power. The results suggest that improvements in HRQoL were independent of the type of program used.

Toshima\(^{609}\) studied over 100 adults with COPD, randomised into rehabilitation group (twelve 4-hour sessions in 8 weeks) or “education control” group (four 2-hour biweekly meetings at which


\(^{607}\) Kaplan RM, Atkins CJ, Reinsch S. Specific efficacy expectations mediate exercise compliance in patients with COPD. *Health Psychol* 1984; 3:223-242


they were given information regarding respiratory disease). There were attentional differences between the two groups - the rehabilitation group had 48 hours of rehabilitation and the control group had only 8 hours of education. The educational content of the two programs differed. The rehabilitation group had more lectures than controls, individual instruction and practice with respiratory care techniques, group meetings with a psychiatrist, and an exercise training program with behavioural techniques. Repeated measures analysis of variance showed a substantial increase in exercise performance and self-efficacy for walking for the rehabilitation group that lasted over six months, but little improvement in the control group. There were no differences between the groups’ quality of well-being or depression scores over time.

Lake\textsuperscript{610} randomly allocated COPD patients into either a control group (n=7), or upper limb training (n=5), lower limb (n=7) or combined (receiving both upper and lower limb training) (n=7) exercise groups. There was a significant training effect in the combined and lower limb groups’ walk distances and the upper limb and combined groups’ arm ergometry. Significant improvement was seen in the self-efficacy scores of the combined group, but no significant changes in the other groups. The study was limited by small sample size, non-validated self-efficacy scale and sub-optimal statistics.

Weiner\textsuperscript{611} compared patients randomly assigned to either inspiratory muscle training with general exercise reconditioning (group A, n=12), or general exercise reconditioning with placebo (group B, n=12) or control (no training) (group C, n=12). After six months group A showed a significant improvement in walking distance compared to the other groups, and both groups A and B showed significant improvement in exercise endurance on a cycle ergometer compared to group C. No measures of quality of life were used, and small samples limit generalisation.


There has been a profusion of new research into many aspects of PR (and the underlying pathophysiologic bases of impairment, disability and handicap in chronic lung diseases). J Cranston, A Crockett and P Frith systematically reviewed the available literature on pulmonary rehabilitation and related topics published between 1995 and 2001. P Frith and J Cranston updated this review with papers published between 2001 and 2004. Since then P Frith has continuously updated review of the literature, with assistance from P Cafarella, J Duffy, J Alison, L Spencer, S Jenkins, and members of the Pulmonary Rehabilitation Toolkit Steering Committee. A number of additional controlled trials were identified, and there was greater use of disease-specific health status measures. More attention had been given to other modalities than exercise training, and to comprehensive pulmonary rehabilitation, as these are reviewed under Comprehensive Pulmonary Rehabilitation, using the meta-analyses by Lacasse\textsuperscript{612, 613} and subsequent randomised controlled trials. Our extensive literature updated in 2001 was conducted using:

1. Gateway™, a Web-based system from the US National Library of Medicine, which includes MEDLINE/PubMed, OLDMEDLINE, LOCATORplus, MEDLINEplus, DIRLINE, AIDS Meetings, Health Services Research Meetings, Space Life Sciences Meetings, and HSRProj.a GATEWAY search.
2. The OVID™ database “Evidence Based Medicine”, which searches the Cochrane Database, Best Evidence and DARE (Database of Reviews of Effectiveness).
3. The search engine “GOOGLE” was used to search the World-Wide Web.

The GOOGLE search without setting year limits yielded 12,800 hits for “standards + pulmonary rehabilitation”, 5,520 hits for “standards + cardiopulmonary rehabilitation”, 20,100 hits for “standards + cardiac rehabilitation”, and 4,140 hits for “pulmonary rehabilitation Australia”.

Using “Gateway”, with the terms “COPD AND pulmonary rehabilitation”, 1,280 citations were found. Using terms “meta-analysis AND pulmonary rehabilitation” produced six meta-analyses and four systematic overviews. Cambach’s “research synthesis” provided a true meta-analysis of non-randomised and randomised controlled trials of pulmonary rehabilitation programs. Lacasse reviewed outcomes without a true meta-analysis. The remaining papers reviewed systematically components of pulmonary rehabilitation – psychoeducational care, physical therapy, ventilatory muscle training, nutrition, walk tests as outcomes, and an overview of all components.

Using the OVID database with the terms “((COPD OR COAD OR COLD) AND pulmonary rehabilitation).mp” with no year limits identified ten citations.

When the search was limited to 1998-2001, to discover publications not included in systematic reviews cited above, 401 citations were found, of which 363 were journal citations. Using “Review AND pulmonary rehabilitation AND (COPD OR COAD OR COLD OR CAL)” with limits set for 1998-2001 yielded 99 journal citations. Using the terms “(randomized OR randomised) AND (trial OR study) AND pulmonary rehabilitation AND COPD” 66 journal citations were identified. The meta-analyses identified did not include a further 32 randomised controlled trials identified in the 1998-2001 search strategy. These studies, the meta-analyses (with their component trials), and the expert panel statements (US, UK, and international guidelines of COPD management, and US, European and UK guidelines for pulmonary...
rehabilitation) form the basis for the critical review presented below. Additional papers of relevance to specific observations or recommendations are referenced.

A similar search methodology was repeated in September 2004, to update the above findings, and has been updated progressively since. More nutrition and mental health papers have been reviewed, and specific searches relating to mental health, self-management, as well as effects on and roles of informal caregivers have been added.

**Peripheral muscle impairments**

In healthy individuals there is a large reserve of muscle metabolic capacity in skeletal muscles. Respiratory muscle demand in healthy subjects can compromise peripheral muscle blood flow, and the metabolic reserve enhanced by 100% oxygen breathing, or other methods to reduce work of breathing. Peripheral muscle impairments is thought to exist in COPD as part of the systemic illness, and contribute to weakness, poor exercise tolerance, fatigue and reduced endurance. This has important consequences on patients’ ability to perform daily activities, and therefore impairs HRQoL. The matter appears to be a circular one, in that deconditioning due to inactivity associated with severe effort-induced dyspnoea is a major determinant of impaired skeletal muscle function of lower limbs, with oxidative stress and nutrition playing modulatory roles. Objective measurements of muscle fatigue using electromyograms (EMG) during sustained isometric contraction of quadriceps muscle has shown

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628 Gosselink R, Troosters T, Decramer M. Peripheral muscle weakness contributes to exercise limitation in COPD. *Am J Respir Crit Care Med* 1996; 153:976-980


633 Serres I, Gautier V, Varray AL, Prefaut C. Impaired skeletal muscle endurance related to physical inactivity and altered lung function in COPD patients. *Chest* 1998; 113:900-905


reduced muscle endurance due to reduced muscle oxidative capacity\textsuperscript{636}, and fatigue\textsuperscript{637}. Wagner has summarised current state of knowledge about muscle impairment\textsuperscript{638}.

Despite the evidence for skeletal muscle dysfunction in severe if not moderate COPD, metabolic reserve may still be present if 100\% oxygen can reduce ventilatory demand\textsuperscript{639}. There are several potential underlying causes – weakness of muscle through disuse atrophy and sometimes steroid myopathy, poor tissue oxygen supply, abnormal neuromuscular conduction and abnormal muscle energetics. Increasing evidence is being mounted to support the hypothesis that the latter is due mainly to release of inflammatory cytokines\textsuperscript{640} and growth factors\textsuperscript{641} and imbalance in the muscle redox systems\textsuperscript{642}. Increased reliance of these muscles on anaerobic glycolysis therefore leads to early lactic acid accumulation and premature muscle fatigue at lower work intensity\textsuperscript{643,644}. Importantly, the reduction in skeletal muscle endurance is poorly predicted by age, gender, level of activity, severity of disease or muscle strength\textsuperscript{645,646}, so each patient deserves careful consideration of their muscle endurance and work capacity. Muscle loss includes both type I and type II fibres in peripheral and ventilatory muscles. Ventilatory muscle function is further impaired by altered chest wall shape from hyperinflation. This subject has been reviewed by Mador and Bozkanat\textsuperscript{647}.

It is worthwhile summarising current understanding of the oxidative stress in skeletal muscle in people with COPD. Both weakness and fatigue may be due to inflammatory cytokines, such as tumour necrosis factor-alpha (TNF-\(\alpha\))\textsuperscript{648,649}. Animal studies suggest that disuse (‘unloading’) of

\begin{thebibliography}{99}
\bibitem{638} Wagner PD. Skeletal muscles in chronic obstructive pulmonary disease: Deconditioning, or myopathy? \textit{Respirology} 2006; 11:681-686
\bibitem{642} Rabinovich RA, Ardite E, Troosters T, et al. Reduced muscle redox capacity after endurance training in patients with chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2001; 164:1114-1118
\bibitem{645} Serres I, Gautier V, Varray AL, Prefaut C. Impaired skeletal muscle endurance related to physical inactivity and altered lung function in COPD patients. \textit{Chest} 1998; 113:900-905
\bibitem{648} Di Francia M, Barbier D, Mege J, Orehek J. Tumor necrosis factor-alpha and weight loss in chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 1994; 150:1453-1455
\end{thebibliography}
lower limbs provides another stimulus for oxidative stress\textsuperscript{650}. In patients with COPD, heavy exercise may induce abnormally high levels of oxidative stress, and this may actually be preventable with oxygen therapy\textsuperscript{651}. The abnormal levels of TNF-\(\alpha\) may be mediated by excess reactive oxygen species\textsuperscript{652}, possibly by releasing preformed TNF-\(\alpha\) directly from muscle independent of induced RNA synthesis\textsuperscript{653}, and this theory of direct release is supported by a lack of gene down-regulation after training\textsuperscript{654}. Further, TNF-\(\alpha\) levels consistently rise after moderate-intensity endurance exercise in COPD patients without changes in levels of sTNFRs or IL-6. This contrasts with the observation in healthy individuals that TNF-\(\alpha\) is increased with strenuous exercise (such as after a marathon), but there is increased gene expression of interleukin-6 (IL-6)\textsuperscript{655}. Reactive oxygen species appear to target creatine kinase (CK) and carbonic anhydrase III (CA-III) in peripheral muscles so that they are carbonylated, resulting in impaired CK function\textsuperscript{656}. Hypoxaemia appears to increase the oxidative stress by damaging lipids and proteins in vastus lateralis muscles in patients with severe COPD, and evidenced by accumulation of lipofucsin in the muscle fibres\textsuperscript{657}, the latter confirmed in a case control study of COPD vs control vastus lateralis muscles\textsuperscript{658}.

The effects of hypoxaemia on muscle structure and function have been well summarised by Fluck\textsuperscript{659}. Diaphragmatic muscle fibres may be particularly susceptible to oxidative stress-induced dysfunction according to case-control studies of diaphragmatic tissue from 6 patients with severe COPD, 6 with moderate COPD and 7 control subjects without COPD, with negative correlations between reactive carbonyl groups and airways obstruction\textsuperscript{660}. Muscles seem to attempt auto-regulation, and antioxidant activity in vastus lateralis muscles of 21 patients with severe COPD and 12 healthy age-matched controls was increased in the COPD muscles\textsuperscript{661}. Lactic acidosis is a consequence of anaerobic metabolism in muscles, and progressively incremental exercise testing can identify gradual a period when lactate accumulation increases sharply, termed ‘anaerobic threshold’\textsuperscript{662}. Lactate accumulation contributes strongly to muscle fatigue. This will occur sooner

\textsuperscript{650} Lawler JM, Song W, Demaree SR. Hindlimb unloading increases oxidative stress and disrupts antioxidant capacity in skeletal muscle. Free Rad Biol Med 2003; 35:9-16
\textsuperscript{652} Chandel NS, Trzyna WX, McClintock DS, Schumacker PT. Role of oxidants in NF-kappa B activation and TNF-alpha gene transcription induced by hypoxia and endotoxin. J Immunol 2000; 165:1013-1021
\textsuperscript{656} Barreiro E, Gea J, Matar G, Hussain SNA. Expression and carbonylation of creatine kinase in the quadriceps femoris muscles of patients with chronic obstructive pulmonary disease. Am J Respir Cell Mol Biol 2005; 33:636-642
\textsuperscript{659} Fluck. Hypoxaemia enhanced peripheral muscle oxidative stress in COPD. Thorax 2005; 60:797-798
\textsuperscript{661} Gosker HR, Bast A, Haenen, Fischer MA, et al. Altered antioxidant status in peripheral skeletal muscle of patients with COPD. Respir Med 2005; 99:118-125
\textsuperscript{662} Wasserman K, Mcllroy MB. Detecting the threshold of anaerobic metabolism in cardiac patients during exercise. Am J Cardiol 1964; 14:844-852
where oxygen supply is impaired, but usually occurs at around 45-65% of VO2max. It can be reasoned that monitoring lactate might provide an index of muscle fatigue, and it is feasible to measure lactate during walking exercise to help determine when rehabilitation may be indicated or contraindicated, what exercise should be prescribed, and how patients are progressing with rehabilitation. It has also been shown that infusion of dichloroacetate (which delays onset of anaerobic metabolism) can reduce blood lactate during maximal exercise in patients with COPD, with consequent improvement in maximal exercise capacity.

The roles of local and systemic inflammation, oxidant / antioxidant imbalance and the proposition of an active myopathy have been usefully summarised recently, along with the nutritional and muscle consequences. An interesting proposal has been examined in a cross-sectional Belgian study, showing lower testosterone levels and higher follicle-stimulating and luteinizing hormone levels in 50% of the 78 men with COPD than in 21 age-matched controls, even in those not using corticosteroids and without hypoxaemia. These features correlated with quadriceps muscle weakness and C-reactive protein, suggesting inflammation may be one underlying mechanism of muscle weakness through gonadal suppression. The plausibility of this finding might be inferred from studies showing improved quadriceps force resulting from testosterone supplementation, either with or without resistance exercise training.

**Physical Training**

Barach pioneered the idea that exercise may be of some use for patients with respiratory diseases. Previously, rest and avoiding breathlessness were the recommended treatments for most chronic respiratory conditions. Pierce reported one of the first studies on the benefits of exercise retraining in COPD, finding that it enabled subjects to perform at the same level of exercise capacity with lower heart-rate, respiratory rate, minute ventilation and CO2 production. Since then there have been many observations, experimental findings and randomised controlled trials confirming beneficial outcomes from exercise retraining.

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663 Tanaka Y, Hino M, Morikawa T, et al. Arterial blood lactate is a useful guide to when rehabilitation should be instigated in COPD. *Respirology* 2008 13:564-568
Mechanisms of exercise intolerance in COPD

The mechanisms underlying exercise performance impairment and improvement from exercise in COPD are complex. Healthy people do not experience ventilatory limitation of exercise, while those with COPD do. People with COPD have reduced ventilatory capacity (e.g. reduced forced expiratory volume in one second, FEV1), with reduced maximum ventilation at the limits of their exercise capacity (VEmax) and often retain significant cardiac reserve. The low ventilatory capacity in turn leads to uneven distribution of ventilation and therefore increased dead space, with resultant abnormal gas exchange and oxygen desaturation during exercise, accompanied by reduced gas transfer. The oxygen cost of breathing is high in people with severe COPD, and there may be weakness of the muscles of ventilation in some.

Dyspnoea refers to discomfort with breathing, so it is the perception rather than the sensation (e.g. of rapid breathing) that delineates the symptom. The American Thoracic Society provided a helpful consensus statement in 1999 on mechanisms and management of dyspnoea, and a conference devoted to the pathophysiology of dyspnoea has recently given an excellent series of insights. How people describe their sensations can be quite variable, and efforts have been made over the years to clarify the descriptors of both stable and induced dyspnoea, even trying to delineate patterns of descriptors for specific pathophysiologic conditions.

In people with severe COPD, expiratory airflow limitation occurs during tidal breathing at rest, and the only way that ventilation can be sustained during exercise is to increase ventilation rate and/or functional residual capacity (FRC). The latter results in restricted

676 Ortega F, Montemayor T, Sanchez A, Cabello F, Castillo J. Role of cardiopulmonary exercise testing and the criteria used to determine disability in patients with severe chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1994; 150:747-751
inspiratory capacity (IC)\textsuperscript{686}, and end-inspiratory volume during tidal breathing in exercise may approach total lung capacity (TLC)\textsuperscript{687}. The IC/TLC ratio has recently come to be known as the “inspiratory fraction”\textsuperscript{688}, in an attempt to develop a functional index that predicts risk of death like a functional cardiac index in ischaemic heart disease. The value of the inspiratory fraction in predicting maximum exercise tolerance (disability) has also been examined and confirmed recently\textsuperscript{689}. The former prevents satisfactory lung emptying, and contributes to dynamic hyperinflation, as described by O’Donnell\textsuperscript{690,691}, Ferguson\textsuperscript{692,693}, and Price\textsuperscript{694}. Dynamic hyperinflation (DH) causes marked increase in work of breathing, with onset of dyspnoea and limitation of inspiratory muscles endurance\textsuperscript{695}, and these act together to reduce exercise capacity\textsuperscript{696}.

Measurement of operational lung volumes has helped to understand and explain exercise limitation imposed by DH and the effects of interventions. A new tool for assessment of breath-by-breath variations of the volume of the rib cage and abdominal compartments is optoelectronic plethysmography (OEP)\textsuperscript{697,698}. The effects of drugs and training on chest wall dimensions during exercise have been well described, and correlations between end-expiratory abdominal volume and improved exercise performance have been demonstrated\textsuperscript{699}. The changes in chest wall volumes (specifically end-expiratory abdominal volume) with DH of exercise are modified by the severity of airflow limitation (i.e. COPD severity), such that greater degrees of chest wall DH occur in more severe COPD and result in less displacement of abdominal volume with greater increase in end-expiratory ribcage volume\textsuperscript{700}. This difference helps to account for the reduced minute ventilation people with severe COPD can generate during exercise. People with Stages I and II COPD closely resemble normal healthy individuals in their chest wall mechanics during


\textsuperscript{692} Ferguson GT. The ins and outs of breathing: an overview of lung mechanics. Eur Respir Rev 2004; 13:30-34

\textsuperscript{693} Ferguson GT. Why does the lung hyperinflated? Proc Am Thorac Soc 2006; 3:176-179


exercise, even if resting hyperinflation is present, meaning expiratory (especially abdominal)
muscles are recruited to reduce end-expiratory abdominal volume and thereby minimize the chest
wall hyperinflation. In more severe COPD (Stages III and IV) this phenomenon cannot be
sustained, and the chest wall and tidal volumes become progressively restricted, and these
patients stop exercise because of dyspnoea.

DH may be a contributor to hypercapnia in the stable resting state in patients with severe COPD
(in addition to weakness of the ventilatory muscles)\textsuperscript{701}. Further, the skeletal muscles of people
with severe COPD are often unable to sustain repetitive contraction, and they fatigue
prematurely, so that patients are unable to perform activities of daily living (ADLs) with comfort\textsuperscript{702,703}. Neuromuscular fatigue appears to be a direct cause in many patients\textsuperscript{704}. The
discovery of the importance (and mechanisms) of dynamic hyperinflation has led to clarification
of the way various interventions improve breathlessness and exercise performance\textsuperscript{705}.

Fatigue, muscle weakness and HRQoL are interrelated. First, the ability to perform ADLs - which
is determined by lung physiology, muscle and exercise function - is the chief component of
functional status. Second, high levels of dyspnoea or fatigue with ADLs, muscle weakness, or
avoidance of ADLs all influence perceived HRQOL. Third, HRQoL combines the physical and
mental impacts of functional status\textsuperscript{706,707,708,709,710}. In a study of 132 Japanese patients with FEV1
41.3\% predicted (SD 19.0\%), generic and lung-specific HRQoL were measured along with post-
bronchodilator lung function. HRQoL was partly explained by airflow limitation (odds ratio,
OR=0.59-0.69), diffusing capacity (OR=0.75-0.82), smoking history (OR=1.20-1.23) and age
(OR=2.13), though their overall contribution was limited\textsuperscript{711}.

Many of the premises on which exercise training in COPD are based derive from training in
normal individuals. Strategies may need to be altered depending on the severity of COPD and the
presence and severity of DH (see above), although this hypothesis has not yet been evaluated in
the current literature. Changes in understanding limitations of exercise in COPD have rather
inhibited standardisation of exercise training regimens in COPD until recent years, and this makes

\textsuperscript{701} Montes de Oca M, Celli BR. Respiratory muscle recruitment and exercise performance in eucapnic and
hypercapnic severe chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2000; 161:880-885
\textsuperscript{702} Decker M, Gosseling R, Troosters T, Verschueren M, Evers G. Muscle weakness is related to
utilization of health care resources in COPD patients. \textit{Eur Respir J} 1997; 1-:417-423
\textsuperscript{703} Yohannes AM, Roomi J, Waters K, Connolly MJ. Quality of life in elderly patients with COPD:
measurement and predictive factors. \textit{Respir Med} 1998; 92:1231-1236
\textsuperscript{704} Maltais F, Jobin J, Sullivan MJ, et al. Metabolic and hemodynamic responses of lower limb during
exercise in patients with COPD. \textit{J Appl Physiol} 1998; 83:1573-1580
\textsuperscript{705} Casaburi R, Porszasz J. Reduction of hyperinflation by pharmacologic and other interventions. \textit{Proc Am
Thorac Soc} 2006; 3:185-189
\textsuperscript{706} Reardon JZ, Lareau SC, ZuWallack R. Functional status and quality of life in chronic obstructive
\textsuperscript{707} Stavem K, Boe J, Eriksinn J. Health status, dyspnea, lung function and exercise capacity in patients
\textsuperscript{708} Fuchs-Climent D, La Gallais D, Varray A, et al. Factor analysis of quality of life, dyspnea, and
physiologic variables in patients with chronic obstructive pulmonary disease before and after rehabilitation.
\textit{Am J Phys Med Rehabil} 2001; 80:113-120
\textsuperscript{709} Hajiro T, Nishimure K, Tsukino M, et al. A comparison of the level of dyspnoea vs disease severity in
indicating the health-related quality of life of patients with COPD. \textit{Chest} 1999; 116:1632-1637
\textsuperscript{710} Monso E, Fiz JM, Izquierdo J, Alonso J, et al. Quality of life in severe chronic obstructive pulmonary
disease: correlation with lung and muscle function. \textit{Respir Med} 1998; 92:221-227
\textsuperscript{711} Tsukino M, Nishimura K, Ikeda A, Koyama H, et al. Physiologic factors that determine the health-
firm conclusions about the reasons for improved exercise performance with exercise training difficult. The consensus of research is that improvements from training do not require major change in lung function. Other mechanisms include improved aerobic capacity, muscle strength and ventilatory muscle function, more effective integration of chest wall and abdominal mechanics to limit DH, increased motivation, desensitisation to the sensation of dyspnoea, and improved technique of test performance. These mechanisms and the evidence base related to exercise training in COPD have been subjected to careful literature review, with regular updates.

Physiotherapists have led the way in developing multi-modality exercise training for patients requiring post-operative rehabilitation, for those recovering from acute events like “Strokes” or myocardial infarctions, and for those with chronic disabling conditions like COPD. They have built upon information developed in healthy individuals and athletes by exercise physiologists. Often the programs developed by physiotherapists have concentrated on exercise training as the lead or sole component in pulmonary ‘rehabilitation’ programs. Indeed, most of the evidence for improved exercise capacity is based on physical training. Exercise is therefore a vital component of pulmonary rehabilitation\textsuperscript{712}, and usually includes activities, task optimisation to reduce unnecessary energy expenditure, breathing control during exertion, and pursed lip breathing, in addition to aerobic training of upper and lower limbs as well as trunk muscles.

Overall activity levels have been correlated with daily fatigue, dyspnoea and health status in patients with COPD\textsuperscript{713}. Benefits are not related to initial lung function\textsuperscript{714}, so PR should be applicable to any Stage of Severity of COPD. It may also be applicable to other respiratory conditions, such as asthma\textsuperscript{715}, bronchiectasis\textsuperscript{716} and interstitial disorders\textsuperscript{717}. Recent surveying of 422 patients completing PR revealed 309 patients with COPD and 113 with non-COPD diagnoses, and no systematic or significant differences were seen between these two groups in 6-minute walk or quality of life improvements\textsuperscript{718}.

Physiologic training effects can be demonstrated in people with COPD following sustained and repeated exercise at or above anaerobic threshold\textsuperscript{719}. Muscle metabolism, such as oxygen extraction, can be improved even by submaximal exercise in people with COPD\textsuperscript{720}. More specific aspects of training are provided below. These training effects might be enhanced by reducing ventilatory loading through providing positive pressure assistance\textsuperscript{721}, with oxygen therapy, or

\textsuperscript{712} Rochester CL. Exercise training in COPD. J Rehabil Res Develop 2003; 40:59-88
\textsuperscript{716} Bradley J, Moran F, Greenstone M. Physical training for bronchiectasis. Cochrane Database Syst Rev 2006; Issue 4
\textsuperscript{718} Ferreira G, Feuerman M, Spiegler P. Results of an 8-week, outpatient pulmonary rehabilitation program on patients with and without chronic obstructive pulmonary disease. J Cardiopulm Rehabil 2006; 26:54-60

93
with medications such as ipratropium\textsuperscript{722} and salmeterol\textsuperscript{723}. In a recent randomised controlled trial, a three-month program improved HRQoL in both males and females, and while continuing supervised training for up to 18 months had no added benefit in females, it did in males\textsuperscript{724}. The effects of oxygen therapy and of ventilatory assistance need brief additional discussion.

**Exercise Prescription**

Formal cardiopulmonary exercise testing is expensive, technically demanding, and often daunting for older people and those with COPD. Other options for estimating VO2max are therefore often used to estimate a person’s exercise capacity for training. In people with COPD or heart failure, for example, a 6-minute walk test may be attractive because of the correlation between 6MWD and VO2max\textsuperscript{725}. However the confidence limits of these inter-relationships are wide\textsuperscript{726} and the exercise demands are quite different\textsuperscript{727}. Attempts have been made to strengthen prediction of VO2max using not only 6MWD but also patient weight, although subsequently this was shown to be unreliable\textsuperscript{728}. It is therefore recommended that, if VO2max is used in training prescriptions, it be measured directly. Activity-specific training plus aerobic training over 10 weeks has shown greater benefit than exercise training alone or with an education lecture program in a randomized study of 43 patients with COPD\textsuperscript{729}. Such an approach requires higher degrees of supervision, but is likely to enhance self-efficacy for exercise, and therefore the likelihood that exercise will be maintained after completion of the formal program.

**Supervision of training**

Supervision of exercise training is recommended at least initially so that the therapist can appreciate the limits to exercise, evaluate breathing pattern and individual mechanisms of fatigue, and help to build the patient’s confidence so improved cardiovascular fitness can be achieved. While some benefit can be gained from low-intensity training, higher intensity training (at a heart rate at or above anaerobic threshold) is more effective\textsuperscript{730,731}. Flexibility and muscle strength should also be addressed. The mode of training (endurance versus strength) determines the outcomes in athletes\textsuperscript{732}, and there is some evidence that this is also true in COPD\textsuperscript{733}. Training

\begin{thebibliography}{99}
\bibitem{724} Foy CG, Rejeski J, Berry MJ, et al. Gender moderates the effects of exercise therapy on health-related quality of life among COPD patients. *Chest* 2001; 119:70-76
\bibitem{726} Carlson DJ. VO2max: the gold standard? *Chest* 1995; 108:602-603
\bibitem{728} Chuang ML, Lin IF, Vintch JRE. Comparison of estimated and measured maximal oxygen uptake during exercise testing in patients with chronic obstructive pulmonary disease. *Intern Med J* 2004; 34:469-474
\end{thebibliography}
benefits are usually progressively lost after initial intensive training so maintenance of activities is essential for continuing the benefits. In a West Australian study, 12 months of physiotherapist-supervised weekly community-based maintenance exercise classes were provided after formal exercise-based PR. Over 4 years, of the 497 patients referred to PR 172 completed the full course, of whom a minority completed the maintenance classes for at least 12 months (n=46). Improvements made in CRQ quality of life and 6-minute walk distance during PR were maintained (at the clinically significant level) in the regular maintenance patients with moderate-severe COPD, and 67% of these patients were performing their own home exercises 3 to 5 days a week as well.

It is feasible for suitably-trained exercise scientists to provide the level of supervision for maintenance classes, and to be involved in some initial physical training, though this would preferably be under medical supervision or in conjunction with physiotherapists.

Substantial evidence exists for the benefits of general (multi-modality) exercise training, with randomised controlled trials demonstrating improvements in exercise tolerance, well-being, symptoms of dyspnoea, and self-efficacy. The effects of exercise training on exercise performance are greater than education alone. Physical training usually includes both strength and endurance training. While optimal intensity, frequency, duration and length of training are yet to be determined, some guidelines for exercise prescription can be suggested, as below.

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Endurance Training

Endurance muscle training can increase the oxidative capacity of skeletal muscles\(^{740}\) (impaired in patients with COPD, as discussed above), and reduce fatiguability of the muscles\(^{741}\). In a systematic review, which included 15 satisfactory randomized controlled trials of exercise intensity or modality of endurance training, there were inconsistent findings across studies\(^{742}\), some showing greater benefits from endurance training, and others with better outcomes from strength training. In five trials that compared endurance training with combined strength and endurance training, little gain was found in exercise capacity or health status. People with FEV1 below 40% predicted are unlikely to undertake endurance training, though they are usually able to do interval training\(^{743}\).

Interval training has also been evaluated, with alternating high and low intensity periods during individual training sessions, and no real difference has been found compared to constant work rate exercise in terms of endurance outcomes\(^{744,745}\). This suggests that these modalities could be

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\(^{743}\) Troosters T, Gosselink R, Decramer M. Exercise training: how to distinguish responders from non-responders. *J Cardiopulm Rehabil* 2001; 21:10-17

used interchangeably, depending on the individual patients’ preferences and capabilities, or even according to the limitations imposed by the training venue, equipment or staff.

As indicated several times, maintenance of exercise following completion of a PR program is vital, as the benefits of exercise training gradually disappear if this does not happen. A recent intervention trial involving 123 patients who completed PR followed by supervised regular walking over 12 months and observation over the next 12 months, showed that those who did persist with regular walking (active essentially every day through 24 months) had slower declines in dyspnoea with ADLs, health status and walking self-efficacy.

### Intensity and Progression

Effective training modalities use one or other of the following initial targets for exercise intensity:

- 60% maximum power output or peak VO2 from a cycle ergometry test.
- 60% of the maximal walking speed achieved on an incremental shuttle walk test.

Dyspnoea score appears a more effective monitoring method than heart rate in COPD, although mechanical efficiency appears to improve more than VO2, particularly for whole body exercise - whole body exercise conducted as interval cycling to high rates, treadmill walking as continuous exercise, and short blocks of stair climbing, all of which have different metabolic demands and responses. Progression of each style needs individual attention.

Patients with moderate to severe COPD demonstrate dynamic hyperinflation (DH), as described above. This increases with the increased ventilation demanded in sustained exercise, and this DH can compromise cardiac performance through increasing intra-thoracic pressure. The combined effects limit exercise endurance, and it has been shown that interval exercise rather than constant-load exercise can moderate these effects and enhance training. A greater total duration of exercise can be achieved using this modality, a finding confirmed in a small (n=10) comparison of intermittent exercise to low VO2 with a sustained exercise regimen, where greater total energy expenditure was achieved with less DH with the intermittent regimen.

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746 Heppner PS, Morgan C, Kaplan RM, Ries AL. Regular walking and long-term maintenance of outcomes after pulmonary rehabilitation. *J Cardiopulm Rehabil 2006; 26:44-53*


749 Mejia R, Ward J, Lentine T, Mahler DA. Target dyspnea ratings predict expected oxygen consumption as well as target heart rates. *Am J Respir Crit Care Med 1999; 159:1485-1489*


751 Milani RV, Lavie CJ. Disparate effects of out-patient cardiac and pulmonary rehabilitation programs on work efficiency and peak aerobic capacity in patients with coronary disease or severe obstructive pulmonary disease. *J Cardiopulm Rehabil 1998; 18:17-22*


**Frequency**

Based on training observations made in healthy people, training effects have been evaluated in people with COPD, and effects can be demonstrated with 3 to 5 sessions per week (but not with two sessions a week)\(^{755}\). It has been recommended to have at least two of these sessions supervised\(^{756}\).

**Duration**

Again based on studies in healthy individuals, each session should ensure the recommended intensity levels are reached for 20 to 30 minutes\(^{757}\).

**Mode**

There should be a mix of leg exercise (such as walking and/or stationary cycling) and arm training, including unsupported arm exercise to improve overall exercise capacity\(^ {758}\). Hydrotherapy may be favoured by some patients, and is feasible\(^ {759}\), though there is no good evidence for benefit (or harm).

**Course Duration**

Courses should run for at least four weeks, and preferably up to 12 weeks. There is a gradient of benefit with increasing duration\(^ {760,761,762}\).

Training benefits decline if training stops. Participation in regular walking following completion of PR is associated with better maintenance of HRQoL and walking self-efficacy, together with less dyspnoea\(^ {763}\). Behavioural techniques can improve adherence to continuing exercise regimens\(^ {764}\). Musical distraction is a well-known device in healthy populations undertaking exercise training. Distractive auditory stimuli can reduce perceived exertion in people with COPD during training and to increase their total exercise time\(^ {765}\), and in other areas to reduce anxiety.

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\(^{763}\) Heppner PS, Morgan C, Kaplan RM, Ries AL. Regular walking and long-term maintenance of outcomes after pulmonary rehabilitation. *J Cardiopulm Rehabil* 2006; 26:44-53


during a variety of interventions\textsuperscript{766,767,768}. This approach was trialled in 24 patients with moderate to severe COPD following PR, in a randomised controlled trial, with either encouragement to continue unsupervised walking or encouragement plus portable audiocassette tape with self-selected music to be used during walking\textsuperscript{769}. Cumulative distances logged on pedometer were 24% higher in the auditory distraction group, and there was significantly lower perceived exertion during ADL. The distraction group increased average 6-minute walk distances by another 445 feet compared to the encouragement-only group having a fall in 6-minute walk distance averaging 169 feet. This may be a cost-effective way for helping patients continue exercise following PR and thereby maintain or build on their gains.

The question of consolidation PR – follow-up enrolment in another 8-week program a year after an initial course, as discussed above - has been addressed in Italy\textsuperscript{770}. Thirty-six patients were studied before, a year after PR and another year later after half had undergone a second course. Both groups had a range of initial improvements, and added long-term effects of a second course were maintenance of lower rates of hospitalisation with exacerbations in the second year.

**Strength Training**

Skeletal muscle mass is low and weakness is present in many patients with moderate-severe COPD, and can affect both upper and lower limbs\textsuperscript{771}. Strength training in such patients can improve muscle strength\textsuperscript{772}, peak work capacity\textsuperscript{773} and endurance time\textsuperscript{774}. A combination of strength and endurance training results in greater increases in both strength and endurance than either form of training alone\textsuperscript{775,776}. A randomised trial of endurance training over 8 weeks compared to the same regimen of endurance training plus sets of five muscle group incrementing resistance training exercises over the 8 weeks showed strength increased in the strength-trained group and declined in the endurance-only group. More importantly, perhaps, functional fitness improvements were greater when strength training was added to endurance training\textsuperscript{777}. More recently, 32 consecutive elderly patients with moderately-severe COPD were clustered into

\textsuperscript{766} Binnings EB. The effect of an auditory distraction on anxiety in ambulatory surgical patients experiencing regional anaesthesia. *AANA J* 1987; 55:333-335

\textsuperscript{767} Chlan L. Effectiveness of a music therapy intervention on relaxation and anxiety for patients receiving ventilatory assistance. *Heart Lung* 1998; 27:169-176

\textsuperscript{768} Zimmerman L, Pierson M, Marker J. Effects of music on patient anxiety in coronary care units. *Heart Lung* 1988; 17:560-566

\textsuperscript{769} Bauldof GS, Hoffman LA, Zullo TG, Sciurba FC. Exercise maintenance following pulmonary rehabilitation. Effect of distractive stimuli. *Chest* 2002; 122:948-954


randomly-assigned groups that undertook endurance training alone or endurance training plus strength training over 8 weeks, and again significant improvements were seen in strength of the skeletal muscles in those doing combined exercises. However no differences were seen between the groups in exercise performance or quality of life. A systematic review included nine trials involving a total of 236 patients with COPD. Substantial gain in strength is possible in such patients. However in only one trial could improved exercise capacity (equivalent to endurance training) be found, and there was no substantive evidence of beneficial effects of strength training alone on health status or ADL functionality. On the other hand, a more recent systematic review of 15 trials suggested some studies had found greater improvements in quality of life from strength training than from endurance training.

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**FIGURE 4.4** STRENGTH TRAINING OF SKELETAL MUSCLES MAY BE A USEFUL COMPONENT OF PULMONARY EXERCISE TRAINING

779 O’Shea SD, Taylor NF, Paratz J. Peripheral muscle strength training in COPD: a systematic review. *Chest* 2004; 126:903-914
Specific muscle group training

Training of specific muscle groups (e.g., upper extremities compared to lower extremities and inspiratory muscles) provides benefits that are not as great as when all are included, and not all studies have shown consistent results. As indicated above, both strength and endurance can be targeted, but individual requirements need to be taken into account.

Upper Limb Training

Upper extremity training specifically improves arm function. Unsupported arm training is more effective than supported arm training, and has proven metabolic training effects. Arm training alone was less effective than leg training or combined training at improving overall exercise function, but had an incremental benefit over leg training alone.

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783 Couser JI, Martinez FJ, Celli BR. Pulmonary rehabilitation that includes arm exercise reduces metabolic and ventilatory requirements for simple arm elevation. Chest 1993; 103:37-41
792 O’Hara WJ, Lasachuk KE, Matheson P, et al. Weight training and backpacking in COPD. Respir Care 1984; 29:1202-1210
796 Couser JI, Martinez FJ, Celli BR. Pulmonary rehabilitation that includes arm exercise reduces metabolic and ventilatory requirements for simple arm elevation. Chest 1993; 103:37-41
798 Couser JI, Martinez FJ, Celli BR. Pulmonary rehabilitation that includes arm exercise reduces metabolic and ventilatory requirements for simple arm elevation. Chest 1993; 103:37-41
Training of general or specific upper limb/pectoral girdle muscles may improve ventilatory muscle function\textsuperscript{801}, perhaps to the same extent as specific ventilatory muscle training\textsuperscript{802}.

**Ventilatory muscle training**

The inefficiencies of the ventilatory muscle pump resulting from altered lung elastic recoil associated with DH, and skeletal muscle weakness already described have encouraged the concept of training ventilatory muscles. However, inspiratory muscles in COPD patients are actually well-conditioned in comparison to control subjects, probably as an adaptive response to constant loading of the muscles\textsuperscript{803}, countering the general logic used in supporting inspiratory muscle training (IMT). Despite this, there is evidence of benefit. In 1976 improved ventilatory muscle strength after five weeks of ventilatory muscle strength training was described in normal subjects, and improved ventilatory endurance after endurance training compared to control individuals\textsuperscript{804}. Benefits declined after 15 weeks of de-training\textsuperscript{805}. An uncontrolled study of 10 patients with COPD before and after endurance IMT for six weeks found significant improvement in maximal sustained ventilatory capacity, VO2 during maximal sustained ventilatory capacity testing, and better maximal exercise capacity and 12-MWD\textsuperscript{806}.

Most randomised studies to 1992 used inadequate training stimulus\textsuperscript{807}, and non-significant improvements in inspiratory pressure were found in 11 studies, and non-significant increase in respiratory muscle endurance in 9 studies. Madsen used a quasi-experimental design with blinded evaluation and found no significant changes in exercise capacity, although increases in inspiratory muscle pressure could not be achieved\textsuperscript{808}. The requirement of an adequate training stimulus for improving dyspnoea and functional exercise capacity is acknowledged\textsuperscript{809, 810}, and more recent meta-analysis concluded that IMT alone or in combination with general exercise training decreases dyspnoea and improves exercise function in people with COPD\textsuperscript{811}. The longevity of these improvements has been shown after twelve weeks of IMT, but declined gradually over the year if the training was not maintained\textsuperscript{812}.

\begin{itemize}
  \item \textsuperscript{803} Newell SZ, McKenzie DK, Gandevia SC. Inspiratory and skeletal muscle strength and endurance and diaphragmatic activation in patients with chronic airflow limitation. *Thorax* 1989; 44:903-912
  \item \textsuperscript{804} Leith DE, Bradley M. Ventilatory muscle strength and endurance training. *J Appl Physiol* 1976; 41:508-516
  \item \textsuperscript{805} Bradley ME, Leith DE. Ventilatory muscle training and the oxygen cost of sustained hyperpnea. *J Appl Physiol* 1978; 45:885-892
  \item \textsuperscript{806} Belman MJ, Mittman C. Ventilatory muscle training improves exercise capacity in chronic obstructive pulmonary disease patients. *Am Rev Respir Dis* 1980; 121:273-280
  \item \textsuperscript{809} Weiner P, Berar-Yannay N, Davidovich A, et al. The cumulative effect of long acting bronchodilators, exercise and inspiratory muscle training on the perception of dyspnoea in patients with COPD. *Chest* 2000; 118:672-678
\end{itemize}
When adequate IMT stimulus is used, along with significant increase in respiratory muscle endurance or strength, better maximal exercise capacity has been shown inconsistently. Changes in dyspnoea correlated with changes in inspiratory muscle pressure. A systematic review of IMT, using 6MWT as the outcome measure, found 8 analyzable studies (6 of them being RCTs) with variable levels of methodological quality but almost uniform improvements in 6-MWD, as long as high levels of inspiratory effort was achieved (30% of maximum inspiratory pressure). In some studies reduced dyspnoea, better quality of life, and improvements in both strength and endurance of inspiratory muscles were demonstrated. IMT conducted at home, in a study of 20 consecutive Italian COPD patients, showed significant dyspnoea reduction and 6-MWD improvement.

IMT may have incremental benefit over general exercise training alone. In a RCT of interval training with threshold loading, significant improvements were found in inspiratory muscle pressures, respiratory muscle endurance, dyspnoea on questionnaire, and Borg-scale.

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816 Preuser BA, Winningham ML, Clanton TL. High- vs low-intensity inspiratory muscle interval training in patients with COPD. *Chest* 1994; 106:110-117
dyspnoea during activities\textsuperscript{828}. Another double-blind RCT of target-flow IMT conducted at home (10 patients in each group) showed better dyspnoea scores and HRQoL at 6 months in the treatment group than in the controls, and shuttle walk test improvements over baseline in the treatment group, but no change in general exercise performance\textsuperscript{829}. In spite of increased inspiratory muscle strength from IMT, however, no added benefit over home-based exercise training could be demonstrated on exercise capacity or exercise-related symptoms\textsuperscript{830}. A small RCT comparing a resistance breathing device with “sham training” (incentive spirometry), showed training effects in both groups, with greater increase in inspiratory muscle endurance in patients treated with resistance muscle endurance training. There were no differences between the two groups in dyspnoea scores, exercise capacity or HRQoL\textsuperscript{831}. In a RCT involving 17 patients with moderate-severe COPD undertaking sham training compared to 16 doing IMT at maximum tolerable threshold load for 8 weeks (three times weekly), and significant differences were seen between the two groups in maximum inspiratory pressure, 6-MWD, and quality of life (CRDQ, including dyspnoea)\textsuperscript{832}. IMT in asthma has been inadequately studied\textsuperscript{833}.

It is remarkable that there have been five meta-analyses with systematic reviews addressing IMT. Little evidence for benefit was found in a meta-analysis of 17 studies\textsuperscript{834}. Later, a further 10 studies were analysed, showing significant improvements in inspiratory muscle strength and endurance, with less dyspnoea during exercise\textsuperscript{835}. Different levels of IMT were evaluated in a third review, and various benefits including dyspnoea and exercise capacity were found\textsuperscript{836}. All these compared IMT with sham or control. A fourth systematic review evaluated studies of IMT versus other rehabilitation interventions, and showed added benefits from IMT for inspiratory muscle function but not for overall exercise capacity\textsuperscript{837}. The most recent systematic review reviewed 156 publications, yielding 18 RCTs of IMT with or without rehabilitation against rehabilitation. Fourteen meta-analyses were possible, and consistent benefits in ventilatory muscle function and exercise capacity were demonstrated where IMT was part of the program\textsuperscript{838}.

\textsuperscript{831} Scherer TA, Spengler CM, Owassapian D, et al. Respiratory muscle endurance training in chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2000; 162:1709-1714
\textsuperscript{833} Ram FSF, Wellington SR, Barnes NC. Inspiratory muscle training for asthma. \textit{Cochrane Database Syst Rev} 2004; Issue 4
\textsuperscript{837} Crowe J, Reid WD, Geddes L, O’Brien K, Brooks D. Inspiratory muscle training compared with other rehabilitation interventions in adults with chronic obstructive pulmonary disease. \textit{COPD: J COPD} 2005; 3:319-329
EXERCISE TRAINING

KEY POINTS

1) Exercise training is highly effective in enhancing exercise capacity and everyday function
2) General physical training improves fitness
3) Specific muscle training improves function of those muscles
4) Upper limb training is as effective in improving respiratory muscle function as inspiratory muscle training
5) Strength training of muscle groups improves their strength and may improve functional fitness
6) Targeted inspiratory muscle training adds benefit to standard pulmonary rehabilitation exercises

Enhancement of training with drugs, gas mixtures and ventilation support

In a recent review of methods for modulating dynamic hyperinflation in COPD, Casaburi and Porszasz\(^{839}\) suggest that this can be achieved by increasing the time available for lung emptying or by increasing potential expiratory flow. The latter might be achieved through bronchodilator administration or by using low density gas mixtures. The former might be achieved by exercise training or by administration of hyperoxic gas mixtures to reduce ventilatory drive. The authors highlighted the potential value in combining a variety of these methods.

Drug Treatment

A systematic review has collated and analysed the evidence for drug therapies improving functional exercise capacity, though the amounts of change in performance were variable and significant effects were described in only half of the studies\(^{840}\). Until recently, there were inadequate explanations for these improvements. Short-acting beta-agonists (e.g. salbutamol and terbutaline) and anticholinergics (ipratropium in Australia) have only small measurable benefits in terms of FEV1, and the duration of any benefits is fairly short. Longer acting bronchodilating agents have only recently emerged for use in COPD, notably long-acting beta-agonists (LABA) like salmeterol and eformoterol and the long-acting anticholinergic, tiotropium.


\(^{840}\) Liesker JJW, Wijkstra PJ, Koeter GH, ET AL. A systematic review of the effects of bronchodilators on exercise capacity in patients with COPD. *Chest* 2002; 121:597-608
Tiotropium has prolonged activity at the M3 muscarinic receptor on bronchial smooth muscle\textsuperscript{841}, and has been shown to sustain significant bronchodilatation and relief of dyspnoea\textsuperscript{842,843}. The concept of dynamic hyperinflation and its reduction with therapy may provide some explanation for functional improvements, and this hypothesis has been tested with tiotropium\textsuperscript{844}. The multicentre 6-week study included 197 patients with moderately severe COPD with demonstrated resting hyperinflation, who performed an initial maximum exercise test (cycle ergometry) to obtain VO\textsubscript{2}\text{max}. They then performed baseline endurance tests on the cycle ergometer set at 75% of their VO\textsubscript{2}\text{max}, and subsequent repeat endurance tests while taking tiotropium. There were improvements in FEV\textsubscript{1} and FVC, reduction in resting hyperinflation, and significant (mean 21%) improvements in endurance time and exertional dyspnoea (by Borg score) at specific times in the tests. These changes were supported by significant improvements in daily dyspnoea measured by BDI/TDI.

Most recently, positive interaction between tiotropium and pulmonary rehabilitation has been examined, based on the premise that, if the drug has the properties demonstrated above, it should allow the patient to undertake more work and therefore gain more benefit from the PR\textsuperscript{845}. In fact, this 25-week study demonstrated significant enhancement of the benefits from PR. In a multi-centre design 108 patients were randomised to tiotropium or placebo, which they took for 5 weeks before starting a minimum of eight weeks of thrice-weekly lower-limb targeted endurance exercise training and continuing tiotropium throughout. Maintenance of benefit effects were also examined 12 weeks after PR was completed and the drug had been continued. Tiotropium alone was better than placebo at increasing constant-work treadmill endurance tests (at 80% of maximum work achieved in a maximal incremental treadmill tests pre-treatment) – over the first 4 weeks the difference was 1.65 minutes (p=0.183). Following PR in addition to tiotropium or placebo there were significant improvements in endurance time in both groups, but tiotropium patients had significantly greater benefit from PR (by 5.35 mins, p=0.025), and the benefit was sustained 12 weeks later (difference + 6.60 mins, p=0.018). TDI dyspnoea improved more in the tiotropium group at all time-points (by clinically-meaningful margins), as did health-related quality of life (SGRQ – by a margin of 4.44 units) (p=0.055)\textsuperscript{846}.

Work is being done with LABA to determine if similar effects can be replicated with a different class of long-acting drugs. If it can be shown that combinations of different classes had at least additive benefits, it might be feasible to utilise these effects to enhance training.

**Oxygen**

The primary rationale for the use of oxygen in hypoxaemic patients with COPD is to prolong life\textsuperscript{847}, and there are concomitant benefits in reducing pulmonary artery pressure (which

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\textsuperscript{841} Disse B. Antimuscarinic treatment for lung diseases from research to clinical practice. *Life Sci 2001; 68:2257-2564*


\textsuperscript{845} Casaburi R, Kukafka D, Cooper CB, ET AL. Improvement in exercise tolerance with the combination of tiotropium and pulmonary rehabilitation in patients with COPD. *Chest 2005; 127:809-817*

\textsuperscript{846} Casaburi R, Kukafka D, Cooper CB, ET AL. Improvement in exercise tolerance with the combination of tiotropium and pulmonary rehabilitation in patients with COPD. *Chest 2005; 127:809-817*

\textsuperscript{847} Nocturnal Oxygen Therapy Trial Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease. *Ann Intern Med 1980; 93:391-398*
contributes to the improved survival\textsuperscript{848}. Intermittent short bursts of oxygen to avoid or reduce dyspnoea during exercise has little documented evidence in patients with COPD who do not have significant hypoxaemia\textsuperscript{849,850,851,852}. On the other hand, in non-hypoxaemic patients, as well as those with hypoxaemia, hyperoxic mixtures have been shown to reduce dyspnoea, attributed to reduced tidal volume and reduced dynamic hyperinflation\textsuperscript{853}. Whether this is due to the oxygen \textit{per se}, or to an effect of gas-driven positive end expiratory pressure (PEEP) from the oxygen mask\textsuperscript{854} is still speculative, but dynamic hyperinflation is an important cause of dyspnoea in people with COPD\textsuperscript{855}. There are further inconsistencies in evidence supporting use of oxygen. Neither oxygen supplementation nor air, provided either before or after exercise in a random-order double-blind study had significant effect on exercise-induced dyspnoea, exercise endurance or recovery time in 52 patients with severe COPD who had previously desaturated during a 6-minute walk test\textsuperscript{856}. In another study of 30 non-hypoxaemic patients with less severe COPD a double-blind trial with air or oxygen at 3LPM was undertaken. The patients used the test gas during exercise training on a cycle ergometer 3 times a week for 7 weeks. Greater training effects were seen in the group receiving oxygen than in those receiving air, with greater endurance and reduced ventilation and dyspnoea at isotime\textsuperscript{857}, but it is important to note that this applied to high intensity exercise training (as recommended from the studies by Casaburi\textsuperscript{858}). The reduced ventilation would have contributed to reduced dynamic hyperinflation (though this was not measured in that study), as shown in subsequent studies\textsuperscript{859,860,861}. Administration of 100% oxygen (rather impractical in everyday circumstances) can enhance work by relieving skeletal muscles of metabolic demand\textsuperscript{862}, and this could allow greater muscle conditioning.

\textsuperscript{848} Ashutosh K, Mead G, Demsky M. Early effects of oxygen administration and prognosis in chronic obstructive pulmonary disease and cor pulmonale. Am Rev Respir Dis 1983; 127:399-404
\textsuperscript{851} Stevenson NJ, Calverley PMA. The effects of oxygen on resolution of breathlessness after exercise. Am J Respir Crit Care Med 2002; 165:A264
\textsuperscript{852} Lewis CA, Eaton TE, Young P, Kolbe J. Short-burst oxygen immediately before and after exercise is ineffective in nonhypoxic COPD patients. Eur Respir J 2003; 22:584-588
\textsuperscript{860} O’Donnell DE, Bain DJ, Webb KA. Factors contributing to relief of exertional breathlessness during hyperoxia in chronic airflow limitation. Am J Respir Crit Care Med 1997; 155:530-535
A recent systematic review that evaluated effects of ambulatory oxygen during exercise compared to placebo included 31 randomised controlled trials involving 534 patients with moderate and severe COPD\(^{863}\). Oxygen treatment significantly improved outcomes related to exercise capacity (maximal and endurance) as well as dyspnoea at isotime of endurance exercise. More specific to exercise training, however, is another recent systematic review which addressed RCTs comparing exercise training with oxygen supplement vs non-supplemented training for patients with COPD not using home oxygen therapy\(^{864}\). Five RCTs matched the inclusion criteria, with only three being included in meta-analysis, providing only 31 treated patients and 32 controls, and there were suboptimal quality issues. The authors found insufficient evidence supporting oxygen supplementation during exercise training and recommended better-constructed trials evaluating relevant patient-centred outcomes.

**Heliox**

There is some attraction to the notion that giving people with severe COPD a gas mixture that is less dense to breathe would reduce dyspnoea. If airways conduct air with turbulent flow, there should be significant improvement in flow with the less-dense gas\(^{865}\). Since a mixture of helium with oxygen was introduced by Barach in 1934\(^{866}\) to reduce dyspnoea in asthma, emphysema and upper airways obstruction, there have been sporadic research reports of its therapeutic use. Ventilatory responses to incremental cycle ergometry exercise in 12 older healthy (and fit) people were increased when they breathed heliox\(^{867}\). An experiment with a mixture of 80% helium with 20% oxygen (heliox) did not change tidal flow limitation, and did not reduce dynamic hyperinflation\(^{868}\). In another study of 12 people with COPD endurance time was higher and dynamic hyperinflation less when they exercised to exhaustion while breathing heliox than when breathing room air, despite heliox increasing ventilatory responses to exercise\(^{869}\). These patients reported less dyspnoea at isotime, and the reduction in dyspnoea correlated with the increase in inspiratory capacity (IC). In a further study, the La Jolla group found that whole body exercise (cycling) by people with COPD was enhanced by heliox breathing due to increased muscle metabolic reserve\(^{870}\). Interestingly, though, the better exercise tolerance experienced during heliox breathing was not translated into better training benefits in another study\(^{871}\). Properly designed randomised controlled trials with double-blinding are therefore warranted, though this is difficult, given the different density, visco-elastic properties and thermal conductivity of helium, and hence likelihood of subjects being aware of which gas mixture is being breathed. Furthermore, it may be interesting to examine whether heliox would enhance exercise training, and secondly whether use


\(^{867}\) Babb TG, DeLorey DS, Wyrick BL. Ventilatory responses to exercise in aged runners breathing He-O2 or inspired CO2. *J Appl Physiol* 2003; 94:685-693


\(^{871}\) Johnson JE, Gavin DJ, Adams-Dramiga S. Effects of training with heliox and noninvasive positive pressure ventilation on exercise ability in patients with severe COPD. *Chest* 2002; 122:464-472
of a more hyperoxic mixture with helium would unload ventilation and work of breathing to allow greater training effects than hyperoxia alone.

Another therapeutic option is to combine helium gas with a hyperoxic mixture. In a double-blind randomised cross-over design, such a mixture has been shown superior to either hyperoxia (28% oxygen) or standard heliox (21% oxygen) in endurance shuttle walk distance\textsuperscript{872}, a finding that elsewhere was determined to be due to reduced DH and reduced respiratory rate\textsuperscript{873,874}.

Applicability of this modality to the rehabilitation setting requires further evaluation. Helium is a limited resource that is increasingly costly, and a health economic evaluation is warranted.

**Ventilation support**

Non-invasive positive pressure ventilation (NPPV) has been suggested as another way of supporting ventilation to enhance training. This strategy is known to increase ventilation and reduce dyspnoea\textsuperscript{875}, with reduced inspiratory effort\textsuperscript{876} and ventilatory loading\textsuperscript{877}. There is some inconsistency in the evidence again that this may allow better training effects from pulmonary rehabilitation\textsuperscript{878,879,880}. Recent evidence suggests this difficult strategy provides little or no benefit in enhancing training\textsuperscript{881}, even though higher pressures can enhance endurance\textsuperscript{882}.

**Education**

The education component “should be part of the care for every patient with COPD”\textsuperscript{883}, and “all patients may benefit from fuller explanation of the disease processes, the effects of treatment,

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\textsuperscript{875} Maltais F, Reissman H, Gottfried SB. Pressure support reduces inspiratory effort and dyspnoea during exercise in chronic airflow obstruction. *Am J Respir Crit Care Med* 1995; 151:1027-1033


\textsuperscript{877} Polkey MI, Kyroussis D, Mills GH, et al. Inspiratory pressure support reduces slowing of inspiratory muscle relaxation rate during exhaustive treadmill walking in severe COPD. *Am J Respir Crit Care Med* 1996; 154:1146-1150


\textsuperscript{879} Dolmage TE, Goldstein RS. Proportional assist ventilation and exercise tolerance in subjects with COPD. *Chest* 1997; 111:948-954

\textsuperscript{880} Johnson JE, Gavin DJ, Adams-Dramiga S. Effects of training with heliox and noninvasive positive pressure ventilation on exercise ability in patients with severe COPD. *Chest* 2002; 122:464-472

\textsuperscript{881} Highcock MP, Shneerson JM, Smith IE. Increased ventilation with NiPPV does not necessarily improve exercise capacity in COPD. *Eur Respir J* 2003; 22:100-105


\textsuperscript{883} American Thoracic Society Official Statement. Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med* 1995; 152:S77-S120
how and when to use inhalers, and when to ask for help”884. The NICE (UK) guidelines for COPD management state that “..education is usually offered as part of a comprehensive pulmonary rehabilitation programme…[despite] little robust evidence relating to COPD patient education”885.

American guidelines for pulmonary rehabilitation886 consider education as “psychosocial intervention components”, and propose four interventions – psychosocial, health behaviour, adherence, and education. Psychosocial interventions include stress management (which has small effects on the Sickness Impact Profile887), progressive muscle relaxation (which has small and brief effects on anxiety and breathlessness888,889), and yoga (which in a single randomised trial showed increased exercise performance and reduced symptoms890). Smoking cessation and nutrition management are included in health behaviour interventions. Attention to smoking cessation has been studied in people with COPD, showing modest results with a variety of intervention891,892,893. A systematic review concluded that combined pharmacological and behavioural interventions are better than no intervention or psychosocial intervention in supporting smoking cessation in COPD, and can be effective, though the strength of this evidence was poor894, and there are no studies of behavioural weight management in COPD. Other behavioural strategies were moderately cost-effective in a small randomised controlled trial895.

Adherence to smoking cessation, exercise regimens and prescribed medications are central to good COPD management896. Adherence to smoking cessation is a complex issue, both in the

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889 Gift AG, Moore T, Soeken K. Relaxation to reduce dyspnoea and anxiety in COPD patients. Nurs Res 1992; 41:242-246
890 Tandon MK. Adjunct treatment with yoga in chronic severe airways obstruction. Thorax 1978; 33:514-517
891 Turner SA, Daniels JL, Hollandsworth JG. The effects of a multicomponent smoking cessation program with chronic obstructive pulmonary disease outpatients. Addict Behav 1985; 10:87-90
short term\textsuperscript{897} and long term\textsuperscript{898}. Yet fully half the people in a large US survey who had ever smoked were not smoking at the time of survey, suggesting self-regulation is often eventually successful\textsuperscript{899}. Methods for improving sustained abstinence are considered elsewhere.

Nonadherence to treatment covers two major components. Primary nonadherence refers to the patient not filling or collecting a prescription, either due to cost limitations or to poor understanding\textsuperscript{900}. Secondary nonadherence refers to the medication being used incorrectly or being prematurely stopped, often due to adverse effects, belief the benefit has been achieved and no more is required, or fear of accumulated “resistance” with repeated use\textsuperscript{901}. Fear of adverse effects particularly relates to use of corticosteroids\textsuperscript{902}. Of course, inhaled medications require use of sometimes seemingly complex devices, and often several different forms of device. Recognition of the importance of this factor has been highlighted by publication by the American College of Chest Physicians of guidelines for clinicians in selecting and educating patients about inhalation device use\textsuperscript{903}. Frequency of prescribed use is an important factor, and once-daily medication determines higher adherence than the need for multiple daily doses\textsuperscript{904}. Oxygen therapy also is affected by adherence issues, with a similar set of perceptions and difficulties being identifiable\textsuperscript{905}, and specific education relating to the use of oxygen equipment improves adherence\textsuperscript{906}.

Despite abundant evidence for the benefits of exercise-centred pulmonary rehabilitation, there is almost equally abundant evidence that many patients fail to attend courses (1% in Australia and New Zealand, 3% in Belgium). Reluctance to take responsibility, and access difficulties are frequently identified reasons. Further, not all who attend achieve significant improvements in exercise performance – perhaps as many as a third fail to improve\textsuperscript{907}, although this does not appear to be determined by disease severity\textsuperscript{908}. A randomised controlled study of cognitive and behavioural interventions showed people with COPD who received combined cognitive-behavioural interventions continued exercise more than those assigned to behaviour modification.
or cognitive modification, and all treatments were more effective than controls. Benefits were lost by 6 months, however. More recent work evaluated 103 patients with COPD who were randomly assigned to one of three types of dyspnoea self-management. Consistent adherence to the exercise prescribed resulted in greatest improvements in physical function.

Modest health gains can be expected from knowledge education for people with COPD, depending on the aim of the education input, and expert panels agree that education should be combined with other components of pulmonary rehabilitation, with emphasis on acquiring relevant techniques and skills, as well as adherence and self-management.

The approach to education influences the level of benefit. Early attempts with group therapy to teach post-myocardial infarction patients about the disease and required treatment, for example,

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were found to increase patient anxiety\textsuperscript{913}, and enforced analysis of the patient’s personality and psychological defences was not helpful\textsuperscript{914}. Provision of written educational materials might be the simplest approach to giving people facts, but a systematic review of the efficacy of such a passive approach for health care workers (eleven studies involving 1,848 physicians) found equivocal results for change in practice\textsuperscript{915}. No such research into passive education for patients has been identified. However, simple teaching about a patient’s lung disease can improve knowledge, and may be associated with reduced use of hospital and primary care facilities\textsuperscript{916}. Use of videotapes has been studied in a randomised trial in 214 patients with COPD, comparing videotape customised to disease type and severity with standard information on videotape and with usual care. There were statistically significant improvements in quality of life and fatigue and better adherence to exercise in patients receiving the customised videotape than the other interventions, and the benefits were sustained for 16 weeks’ observation\textsuperscript{917}.

Guidelines recommend that there should be input from a range of health professionals working together to improve the patient’s knowledge about breathing and the various treatments available to control breathlessness. There is an emerging emphasis on boosting psychosocial supports, and in particular instilling hope, and removing feelings of isolation and helplessness\textsuperscript{918,919}. Fahrenfort favours “emancipation: liberating people to make their own decisions on their own terms”\textsuperscript{920}.

Knowledge of facts, and understanding concepts that allow application of facts, are the basic foundations of patient education. Knowledge acquisition, emphasis on the need to quit smoking, assistance in quitting, support to maintain tobacco abstinence, optimising activities and nutrition, enabling control over anxiety, panic or depression, and training in use of medications and therapeutic devices to their best advantage appear relevant in chronic lung disease. Behavioural change, though, is likely to occur only when the patient is able to identify the relevance of the concepts to their own condition and treatment. Indeed, in COPD specific efficacy expectations in relation to activity tasks can improve compliance with exercises and improved functional status\textsuperscript{921}.

The ATS guidelines on COPD management support a tailored approach for individual patients, but recommends combining group discussions with education at each interaction between health professional and patient. Education alone has limited documented benefit\textsuperscript{922,923}. In asthma, for

\textsuperscript{916} Tougaard L, Krone T, Sorknaes A, Ellegaard H. Economic benefits of teaching patients with chronic obstructive pulmonary disease about their illness. The PASTMA Group. Lancet 1992; 339:1517-1520
\textsuperscript{919} Yalom ID. The theory and practice of group psychotherapy. 2nd ed. New York: Basic Books; 1985
\textsuperscript{920} Fahrenfort M. Patient emancipation by health education: an impossible goal? Patient Ed Counsel 1987; 10:25-37
\textsuperscript{921} Kaplan RM, Atkins CJ, Reinsch S. Specific efficacy expectations mediate exercise compliance in patients with COPD. Health Psychol 1984; 3:223-242
example, it is known that information-only approaches to education do not improve health care utilisation\(^9\). For smoking cessation, simple advice, support and group therapy sessions do have a small role\(^9\), though they are less efficacious than a more comprehensive approach\(^9\). Further information on strategies for helping people quit smoking can be found in other texts, as discussed above, and in two further meta-analyses\(^9,9\).

Several different types of education for COPD have been studied in one semi-controlled trial, and improvements were seen in well-being, self-efficacy, compliance with recommended exercise regimens and actual exercise tolerance\(^9\). This group also performed an attention-controlled randomised trial of specific training for exercise compliance in 60 COPD patients, and confirmed this intervention resulted in greater compliance with the exercise regimen. Few studies have examined the effects of education-only pulmonary rehabilitation on health outcomes. There is no significant effect on lung function or on exercise performance\(^9,9,9\). A randomised trial of education alone versus comprehensive pulmonary rehabilitation in COPD patients was conducted in 119 patients\(^9\). All received small-group teaching about COPD and coping strategies, and 57 also had individual chest physiotherapy, group psychosocial support sessions and weekly exercise training. Improvements were significantly greater with comprehensive PR than education alone for exercise capacity and endurance, perceived breathlessness, muscle fatigue, dyspnoea and walking self-efficacy, although these benefits slowly waned over 2 to 4 years. No differences were seen in health economic outcomes, survival, depression or quality of life.

There is increasing interest in training patients and their carers to develop a **partnership** approach to treatment with their medical mentors. With this approach they should be able to self-monitor their disease more effectively, to adhere to medications and use them correctly, and to manage their disease on a day-to-day basis, so preventing or limiting exacerbations. Asthma self-management programs have shown generally good results in adults\(^9,9,9,9\) (with some

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inconsistencies\textsuperscript{937} and in children\textsuperscript{938,939,940,941}. Medication compliance/adherence in asthma may be improved by specific education\textsuperscript{942,943}.

American/European guidelines for pulmonary rehabilitation now include self-management education for COPD\textsuperscript{944}. One randomised uncontrolled study in COPD patients showed that patient education by group and individual sessions did alter patients’ medication habits, in that less short-acting beta-agonist bronchodilator was dispensed, but there was no change in compliance with inhaled corticosteroid use in either asthmatics or people with COPD\textsuperscript{945}. HRQoL effects were significant for asthma but not for COPD patients\textsuperscript{946}. Self-management education for people with COPD resulted in no changes in dyspnoea, but self-efficacy was found to be better in a small quasi-experimental non-random uncontrolled study\textsuperscript{947}. A non-randomised but controlled study in people with COPD has shown improvements in self-efficacy with education alone but not as great as they were with combined education and supervised exercise training\textsuperscript{948}. A meta-analysis of 65 studies meeting specific requirements of experimental design found few studies of education-alone in COPD, with relatively small numbers in the studies, and small sized effects for accuracy in performing inhaler skills, health care utilisation and adherence to treatment\textsuperscript{949}. In addition, small improvements have been demonstrated for aspects of quality of

\textsuperscript{935} Snyder SE, Winder JA, Creer TL. Development and evaluation of an adult asthma self-management program. \textit{J Asthma} 1987; 24:154-158
\textsuperscript{936} Bailey WC, Richards JM, Brooks CM, Soong SJ, et al. A randomized trial to improve self-management practices of adults with asthma. \textit{Arch Intern Med} 1990; 150:1664-1668
\textsuperscript{937} Bailey WC, Kohler CL, Richards JM, Windsor RA, et al. Asthma self-management: do patient education programs always have an impact? \textit{Arch Intern Med} 1999; 159:2422-2428
\textsuperscript{939} Bruhn JG. The application of theory in childhood asthma self-help program. \textit{J Allergy Clin Immunol} 1987; 72:562-577
\textsuperscript{940} Madge P, McColl J, Paton J. Impact of a nurse-led home management training programme in children admitted to hospital with acute asthma: a randomized controlled study. \textit{Thorax} 1997; 52:223-228
\textsuperscript{941} Wesseldine L, McCarthy P, Silverman M. A structured discharge procedure for children admitted to hospital with acute asthma: a randomized controlled trial of nursing practice. \textit{Arch Dis Child} 1999; 80:110-114
\textsuperscript{942} Windsor RA, Bailey WC, Richards JM, Manzella B, et al. Evaluation of the efficacy and cost effectiveness of health education methods to increase medication adherence among adults with asthma. \textit{Am J Publ Health} 1990; 80:1519-1521
\textsuperscript{943} Allen RM, Jones MP, Oldenburg B. Randomised trial of an asthma self-management programme for adults. \textit{Thorax} 1995; 50:731-738
\textsuperscript{945} Gallefoss F, Bakke PS. How does patient education and self-management among asthmatics and people with chronic obstructive pulmonary disease affect medication? \textit{Am J Respir Crit Care Med} 1999; 160:2000-2005
\textsuperscript{946} Gallefoss F, Bakke PS, Kjaersgaard P. Quality of life assessment after patient education in a randomized controlled study on asthma and chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 1999; 159:812-817
\textsuperscript{948} Scherer YK, Schmieder LE, Shimmel S. The effects of education alone and in combination with pulmonary rehabilitation on self-efficacy in patients with COPD. \textit{Rehabil Nurs} 1998; 23:71-77
life and dyspnoea from education-alone in randomised controlled trials\textsuperscript{950,951,952}. Self-management in asthma is well established and validated, but there is still much work needed in demonstrating effectiveness and cost-effectiveness in COPD\textsuperscript{953}. A recent systematic review evaluated 17 RCTs of self-management education by lay leaders among 7,442 participants with a range of chronic health conditions, all but one relatively short term\textsuperscript{954}. Small short-term improvements were seen in patient self-efficacy, symptom management and frequency of programmed exercises, but no significant changes in mental health, HRQoL, respiratory symptoms or use of healthcare resources. The potential benefits, limitations and costs of such self-management education programs have recently been highlighted in Australia\textsuperscript{955}. Another recent systematic review examined self-management education in general for COPD, and included 14 RCTs, though meta-analysis could not be undertaken for all outcomes because of marked heterogeneity in the measures used and designs of trials. Reduced hospital utilization was the major outcome identified\textsuperscript{956}. Efficacy for action plans as a modality of self-management could not be identified due to inadequate data, but a specific review has identified efficacy\textsuperscript{957}.

The improvements in performance parameters seen following exercise training regimens in people with COPD has tended to bias some professionals against the role of detailed education programs. Rising interest in self-management for people with COPD, particularly around exacerbations, is slowly changing these attitudes. For patients to respond to exacerbations in a timely and appropriate way, they need to be aware of new symptoms, understand what they and their medical care providers mean by exacerbations, and act accordingly. A recent report from a multicentre European qualitative interview-based study of patient understanding and recognition of exacerbations of COPD (n=125) showed poor understanding of the term exacerbation and wide variations in symptomatology, but individuals were able to identify their own exacerbations\textsuperscript{958}. A New Zealand prospective randomised controlled trial (n=159) of structured education about use of self-management plans that included use of courses of antibiotics and steroids for early exacerbations detected by patients themselves found self-management knowledge was higher in the treatment group, but there was no difference between the groups in quality of life\textsuperscript{959}. Written action plans were provided to patients with moderate to severe COPD in an Australian prospective randomised controlled trial (n=139) showed greater use of antibiotics and steroids in


\textsuperscript{953} Bourbeau J. Disease-specific self-management programs in patients with advanced chronic obstructive pulmonary disease: A comprehensive and critical evaluation. Dis Management Health Outcomes 2003; 11:311-319


\textsuperscript{959} McGeoch GRB, Willsman KJ, Dowson CA, Town GI, et al. Self-management plans in the primary care of patients with chronic obstructive pulmonary disease. Respirology 2006; 11:611-618
patient-identified exacerbations, but no significant differences between groups in use of health care resources.\textsuperscript{960}

Most studies have addressed group education, even with self-management. However, there are reasons to expect that an individualised approach might be helpful (although resource-intensive). One randomised trial evaluated the effects of a “dyspnoea self-management program”\textsuperscript{961}, which gave each patient three hours of individual identification of triggers for dyspnoea, strategies to control breathlessness, understanding dyspnoea, using medications correctly, and provision of a personalised reference manual. This extended over four sessions in 8 weeks. In addition regular exercise was emphasised and each patient received an individualised home exercise program. The 36 patients who completed the program had no changes in Borg Dyspnoea levels with exercise, non-significant improvement in exercise endurance performance, no significant change in dyspnoea scales, but small improvements in some sub-scales. Small numbers and no “usual treatment” control group limited the power to detect true differences. However, comparison with two other groups was instructive. The first comparison group included patients who undertook dyspnoea self-management training with exposure to four treadmill walking sessions over the 8-week program. The second group undertook a full exercise training program for the 8 weeks. The latter group did achieve significant improvements in exercise performance, dyspnoea during exercise, and a number of HRQoL parameters.

In assessing and educating patients to achieve health gains from PR it may be useful to understand the specific limitations imposed by their lung disease and to help them set goals to overcome or minimize those limitations. \textbf{Goal achievement} can then be used as an outcome measure. Two systematic reviews are relevant. In the first, a mix of rehabilitation interventions was examined\textsuperscript{962}, evaluating randomised controlled trials on the therapeutic effectiveness of goal setting for patients with disabilities due to degenerative diseases (including COPD). Thirteen studies that met the criteria of goal-setting within a rehabilitation program were identified. Small improvements in adherence to treatment recommendations by patients were noted, and larger improvements in some specific patient performance, but the findings were inconsistent. In the second, scaled scores of goal achievement in older people undergoing rehabilitation for a variety of conditions (not including COPD) were evaluated\textsuperscript{963}. \textbf{Goal attainment scaling} had good reliability, validity and sensitivity, but goal setting had lower reliability and sensitivity.

\textsuperscript{960} Wood-Baker R, McGlone S, Venn A, Walters EH. Written action plans in chronic obstructive pulmonary disease increase appropriate treatment for acute exacerbations. \textit{Respirology} 2006; 11:619-626
\textsuperscript{963} Hurn J, Kneebone I, Cropley M. Goal setting as an outcome measure: A systematic review. \textit{Clin Rehabil} 2006; 20:756-772
EDUCATION IN PULMONARY REHABILITATION

KEY POINTS

1) Behavioural modification approaches:
   • help smokers quit smoking
   • improve adherence to medications and to exercise and diet recommendations
   • increase self-efficacy for shared care

2) Education should be part of a comprehensive pulmonary rehabilitation program for people with chronic lung diseases

Physiotherapy

A range of physical therapies has been applied in COPD, mostly adapted from other conditions.

Secretion clearance

Difficulty with clearance of respiratory secretion is an issue in people with bronchiectasis or severe chronic bronchitis, especially during exacerbations. Coughing can be ineffective because it produces flow-limitation, and it can also cause fatigue. Assisted or directed huffing may be a partial solution, and it has benefit in bronchiectasis, though no evidence has been provided in COPD even when there are excessive or tenacious secretions. Postural drainage, of benefit in bronchiectasis, also has no published evidence of benefit in COPD. A systematic review of “bronchial hygiene therapy” identified ten randomised controlled trials including only 153 people with COPD and bronchiectasis. Different outcome measures prevented statistical aggregation, but significant sputum clearance from the lung was shown in the 67 patients who had a positive result, without demonstrable change in lung function or health status. In patients with cystic fibrosis directed coughing was additive to postural drainage in clearing secretions, but this therapy may be associated with significant hypoxaemia. A recent systematic review of “chest

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964 Hietpas BG, Roth RD, Jensen WM. Huff coughing and airway patency. Respir Care 1979; 24:710-713
965 Kirilloff LH, Owens GR, Rogers RM, Mazzacco MC. Does chest physiotherapy work? Chest 1985; 88:436-444
966 Jones AP, Rowe BH. Bronchopulmonary hygiene physical therapy in chronic obstructive pulmonary disease and bronchiectasis. The Cochrane Library 1998; Issue 3
physiotherapy” in cystic fibrosis from 1966 to the present found no randomised or quasi-
randomised or cross-over trials with a control arm, though short-term uncontrolled cross-over
trials suggested some benefit from sputum clearance techniques\textsuperscript{970}.

Sputum clearance with a simple mechanical device, the Flutter VRP\textsuperscript{TM}, has been studied in a
small comparison with sham therapy (10 patients with COPD and mucus hypersecretion in each
group) over 3 months. There were small (statistically but not clinically significant) changes in
lung function and 12-minute walk distance (12WD) in the treatment group compared to the sham
treated group, and significant improvement in COPD symptom scores over baseline levels in the
treatment group\textsuperscript{971}. Even for patients with severe COPD (and other respiratory problems requiring
non-invasive ventilation) there are devices being trialled, such a mechanical insufflation-
exsufflation device. In such people (including nine with chronic respiratory failure due to COPD)
this was well tolerated and effective in clearing troublesome airway secretions\textsuperscript{972}. Other devices
operate on similar principles, but no trials have been found giving significant benefits.

**Breathing Retraining Techniques**

The goal of breathing retraining techniques (BRT) is to reduce dyspnoea and improve
the mechanical efficiency of ventilation. Dyspnoea has been associated with dysynchrony of
thoraco-abdominal motion\textsuperscript{973,974}. An early observational study conducted in 22 patients with
severe COPD provided treadmill training for six weeks, adding BRT for 10 of the patients for the
final three weeks while the controls continued treadmill training alone\textsuperscript{975}, and concluded greater
increments in exercise capacity were seen in the BRT group. BRT includes diaphragmatic
breathing (DB)\textsuperscript{976,977}, pursed lips breathing (PLB)\textsuperscript{978}, and teaching thoraco-abdominal
synchrony\textsuperscript{979}. Many patients with severe COPD actually develop these techniques for themselves,
but studies have shown inconsistent results.

In spite of physiologic observations relating to beneficial breathing pattern, and widely applied
recommendation for DB and PLB to reduce breathlessness, there has been essentially no well-
powered randomised controlled trial of any of these therapy techniques in COPD, particularly

\textsuperscript{970} van der Schans C, Prasad A, Main E. Chest physiotherapy compared to no chest physiotherapy for cystic
fibrosis. *Cochrane Database of Systematic Reviews* 2001; Issue 4

\textsuperscript{971} Weiner P, Zamir D, Waizman J, Weiner M. Physiotherapy in chronic obstructive pulmonary disease:
oscillatory breathing with flutter VRP1. *Harefuah* 1996; 131:14-17

on respiratory parameters for patients with chronic airway secretion encumbrance. *Chest* 2004; 126:774-780

\textsuperscript{973} Sharp J, Goldberg N, Druz W, et al. Thoraco-abdominal motion in chronic obstructive pulmonary

\textsuperscript{974} Delgato H, Braun S, Skatrud B, et al. Chest wall and abdominal motion during exercise in patients with

\textsuperscript{975} Casciari RJ, Fairshter RD, Harrison A, et al. Effects of breathing retraining in patients with chronic

\textsuperscript{976} Girodo M, Ekstrand KA, Metivier GJ. Deep diaphragmatic breathing: rehabilitation exercises for the

\textsuperscript{977} Gosselink RA, Wagenaar RC, Rijswijk H, et al. Diaphragmatic breathing reduces efficiency of breathing


\textsuperscript{979} Willeput R, Vashaude JP, Landers D, Nys A, et al. Thoracoabdominal motion during chest
from the viewpoint of dyspnoea or health status. A review of breathing re-training in asthmatics identified five randomised controlled trials meeting Cochrane Review criteria, all of them small. The largest showed reduced use of rescue medications, but no overall conclusions about the benefit or otherwise of this technique in asthma could be derived. Since this systematic review, a well-designed study has shown that encouragement of slower and deeper breathing patterns during exercise training, using ventilation feedback techniques, provided greater benefits from endurance training than allowing subjects to use their own breathing patterns.

**Pursed-lip breathing (PLB)**

PLB alters respiratory muscle functions in favour of enhanced efficiency and reduced work of breathing. Dyspnoea can be improved with PLB, and the extent of relief has been associated with reduced respiratory rate and increased tidal volume. However, in an observational study, PLB has been reported to increase air trapping and work of breathing. PLB was found to have variable effects in eight COPD patients, but reduction in dynamic hyperinflation was associated with lower levels of perceived dyspnoea.

**Diaphragmatic breathing (DB)**

DB involves encouraging diaphragmatic excursion while reducing upper rib cage motion, which causes the abdominal wall to move outwards during inhalation. It therefore aims to improve chest wall motion and the distribution of ventilation to better-perfused lower lung zones. It has been prescribed for at least 50 years, with some accumulated experimental rationale. Improved ventilation (with reduced respiratory rate and arterial carbon dioxide levels) has been demonstrated, although increased dys-synchrony, work of breathing and dyspnoea have also been found, without improvement in regional ventilation to lung bases. Recent

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981 Holloway E, Ram FSF. Breathing exercises for asthma. *Cochrane Database Syst Rev* 2001; Issue 4
research suggests greater benefits from endurance training can result from deep slow breathing during training.\(^{993}\)

Given the lack of clear benefit in well-conducted trials, and the evidence of adverse effects, retraining of patients with COPD for PLB and DB cannot be strongly recommended as routine group exercises. However, in view of some observations of improved dyspnoea in some patients, it seems sensible to assess individuals for poor breathing technique and direct individual training where necessary.

**Positioning and Relaxation**

The lean forward position, with fixation of the shoulder girdle to enhance the action of the accessory muscles of ventilation, can relieve breathlessness.\(^{995, 996}\) Many patients adopt this position themselves without receiving specific training. In addition, relaxation training can help to avert the panic associated with breathlessness (see also above). Slumped and upright seated postures have been compared in 14 patients with moderately severe COPD, and no improvements in cardiovascular or respiratory functions were found.\(^{997}\)

**Massage and manipulation**

These are sometimes recommended in asthma and COPD. A systematic review of randomised trials of “manual therapy” in asthma\(^{998}\) found five randomised controlled trials amounting to 290 patients. One trial of chiropractic manipulation was methodologically well done, but it and only one other trial of the same therapy showed significant differences between this therapy and a sham procedure. Otherwise trials were inadequate to show statistical differences with “chest physiotherapy”, “footzone therapy”, “massage therapy” or “relaxation” in asthma.

**Task Optimisation**

Task simplification may appear counter-intuitive when the therapeutic goal is physiological training, but task performance can be optimised without sacrificing true training. After all, the aim of PR is to “achieve and maintain the individual’s maximum level of independence and functioning in the community”.\(^{999}\) Total daily energy expenditure is often increased in patients with COPD, perhaps in part due to raised resting energy expenditure, and in part due to


\(^{998}\) Hondras MA, Linde K, Jones AP. Manual therapy for asthma. *Cochrane Database of Syst Rev* 2001; Issue 4


mechanical inefficiency of human movement, of breathing or of specific muscle groups\textsuperscript{1002}. Training in activities of daily living (ADL) not only includes the overall exercise training but learning how to work efficiently and therefore minimise the daily metabolic costs associated with ADLs, allowing more energy for recreational and social activities. Pacing, and breathing techniques linking effort to the respiratory cycle during ADLs, avoiding anxiety-provoking situations, mastery training, and cognitive behaviour therapy all contribute to energy optimisation. Further, recent research has shown that COPD patients have significant difficulties with coordination, balance and mobility (correlated with the severity of FEV1 impairment and not the level of hypoxaemia), which may compound strength, endurance and behavioural problems\textsuperscript{1003}. While it is not possible to design a randomised controlled trial to prove the benefits of energy conservation, it is logical, and an intrinsic part of PR programs worldwide\textsuperscript{1004,1005,1006}.

\begin{table}
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\begin{tabular}{|l|}
\hline
PHYSIOTHERAPY \hline
KEY POINTS \hline
1) Secretion clearance techniques are useful where there are tenacious or increased secretions \hline
2) Breathing re-training may reduce dyspnoea \hline
3) Pursed-lip breathing can reduce dyspnoea \hline
4) Slow deep breathing during training may increment benefits of exercise training \hline
5) Gait and mobility assessment help to individualise training \hline
6) Water-based exercise is of unproven benefit in COPD \hline
7) Massage and manipulation are of unproven benefit in COPD \hline
\end{tabular}
\end{table}
Psychological Interventions

Prevalence and Impact
There is controversy about the importance of psychological impairments and their treatment in chronic lung disease. American guidelines for PR formerly stated that “depression and anxiety may affect a substantial number of patients with COPD, but [they] are not necessarily concomitants of chronic lung disease.” On the other hand, recently updated guidelines of American and European professional societies state “Chronic respiratory disease is associated with increased risk for anxiety, depression, and other mental health disorders”, indicating a significant shift in understanding. Furthermore, they acknowledge the significant impact on other aspects of the experience of people with COPD – “psychological distress ...[in]... COPD predicts impaired quality of life and restricted ADLs. Functional capacity is more strongly associated with emotional/psychosocial factors...than with traditional physiological indicators.”

It is true that there are inconsistencies among studies of psychological issues, and many of them have been poorly controlled. In a systematic review, rates of depression were generally not significantly higher than in matched populations – between 7% and 42%. A number of robust though non-controlled studies, however, were not included, and anxiety was not addressed. A cross-sectional study of 109 oxygen-dependent patients with severe COPD showed 57% had significant depressive symptoms, and 18% were severely clinically depressed. Other cross-sectional studies in non-selected populations have confirmed that depression is not uncommon in stable patients with severe COPD. Observed risks of depression were 2.5-fold higher in people with severe COPD than in age-matched controls, and this finding is especially so in smokers. Fear and anxiety are expected to be associated with episodes of dyspnoea, and in turn these disorders can add to the awareness of uncomfortable breathing. The prevalence of clinically significant anxiety also varies widely – between 10% and 96%. Mental health issues predict worse HRQOL and restrictions in activities of daily living, but appear not to be associated with worse survival in COPD.

Despite methodological inconsistencies, the research does indicate that, as in other chronic diseases, psychological impairment presents significant challenges with respect to effective treatment of COPD. Health related quality of life (HRQoL) impairment in people with COPD is reflected by reduced energy, mobility and sleep, poor emotional function such as depression, anxiety and dissatisfaction with life, and somatic preoccupation. Poor emotional functioning has been found a univariate predictor of increased mortality, increased health-care utilisation, decreased medication compliance and reduced productivity. A useful review has recently been published addressing prevalence, risks, diagnostic issues and treatments for anxiety and depression in late-stage COPD.

**Depression**

Estimates of depression in patients with COPD vary from 6% to 60% 

1021, 1022. Such a wide range can be explained, at least in part, by differences in research methodologies and in characteristics of the study populations including severity of COPD. However, it is generally accepted that the prevalence rate is around 40% 

1023. Depression is associated with increased morbidity and mortality in COPD patients. It impacts upon a range of health outcomes including poorer physical and social functioning, an increased symptom burden and rates of hospitalization and contributes to the failure to quit smoking or maintain abstinence. A small number of studies have attempted to find a correlation between disease severity and depressive symptomatology in patients with COPD. One study found that patients with severe COPD had a 2.5 times greater risk of depression than controls and this was increased in patients with more severe physical limitation.

**Anxiety**

As with depression the literature is unclear on the prevalence rates of anxiety in patients with COPD. An analysis by Brenes found that studies reported rates between 10% and 49%. A

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1020 Hill K, Geist R, Goldstein RS, Lacasse Y. Anxiety and depression in and-stage COPD. *Eur Respir J* 2008; 31:667-677


meta-analysis estimated rates at approximately 36%\textsuperscript{1029}. Research on the different subtypes of anxiety disorders in COPD patients is limited. Studies have estimated rates of Generalised Anxiety Disorder (GAD) between 10% and 33% and Panic Disorder rates between 8% and 67%\textsuperscript{1030,1031,1032,1033}, which are much higher than rates in the general and healthy elderly population\textsuperscript{1034}, and in patients with other chronic medical conditions\textsuperscript{1035,1036,1037}.

**Coexisting depression and anxiety**

These comorbidities occur together commonly in COPD patients, with prevalence rates estimated to be between 23% and 64%\textsuperscript{1038,1039,1040,1041,1042,1043}, with increased rates even in people with mild COPD\textsuperscript{1044}, and higher rates in women than men\textsuperscript{1045,1046}. This combination has been linked to higher levels of symptoms, worse quality of life, impaired functional status and re-presentation after emergency treatment in COPD patients\textsuperscript{1047,1048,1049}. Depression and anxiety are under-

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\textsuperscript{1030}Porzelius J, Vest M, Nochomovitz M. Respiratory function, cognitions, and panic in chronic obstructive pulmonary patients. \textit{Behav Res Ther} 1992;30:75–77

\textsuperscript{1031}Moore M, Zebb B. The catastrophic misinterpretation of psychological distress. \textit{Behav Res Ther} 1999; 37:1105-1118


\textsuperscript{1033}Dowson CA, Kuijer RG, Mulder RT. Anxiety and self-management behaviour in chronic obstructive pulmonary disease: what has been learned? \textit{Chron Respir Dis}. 2004;1:213-220


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\textsuperscript{1038}Cleland JA, Lee AJ, Hall S. Associations of depression and anxiety with gender, age, health-related quality of life and symptoms in primary care COPD patients. \textit{Fam Pract} 2007;24:217-223


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\textsuperscript{1041}Kunik ME, Roundy K, Veazey C. Surprisingly high prevalence of anxiety and depression in chronic breathing disorder. \textit{Chest} 2005;127:1205-1211

\textsuperscript{1042}Ferguson CJ, Stanley M, Souchek J, \textit{et al.} The utility of somatic symptoms as indicators of depression and anxiety in military veterans with chronic obstructive pulmonary disease. \textit{Depress Anxiety} 2006;23:42-49


\textsuperscript{1044}Di Marco F, Verga M, Reggente M, \textit{et al.} Anxiety and depression in COPD patients: The roles of gender and disease severity. \textit{Respir Med} 2006;100:1767-1774

\textsuperscript{1045}Chavannes NH, Huibers MJH, Schermer TRJ, \textit{et al.} Associations of depressive symptoms with gender, body mass index and dyspnea in primary care COPD patients. \textit{Fam Pract} 2005;22:604-607


\textsuperscript{1047}Cully JA, Graham DP, Stanley MA, \textit{et al.} Quality of life in patients with chronic obstructive pulmonary disease and comorbid anxiety and depression. \textit{Psychosomatics} 2006;47:312-319
diagnosed and hence under-treated in patients with COPD\textsuperscript{1050}, perhaps because of confusion between the somatic symptoms (especially dyspnoea) related to pathophysiology and true mental health disorder\textsuperscript{1051,1052}.

Given the impact of psychological impairment on COPD patients and their carers, and the expected increase of the disease burden as the population ages (especially among women)\textsuperscript{1053}, there is a need to address methodological issues in research on all COPD populations.

One problem with estimating prevalence of mood disorders in people with COPD (and their carers) is the variety of measurement tools. These vary from broad-based psychological health questionnaires to specific anxiety or depression inventories and structured interviews for a codable psychiatric diagnosis. As with most chronic health problems, patients with COPD experience many negative psychological effects that impact on their quality of life. Whether the underlying disease is responsible, or the impact is greater in those with poor mental health resources is difficult to determine. In a longitudinal study of people with chronic respiratory and cardiac diseases and those with chronic back pain, 1784 people were followed for 6 years, significant predictors of deterioration in physical functioning were low income, excess alcohol consumption, external locus of control and other social determinants, suggesting underlying disease is a less important risk factor for changes in physical functioning\textsuperscript{1054}.

\section*{Interventions for mental health disorders in COPD}

\subsection*{Pharmacological Therapy}

Studies evaluating drug therapy for COPD patients with depression and anxiety are inconclusive. Early studies did not demonstrate improvement in depression or anxiety from antidepressant treatment in patients with COPD\textsuperscript{1055,1056}. Later relatively small trials (RCTs and case series) have shown patients with end-stage COPD might benefit from treatment with Selective Serotonin Reuptake Inhibitors (SSRIs) or Tricyclic Antidepressants (TCAs) when significant depressive or anxiety symptoms are present\textsuperscript{1057,1058,1059,1060}. It is important to be aware, however, that

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\item \textsuperscript{1054}Mackenbach JP, Borsboom GJ, Nusselder WJ, \textit{et al.} Determinants of levels and changes of physical functioning in chronically ill persons: results from the GLOBE Study. \textit{J Epidemiol Community Health} 2001; 55:631-638
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\item \textsuperscript{1057}Lacasse Y, Beaudoin L, Rousseau L, \textit{et al.} Randomized trial of paroxetine in end-stage COPD. \textit{Mondali Arch Chest Dis} 2004; 61:140-147
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antidepressants with sedating properties, such as the TCAs and mirtazapine, may increase the risk of respiratory depression in patients with moderate-severe COPD, while SSRIs combined with anxiolytics have a relatively small potential for pulmonary side effects and may be effective for coexisting depression and anxiety\textsuperscript{1061}. Anxiolytics (especially benzodiazepines) are best avoided because of their potential for dependence, drug interactions and side effects\textsuperscript{1062}, such as accident proneness, a problem of particular concern for people using domiciliary oxygen therapy, where equipment and oxygen tubing increase the risk of injury. Buspirone, a non-benzodiazepine, has been studied in two RCTs, with diverging effects being reported for anxiety, dyspnoea and adverse effects\textsuperscript{1063,1064}.

**Psychological Treatments**

There is a paucity of research on psychological treatments for anxiety and depression in patients with COPD. A systematic review concluded there was insufficient evidence to recommend (or withhold) psychological based interventions to reduce anxiety in COPD although methodological problems limit further conclusions\textsuperscript{1065}. A small number of clinical studies have assessed the efficacy of Cognitive Behaviour Therapy (CBT) on depression and anxiety in COPD patients\textsuperscript{1066}. Significant improvements in anxiety and depression scores in an elderly population of COPD patients have been shown from the implementation of a single 2-hour session of CBT compared with education alone\textsuperscript{1067}. Upon completion of a CBT self-help education programme, participants demonstrated less irrational reasoning and psychosocial disability although no reduction in anxiety symptoms\textsuperscript{1068}. In another study, six sessions of CBT produced a sustained improvement in exercise tolerance in people with moderately severe COPD, without any changes

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in anxiety scores\textsuperscript{1069}. A recent systematic review concluded that there is scope for a randomized trial to evaluate the effectiveness and acceptability of CBT in this medical population\textsuperscript{1070}.

There is no identifiable research published evaluating the effectiveness of \textbf{Interpersonal Therapy} (IPT) in COPD patients. There is a single study evaluating \textbf{Supportive Therapy} (ST) for patients who have severe COPD requiring domiciliary oxygen therapy; the non-pharmacologic component was a patient support group. In this study ST enabled these patients to participate in support groups, entertainment, lectures and other social activities while reducing the impact of the disease and improving their quality of life\textsuperscript{1071}. \textbf{Relaxation Therapy} (RT) for patients with COPD has been shown to decrease anxiety and increase HRQOL\textsuperscript{1072,1073}. A meta-analysis found statistically significant beneficial effects on both dyspnea and psychological well being from the use of RT\textsuperscript{1074}. Other studies have found that \textbf{Progressive Muscle Relaxation} (PMR) reduces anxiety and decreases dyspnea and airways obstruction\textsuperscript{1075,1076,1077}, and \textbf{guided imagery} can produce improvements in breathing\textsuperscript{1078,1079}.

\textbf{HOME CARE}

This has long been practised in US centres, albeit with little objective evidence of benefit to health status or cost savings in observational studies. Home care could be used for a range of purposes, from home oxygen monitoring to management of exacerbations of COPD. Moreover, a variety of challenges, funding systems and administrations between different countries make generalisable recommendations difficult. A systematic review found no consistent evidence of cost savings or benefits from home care, mainly due to the range of interventions covered\textsuperscript{1080}. This has been updated recently, with firmer conclusions based on some of the studies detailed below\textsuperscript{1081}. Improved health related quality of life has been described in Canada\textsuperscript{1082}, though other earlier studies found fewer benefits and no savings of mortality or conventional

\textsuperscript{1070}Coventry PA, Gellatly JL. Improving outcomes for COPD patients with mild-to-moderate anxiety and depression: A systematic review of cognitive behavioural therapy. \textit{Br J Health Psychol} 2007 April 18; [Epub ahead of print]
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A Spanish trial of 222 COPD patients randomised to usual hospital care or ‘home hospitalisation’ from the Emergency Department (ED) found better outcomes (fewer ED re-visits, better quality of life, better self-management and satisfaction) at lower cost. Another non-randomised analysis of Spanish patients agreeing to supported discharge after initial stabilisation of an exacerbation showed shorter length of stay without increase in readmission rates, and with concomitant cost savings. In Italy, home care programs for home oxygen therapy and home mechanical ventilation were evaluated in 34 COPD patients, with a historical comparison group, and fewer hospital admissions were seen in the home care group.

Two randomised controlled trials of early supported discharge of patients from hospital in exacerbations of COPD were published in 2000. The first showed no disadvantage for the patients, no difference in subsequent re-hospitalisation, but no indication of the costs of providing a home support service. The second bore the same conclusions, but it also suggested no extra costs were incurred.

Clarification of personal and societal benefits and costs of home care in Australia for patients with chronic respiratory disease is still required. Smith conducted a randomised study of patients discharged from hospital following exacerbation of COPD or referred from their GP or outpatient department, with 48 control patients and 48 patients randomised to a home based nursing intervention. No significant differences between the two groups could be identified in terms of QOL, carer wellbeing, or hospital services utilisation over the 12 months of observation, though there was inadequate follow-up of controls. Davies reported results of a study of patients with exacerbations of COPD randomised to hospitalisation (n=50) or home care (n=100). Only 9% of home care patients required subsequent hospital admission, demonstrating that such an approach is feasible. No differences were seen between the two groups at 3 months in

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hospitalisations, lung function or HRQoL. No economic analysis was reported. Cost savings of around 50% were identified in a New South Wales randomised controlled trial of home care for a range of acute medical conditions. A nurse-led hotline providing telephone advice on demand 24 hours a day proved safe (no adverse events), and reduced hospital presentations.

While it may be feasible to set up hospital outreach or community-based programs to treat sick patients at home, the studies so far reported have not demonstrated convincingly either efficacy in COPD or cost-effectiveness. Home-based pulmonary rehabilitation is also a feasible option.

**PSYCHOLOGICAL INTERVENTIONS**

**KEY POINTS**

1) Depression and anxiety are common in COPD
2) Carers are also affected by psychological stresses
3) Specific psychological support can reduce anxiety and panic in breathless patients and their carers
4) Home care is attractive but of unproven cost-effectiveness

**Nutritional Interventions**

Poor nutritional status is common in severe COPD, and is a bad prognostic sign. Body mass index (BMI) is an independent predictor of mortality in severe COPD, and fat free mass (FFM), which more closely reflects muscle mass, also predicts survival in COPD patients with normal BMI. Loss of lean body mass (FFM) is related to impaired muscle function. Nutritional Screening Measures

There are many factors proposed to be playing potential roles in nutritional depletion in such patients, including hypermetabolism in the resting state and insufficient energy intake. Energy

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1095 Board N, Brennan N, Caplan GA. A randomised controlled trial of the costs of hospital as compared with hospital in the home for acute medical patients. *Aust NZ J Publ Health* 2000; 24:305-311
1096 Roberts MM, Leeder SR, Robinson TD. Nurse-led 24-h hotline for patients with chronic obstructive pulmonary disease reduced hospital use and is safe. *Inern Med J* 2008;
Expenditure might be consumed in the metabolic demands of the ventilatory muscles, by inflammation, by smoking, through pharmacotherapeutic or hormonal thermogenesis, or thermogenesis in digestion or activities. The lead candidates as causes of increased energy expenditure are the high oxygen cost of breathing in severe COPD (though this is probably not so at rest), and release of inflammatory mediators, such as TNF-α, C-reactive protein, etc. Smoking 20 cigarettes a day can also increase energy expenditure by around 10%. Energy intake may be insufficient for the metabolic demands present in COPD. Depression, abdominal bloating and loss of appetite, dyspnoea that interferes with chewing and swallowing, inflammatory mediators (see above), leptins (increased by smoking or inflammation), and inadequate tissue oxygen supply for muscle (and gut) metabolic activity are all possible causes. The cause of nutritional insufficiency is probably multi-factorial\textsuperscript{1101}, and systemic inflammation is currently favoured as a major contributor\textsuperscript{1102}.

Poor nutritional balance may contribute to development or progress of COPD. Predominating recent research has been the importance of oxidant-antioxidant balance (discussed in 5.2 above), and a protective effect of fish oils and/or fruit and vegetables as sources of polyunsaturated fatty acids and antioxidants has been supported by some epidemiological studies\textsuperscript{1103}. Nutritional advice may have a primary prevention role for COPD and other respiratory conditions, though evidence directly supporting this is not available.

Nutritional depletion has important consequences for the muscles involved in both ventilation and locomotion (see above), and there is logic in preventing this depletion, detecting a trend to depletion early, and to provide nutritional interventions. Initial assessment of patients should screen for nutritional impairment. Simple advice and more formal education both have roles in PR. Dietary supplementation was found in a meta-analysis to have been poorly studied (total patient numbers in the six RCTs, only two of which were double-blind was 277), but supplements were considered not to have significantly greater benefit than dietary advice\textsuperscript{1104}. Behaviour change to encourage and entrench better dietary intake is an important role for nutritionists in COPD.

Anabolic agents have been evaluated in both chronic disease and acute events, in non-respiratory and respiratory conditions. Ina randomised placebo-controlled trial of 217 COPD patients nutritional intervention was compared to the same intervention plus nandrolone decanoate, and greater changes in FFM and ventilatory muscle strength were seen in the depleted patients who received the anabolic steroid\textsuperscript{1105}. In a longer-term (6-month) randomised placebo-controlled trial of stanozolol in 23 male COPD patients with nutritional depletion and ventilatory muscle weakness, preceded by a single testosterone injection, accompanied by IMT and cycle ergometer

\textsuperscript{1101} Hugli O, Fitting JW. Alterations in metabolism and body composition in chronic respiratory diseases. \textit{Eur Respir Mono} 2003; 24:11-22
\textsuperscript{1102} Agusti AGN, Noguera A, Sauleda J, Busquets X. Systemic inflammation in chronic respiratory disease. \textit{Eur Respir Mono} 2003; 24:46-55
\textsuperscript{1103} Tabak C, Arts IC, Smit HA, et al. Chronic obstructive pulmonary disease and intake of catechins, flavonols, and flavones: the MORGEN Study. \textit{Am J Respir Crit Care Med} 2001; 164:61-64
\textsuperscript{1104} Ferreira IM, Brooks D, Lacsaye Y, Goldstein RS. Nutritional support for individuals with COPD: a meta-analysis. \textit{Chest} 2000; 117:672-678
training, but no nutritional supplementation, body weight did increase, but there were no significant changes in muscle strength or functional capacity\textsuperscript{1106}. The story is to date incomplete.

**Exercise training** has been described as inducing useful changes in body composition of people with COPD, which is well-known in healthy individuals. Fifty patients were compared with 36 age-matched controls for initial body composition (BMI, FFM), and the 50 patients were enrolled in intensive inpatients training over 8 weeks. Age and FFM predicted muscle / exercise function, and PR induced increase in FFM, reduction in body fat, and improvements in exercise performance and muscle strength out of proportion to the changes in body composition\textsuperscript{1107}. The authors concluded that exercise itself is anabolic.

### NUTRITIONAL INTERVENTIONS

<table>
<thead>
<tr>
<th>KEY POINTS</th>
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<tr>
<td>1) Nutritional assessment to detect early loss of muscle mass and nutritional advice are warranted but unproven</td>
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<tr>
<td>2) Nutritional interventions and exercise training may provide complementary benefits</td>
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**Comprehensive Pulmonary Rehabilitation**

Pulmonary rehabilitation and cardiac rehabilitation are applied to two of the largest patient populations with chronic disabling disease in the developed world – COPD, and coronary heart disease. The goals are similar, namely improved functionality and confidence, with physical reconditioning. However, physical training has different effects in the two patient populations. In coronary heart disease increased aerobic capacity can be achieved, and this is a major contributor to better exercise tolerance, whereas in COPD improvements in exercise tolerance are achieved by better peripheral muscle work efficiency with little or no change in aerobic capacity\textsuperscript{1108}. In this trial, similar exercise sessions and nutritional advice were provided, with disease- and treatment-specific education sessions, and for COPD patients breathing retraining. The exercise benefits were reflected in better quality of life and reduced somatisation in both groups. While similarities and overlaps exist in components of exercise training and psychosocial support between cardiac and pulmonary rehabilitation, there are substantial differences in the style of exercise training as well as in the emphasis of education and specific breathing strategies.

\textsuperscript{1106} Ferreira IM, Verreschi IT, Nery LE, et al. The influence of 6 months of oral anabolic steroids on body mass and respiratory muscles in undernourished COPD patients. *Chest* 1998; 114:19-28


\textsuperscript{1108} Milani RV, Lavie CJ. Disparate effects of out-patient cardiac and pulmonary rehabilitation programs on work efficiency and peak aerobic capacity in patients with coronary disease or severe obstructive pulmonary disease. *J Cardiopulm Rehabil* 1998; 18:17-22
It is important that pulmonary rehabilitation works in an environment of disease management and patient support, with close liaison among all care providers and the patient. Clear goals should be developed for each patient, communicated to the care providers, and reviewed regularly. Since benefits wane after six months or so involvement in an exercise program should continue, knowledge should be refreshed and updated regularly, and social support structures should be encouraged. While the individual components have benefits, greater efficacy is derived from a comprehensive integrated program.

Several systematic reviews or overviews reveal the weight of evidence in favour of comprehensive pulmonary rehabilitation for moderate and severe COPD. Most of the benefits have been observed in hospital-based programs, but there is increasing appreciation of the need to develop rehabilitation in the community.

**A critical review of comprehensive pulmonary rehabilitation**

This review was published in 1999\(^{109}\), selected research papers from the previous 45 years that demonstrated good patient and outcome descriptors, use of control groups, and use of adequate statistical analyses for meta-analysis. Of 79 studies identified, 42 had inadequate controls while a number of others had insufficient descriptions or lack of adequate exercise training, leaving 18 articles. Highly significant and homogeneous improvements in maximal exercise capacity and walking distance were found for up to 9 months after comprehensive PR. There were also homogeneous significant improvements in HRQoL, dyspnoea, fatigue, emotion and mastery. This meta-analysis extended the findings of an earlier meta-analysis\(^{110}\), though with some more homogeneous results, notably in improved exercise capacity (influenced by starting spirometry heterogeneity in the earlier paper).

Since the 1999 meta-analysis a number of randomised controlled and other trials have been published. Griffiths\(^{111}\) evaluated 200 patients with chronic disabling lung disease (a mix of diagnoses, but mostly COPD) randomly assigned to outpatient comprehensive PR or a “usual medical care” group. As a reflection of the severity of their conditions, 14 patients died before the one-year follow-up, and for some patients data were incomplete. Intention-to-treat analysis, however, showed significant treatment effects for all dimensions of generic and disease-specific health status and for exercise capacity immediately after PR, still significant at one year. There was also less hospitalisation and use of primary care resources over the year of observation.

Green\(^{112}\) studied 44 patients with moderate COPD, randomised to either a condensed four-week or a full seven-week program of comprehensive PR. There were statistically greater benefits accrued over 7 weeks than over 4 weeks in HRQoL, with trends to more exercise capacity.

Finnerty\(^{113}\) reported a randomised controlled trial of outpatient PR. There were 36 patients randomised to the active group, who had a 2-hour education and 1-hour exercise training session

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twice a week for weeks as well as voluntary patient support group attendance and follow-up exercise maintenance sessions at 8, 9, and 10 weeks. There were 29 controls who simply attended weekly outpatient clinical reviews. HRQoL improved in the treatment group by well over the “minimal clinical effect”, but did not change in the controls. Small but clinically significant improvements were also seen in walking distance.

In New Zealand, Young\textsuperscript{1114} conducted an uncontrolled prospective longitudinal study of 51 patients with severe COPD enrolled in a “pragmatic” outpatient hospital-based PR program with multidisciplinary education group sessions and progressive aerobic exercise training. Significant improvements were seen in exercise capacity, perceived dyspnoea and HRQoL at 3 and 6 months after the program. Further, there were reduced hospital bed-days and courses of oral corticosteroids for exacerbations in the 6 months after completion than in the 6 months before PR.

Ries\textsuperscript{1115} compared comprehensive PR to education alone in 119 patients with COPD, with an initial 8-week program followed by monthly sessions for one year in the comprehensive group, and good follow-up was obtained over 4 years. Significant benefits were described for exercise capacity, walking self-efficacy, and perceived breathlessness and fatigue at 2 months, with loss of all but exercise endurance and walking self-efficacy by 18 months, and essentially no difference between the groups by 2 years. Over 4 years there were no differences in survival, quality of life, depression, or hospitalisation.

Guell\textsuperscript{1116} conducted a randomised controlled trial of outpatient comprehensive PR with 30 COPD patients in the therapy group and 30 matched controls in a “usual care” group. By 3 months there were significant differences in dyspnoea, fatigue and emotional function, which then declined slightly by 2 years. There were reduced exacerbations in the PR group, but no differences were seen in hospitalisation. Importantly, only three patients needed to be treated to achieve significant benefit in HRQoL for one patient over 2 years.

These studies and others were included in a Cochrane Systematic Review\textsuperscript{1117}. This identified a further nine papers since the earlier review, and confirmed highly significant improvements in mastery, fatigue, emotional function and dyspnoea. All outcomes were greater than the minimum clinically relevant improvements, with the exception of emotional function. Maximum exercise capacity evaluated by incremental treadmill ergometry was measured in fourteen trials (n=255 rehabilitation, n=233 usual care), but the effects were inconsistent and small. Functional exercise capacity was measured in ten trials using the six-minute walk test (n=235 rehabilitation, n=219

\textsuperscript{1114} Young P, Dewse M, Fergusson W, Kolbe J. Improvements in outcomes for chronic obstructive pulmonary disease (COPD) attributable to a hospital-based respiratory rehabilitation program. \textit{Aust NZ J Med} 1999; 29:39-65
\textsuperscript{1115} Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with chronic obstructive pulmonary disease. \textit{Ann Intern Med} 1995; 122:823-832
controls). The weighted mean average was 49 metres, slightly less than the quoted minimum clinically significant difference of 54 metres (96%CI=37-71 m)\textsuperscript{1118}.

The findings from these reviews of effectiveness, and other observations of extended exercise endurance\textsuperscript{1119}, better self-efficacy for exercise\textsuperscript{1120}, less dyspnoea with exertion\textsuperscript{1121}, reduced dependence\textsuperscript{1122}, less depression\textsuperscript{1123,1124}, reduced levels of anxiety\textsuperscript{1125}, and better HRQoL following comprehensive PR, indicate the superiority of this approach over single modality therapy. The most recent systematic review of pulmonary rehabilitation has added another 9 randomised controlled trials to the original review (23 in total met inclusion criteria)\textsuperscript{1126}. Statistically and clinically significant improvements were confirmed for CRDQ domains of dyspnoea, fatigue and mastery, while the improvements in 6-minute walk distance were borderline (49 metres).

It is important to reiterate that COPD in particular is a multifactorial and systemic condition, and it frequently coexists with other comorbid conditions\textsuperscript{1127,1128}. These play a role in the poor HRQoL seen in COPD patients\textsuperscript{1129}, add to the exercise impairment\textsuperscript{1130}, contribute to worse survival, and help determine outcomes from PR\textsuperscript{1131}.

After pulmonary rehabilitation patients should therefore have better capacity in many different aspects, and be confident to monitor and manage their lung condition more effectively so that they need to access emergency treatment only rarely, and their dependency level is reduced. Pulmonary rehabilitation should enable patients to collaborate in a more informed manner with

\begin{itemize}
  \item \textsuperscript{1118} Redelmeier DA, Bayoumi AM, Goldstein RS, Guyatt GH. Interpreting a small difference in functional status: the six-minute walking test in chronic lung disease patients. \textit{Am J Respir Crit Care Med} 1997; 155:1278-1282
  \item \textsuperscript{1119} Cockcroft AE, Saunders MJ, Berry G. Randomised controlled trial of rehabilitation in chronic respiratory disability. \textit{Thorax} 1981; 36:200-203
  \item \textsuperscript{1120} Kaplan RM, Atkins CJ, Reinsch S. Specific efficacy expectations mediate exercise compliance in patients with COPD. \textit{Health Psychol} 1984; 3:223-242
  \item \textsuperscript{1121} Reardon J, Awad E, Normandin E, et al. The effect of comprehensive outpatient pulmonary rehabilitation on dyspnoea. \textit{Chest} 1994; 105:1046-1052
  \item \textsuperscript{1122} Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, et al. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. \textit{Lancet} 2000; 355:362-368
  \item \textsuperscript{1123} Ojanen M, Lahdenso A, Laitinen J, Karvonen J. Psychosocial changes in patients participating in a chronic obstructive pulmonary disease rehabilitation program. \textit{Respiration} 1993; 60:96-102
  \item \textsuperscript{1124} Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with chronic obstructive pulmonary disease. \textit{Ann Intern Med} 1995; 122:823-832
  \item \textsuperscript{1125} Withers NJ, Rudkin ST, White RJ. Anxiety and depression in severe chronic obstructive pulmonary disease: the effects of pulmonary rehabilitation. \textit{J Cardiopulm Rehabil} 1999; 19:362-365
  \item \textsuperscript{1127} Soriano JB, Visick GT, Muellerova H, et al. Patterns of comorbidities in newly diagnosed COPD and asthma in primary care. \textit{Chest} 2005; 128:2099-2107
  \item \textsuperscript{1128} Sidney S, Sorel M, Quesenberry CP, et al. COPD and incident cardiovascular disease hospitalisations and mortality. Kaiser Permanente Medical Care Program. \textit{Chest} 2005; 128:2068-2075
  \item \textsuperscript{1129} Wijnhoven HA, Kriegsman DM, Hesselink AE, et al. The influence of comorbidity on health-related quality of life in asthma and COPD patients. \textit{Respir Med} 2003; 97:468-475
  \item \textsuperscript{1130} Roomi J, Jonson MM, Waters K, et al. Respiratory rehabilitation, exercise capacity and quality of life in chronic airways disease in old age. \textit{Age Ageing} 1996; 25:12-16
  \item \textsuperscript{1131} Crisafulli, Costi S, Luppi F, et al. Role of comorbidities in a cohort of patients with COPD undergoing pulmonary rehabilitation. \textit{Thorax} 2008; 63:487-492
\end{itemize}
their doctor and other health care providers in planning their own care. Their spouse or carers
should also feel more confident and less restricted. Most of these outcomes have not been
evaluated in controlled trials.

4.3 Health Economics and Pulmonary Rehabilitation

The economics of health care are quite different in different countries, and firm conclusions for
Australia about costs of a complex treatment modality like rehabilitation are hard to draw from
research performed overseas. It has become possible only in the last decade to attach dollar
benefits to burden of illness or to gains in HRQoL, so that true cost-benefit analysis for
treatments that do not affect impairments while improving disability is a very recent science. It is
not surprising that there is very little information about cost-benefit of pulmonary rehabilitation in
the world literature.

Guidelines of pulmonary rehabilitation have given little attention to health economics, and studies
from one country are readily generalisable due to different funding and administrative
arrangements. The American guidelines\textsuperscript{1132} only addressed health care utilisation, and concluded
that there was insufficient information even about this component of economic analysis. They
identified eight observational studies and two non-randomised controlled trials\textsuperscript{1133,1134}, which until
1997 had suggested pulmonary rehabilitation resulted in reduced numbers of hospital admissions
as well as reduced hospitalisation days following PR. One randomised controlled trial that
addressed these issues showed non-significant differences\textsuperscript{1135}, and another showed significantly
reduced numbers of hospital admissions in 6 months after PR compared to usual care\textsuperscript{1136}. The
European guidelines in 1997\textsuperscript{1137} did not address themselves to health economics, while the British
guidelines\textsuperscript{1138} (2001) briefly commented on costs for programs, and made the statement “The
complete impact of rehabilitation on the lives of patients and their relatives is largely unexplored
and the health economic issues are currently being addressed”. Neither the 1997 nor the 2002
meta-analyses of components of PR\textsuperscript{1139,1140} examined health economics. The most recent joint

\textsuperscript{1132} AACVPR/ACCP Pulmonary Rehabilitation Guidelines Panel. Pulmonary Rehabilitation. Joint
ACCP/AACVPR evidence-based guidelines. \textit{Chest} 1997; 112:1363-1396

\textsuperscript{1133} Sneider R, O’Malley JA, Kahn M. Trends in pulmonary rehabilitation at Eisenhower Medical Center:

\textsuperscript{1134} Lewis D, Bell SK. Pulmonary rehabilitation, psychosocial adjustment, and use of healthcare services. \textit{Rehabil Nurs} 1995; 20:102-107

\textsuperscript{1135} Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic
and psychosocial outcomes in patients with chronic obstructive pulmonary disease. \textit{Ann Intern Med} 1995;
122:823-832

\textsuperscript{1136} Jensen PS. Risk, protective factors, and supportive interventions in chronic airway obstruction. \textit{Arch Gen Psychiatry} 1983; 40:1203-1207

\textsuperscript{1137} Donner CF, Muir JF. Selection criteria and programmes for pulmonary rehabilitation in COPD patients. \textit{Eur Respir J} 1997; 10:744-757

\textsuperscript{1138} British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation. “Pulmonary
rehabilitation”. \textit{Thorax} 2001; 56:827-834

\textsuperscript{1139} Lacasse Y, Guyatt GH, Goldstein RS. The components of a respiratory rehabilitation program: a
systematic overview. \textit{Chest} 1997 111:1077-1088

\textsuperscript{1140} Lacasse Y, Brosseau L, Milne S, Martin S, et al. Pulmonary rehabilitation for chronic obstructive
pulmonary disease. \textit{Cochrane Database of Systematic Reviews} 2002; Issue 3
ATS/ERS statement on PR\textsuperscript{1141} does address health care utilization, but conclude further research is needed to examine the health economic impacts long term of PR.

In 1997 a prospective randomised controlled study of the costs of a two-month inpatient PR program in Ontario was reported in terms of HRQoL, from which a cost-effectiveness ratio was derived \textsuperscript{1142}. The numbers needed to treat with PR to achieve a clinically significant improvement in HRQoL was also determined from multiplying the incremental cost of providing PR over usual care by the numbers needed to treat to calculate cost-effectiveness. This expensive inpatient program had an incremental cost of CDN$11,597 per patient per year, but only 2.5 patients needed to be treated to improve one patient’s mastery, or 4.4 patients to improve one patient’s fatigue. To put these costs in perspective, a US pharmaco-economic analysis of the costs of providing treatment for COPD found Stage III (severe) COPD costed on average US$10,812 per patient per year\textsuperscript{1143}.

In a randomised controlled trial no advantage in numbers of hospital admissions after PR could be found over the control group, but reduced lengths of stay per admission in the PR group\textsuperscript{1144}. There was overall incremental cost effectiveness from adding comprehensive outpatient PR to usual care in a randomised controlled trial, using the utility in terms of changes in quality-adjusted life years (QALYs) based on the SF-36, and a “bootstrapping” analysis to determine whether societal or health administrators’ preferences were met. The program “produced cost per QALY ratios within bounds considered to be cost effective and…likely to result in financial benefits to the health service”\textsuperscript{1145}.

In a recent review of health economics in COPD, Halpin based most of his analysis on UK calculations\textsuperscript{1146}. He demonstrated that costs of COPD increase with severity of disease (£781 to £1,154 per patient per year). He also referred to the estimate of cost-utility of PR, being £2,000 to £6,000 per QALY\textsuperscript{1147}, and the high level of cost-effectiveness of this intervention. Work still needs to be done on incremental cost-effectiveness of PR in Australia.

### 4.4 Shared care and self-management

People exhibit a range of capacities to self-manage, and the factors predicting their levels of self-management behaviour can be explained by theoretical models. These models of coping with

\begin{itemize}
  \item \textsuperscript{1141} Nici L, Donner C, Wouters E, ZuWallack R, et al, on behalf of the ATS/ERS Pulmonary Rehabilitation Writing Committee. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. \textit{Am J Respir Crit Care Med} 2006; 173:1390-1413
  \item \textsuperscript{1142} Goldstein RS, Gort EH, Guyatt GH, Feeny D. Economic analysis of respiratory rehabilitation. \textit{Chest} 1997; 112:370-379
  \item \textsuperscript{1143} Hilleman DE, Dewan N, Malesker M, Friedman M. Pharmacoeconomic evaluation of COPD. \textit{Chest} 2000; 118:1278-1285
  \item \textsuperscript{1144} Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, et al. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. \textit{Lancet} 2000; 355:362-368
  \item \textsuperscript{1146} Halpin DMG. Health economics of chronic obstructive pulmonary disease. \textit{Proc Am Thorac Soc} 2006; 3:227-233
  \item \textsuperscript{1147} Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, et al. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. \textit{Lancet} 2000; 355:362-368
\end{itemize}
chronic illness in general\textsuperscript{1148}, or specifically with COPD\textsuperscript{1149}, are complex in that they incorporate interactions among a range of physical, psychological, medical and demographic variables. The primary aim of these models is to identify the variables related to how patients deal with their illness, and to use the knowledge to predict and manipulate the relationships among illness perceptions, coping strategies and bio-psycho-social outcomes.

**Behaviour change**

For patients to change health-related behaviour they do need knowledge, yet provision of knowledge alone has little effect on health behaviour\textsuperscript{1150}. Instead, knowledge needs to be supported by behavioural approaches, in which patients learn, practice and rehearse strategies that lessen the impact of the illness, and from this they can develop the self-confidence (self-efficacy) to self-manage\textsuperscript{1151,1152}. It is important, too, that the patient’s medical attendants have skills and understanding in sharing care with the patient. The doctor and other health professionals involved in this care partnership need effective communication skills (for listening to their patients as well as educating them). Training programs to enhance such capabilities can improve their patients’ health outcomes, at least in asthma, hypertension and the paediatrics areas\textsuperscript{1153,1154,1155}.

**Chronic disease self-management programmes**

CDSMPs were developed for the purpose of reducing the morbidity and economic burden associated with chronic disease and improving patient HRQoL\textsuperscript{1156,1157,1158}. The aim of CDSMPs is to disseminate a range of evidence-based interventions to a specific medical population to assist with coordination of disease management and improve quality of care. The multi-factorial components of CDSMPs include supporting the physician or practitioner/patient relationship and plan of care, emphasizing the need for accurate diagnosis (including systemic effects and comorbidities), symptom control, better functioning, and prevention of exacerbations and complications. These goals are underpinned by evidence-based practice guidelines and patient empowerment strategies, and achievement of goals is evaluated using clinical, humanistic, and economic outcomes\textsuperscript{1159}. CDSMPs have been developed for a variety of medical populations and

\begin{itemize}
\item Becker MH. Patient adherence to prescribed therapies. *Med Care* 1985; 23:539-555
\item Clark NM, Starr NS. Management of asthma by patients and families. *Am J Respir Crit Care Med* 1994; 149:S54-S66
\item Inui TS, Yourtee EL, Williamson JW. Improving outcomes in hypertension after physician tutorials. *Ann Intern Med* 1976; 84:646-651
\item Wagner EH, Austin BT, Von Koroff M. Improving outcomes in chronic illness. *Manag Care Q* 1996;4:12-24
\item Stuart M, Weinrich M. Integrated health system for chronic disease management: lessons learned from France. *Chest* 2004;125:695-703
\end{itemize}
implemented in a wide range of clinical and primary care settings, and are based on one of four models.

(1) The **Stanford Model** utilizes peer educators in a structured group setting to help patients learn the skills and strategies of disease self-management\(^{1160}\).

(2) The **PRECEDE- PROCEED Model** uses a nine-step process to first identify population health needs, resource enabling factors and barriers, and then implement and evaluate the program\(^{1161}\).

(3) The **Chronic Care Model** identifies the elements for an effective system-based model for chronic disease management, including patient self-management support, clinical information systems, delivery systems and healthcare and community resources\(^{1162,1163,1164,1165}\).

(4) Underpinned by CBT principles, the **Flinders Model** can be used for any psychiatric or medical condition with comorbidities through the provision of a structured, patient-centred framework in which interventions are tailored to patient needs and priorities identified with the individual\(^{1166}\). Clinically important patient benefits have been reported from CDSMPs in a variety of chronic diseases including asthma\(^{1167}\). Most CDSMPs focus upon physiologic outcomes in patients with chronic conditions\(^{1168}\), but improved mental health outcomes have also been shown following CDSMPs in patients with depression\(^{1169,1170}\) and anxiety\(^{1171}\).

Self-Management and Medical Management may not at first glance appear to be complementary\(^{1172}\), but collaborative care that includes training and support of health providers,


\(^{1162}\)Wagner EH, Austin BT, Von Koroff M. Organizing Care for Patients with Chronic Illness. *Milbank Q* 1996; 74: 511-44


\(^{1164}\)Bodenheimer T, Wagner EH, Grumback K. Improving primary care for people with chronic illness. *JAMA* 2002; 288:1775-1759


\(^{1169}\)Neumeyer-Gromen A, Lampert T, Stark K et al. Disease management programs for depression; a systematic review and meta analysis of randomized trials. *Med Care* 2004; 42: 1211-21


\(^{1172}\)Gruman J, Von Korff M. Self-management services. Their role in disease management. *Dis Manage Hlth Outcomes* 1999; 6:151-158
patients and carers improves outcomes across a range of chronic conditions\textsuperscript{1173}. The Stanford Model has been at the forefront of self-management programs aiming at people with a range of chronic conditions\textsuperscript{1174}, targeting ability to deal with frustration, fatigue and pain, exercise programs, correct medication use, communication, nutrition and evaluation of treatments. Significant improvements have been described for participants’ exercise, cognitive symptom management, communication with doctors, self-reported general health, health distress, fatigue, disability management and social role activities. In diabetes, for example, patients perceived greater sense of control over their condition\textsuperscript{1175,1176} and hence better glycaemic control. The programs are well-suited to community-based care as they often employ trained lay-leaders.

Self-management features extensively in the management of \textit{asthma}. Specific education programs and supports demonstrate better knowledge about asthma, reduced hospitalisation and better health-related quality of life in randomised and controlled trials lasting for up to one year\textsuperscript{1177,1178,1179,1180,1181,1182,1183,1184}. A systematic review has analysed the benefits noted in the fifteen trials meeting inclusion criteria for asthma self-management\textsuperscript{1185}. More intensive training of patients in how to adjust medications was more effective in changing behaviour and reducing health care costs.

Based on these successes in non-respiratory and asthma areas, self-management was suggested as a specific strategy for \textit{COPD}\textsuperscript{1186}, and results of such approaches have recently been reported. Medication adjustment in addition to usual GP care has been compared to usual GP care in a

\begin{itemize}
  \item \textsuperscript{1173} Von Korff M, Gruman J, Schaefer J, et al. Collaborative management of chronic illness. \textit{Ann Intern Med} 1997; 127:1097-1102
  \item \textsuperscript{1174} Lorig KL, Sobel DS, Stewart AL, Brown BW, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalisation – A randomised trial. \textit{Med Care} 1999; 37:5-14
  \item \textsuperscript{1175} Halford WK, Goodall TA, Nicholson JM. Diet and diabetes (II): A controlled trial of problem solving to improve dietary self-management in patients with insulin dependent diabetes. \textit{Psychol Health} 1997; 12:231-238
  \item \textsuperscript{1178} Allen RM, Jones MP, Oldenburg B. Randomised trial of an asthma self-management program for adults. \textit{Thorax} 1995; 50:731-738
  \item \textsuperscript{1179} D’Souza W, Burgess C, Ayson M, Crane J, et al. Trial of a “credit card” self-management plan in a high-risk group of patients with asthma. \textit{J Allergy Clin Immunol} 1996; 97:1085-1092
  \item \textsuperscript{1183} Cote J, Bowie DM, Robichaud, Parent JG, et al. Evaluation of two different educational interventions for adult patients consulting with an acute asthma exacerbation. \textit{Am J Respir Crit Care Med} 2001; 163:1415-1419
  \item \textsuperscript{1185} Powell H, Gibson PG. Options for self-management education for adults with asthma. \textit{Cochrane Database Syst Rev} 2006; Issue 4
  \item \textsuperscript{1186} Worth H. Self management in COPD: One step forward? \textit{Patient Educ Counsel} 1997; 32 (Suppl 1): S105-S109
\end{itemize}
randomised controlled trial, with significant improvements seen in initiation of medications for increased symptoms and correct antibiotic use\textsuperscript{1187}. A similar study of patients with asthma and COPD also found significantly fewer GP visits and better health-related quality of life in the intervention group\textsuperscript{1188}. Whether this single dimension of medication self-management, which is so important in asthma, can be translated to other aspects of self-management was examined in a large prospective randomised controlled study. After one year the patients with asthma who had received the comprehensive self-management training had significantly more perceived control and self-confidence regarding their asthma, though there were no significant improvements in clinical outcomes\textsuperscript{1189}.

Several CDSMPs have been trialled with COPD patients. Some studies found that CDSMPs reduced the frequency or length of hospitalisations\textsuperscript{1190,1191,1192,1193}, and were cost effective\textsuperscript{1194} while others found little evidence of their effectiveness\textsuperscript{1195,1196,1197}. A systematic review in 2003 concluded that, due to the paucity of good quality studies there was a need for further research on the efficacy of CDSMPs for patients with COPD in well-designed trials\textsuperscript{1198}. Moreover, several authors concluded that the inclusion of a mental health component may be critical to the effectiveness of CDSMPs for COPD patients\textsuperscript{1199,1200,1201,1202,1203}. Importantly, mental health issues


\textsuperscript{1188} Gallefoss F, Bakke PS, Rsgaard PK. Quality of life assessment after patient education in a randomized controlled study on asthma and chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 1999; 159:812-817

\textsuperscript{1189} Lorig K, Holman H, Sobel D. Living a Healthy Life With Chronic Conditions. \textit{Palo Alto, California: Bull Publishing Co} 1994


\textsuperscript{1193} Poole PJ, Chase D, Frankel A, et al. Case management may reduce the length of hospital stay in patients with recurrent admission for chronic obstructive pulmonary disease. \textit{Respirology} 2001;6:37-44


\textsuperscript{1196} Martin IR, McNamara D, Sutherland FR, et al. Care plans for acutely deteriorating COPD: a randomized controlled trial. \textit{Chron Respir Dis} 2004;1:191-195

\textsuperscript{1197} McGeoch GR, Willsman KJ, Dowson CA, et al. Self-management plans in the primary care of patients with chronic obstructive pulmonary disease. \textit{Respirology} 2006;11:611-618


\textsuperscript{1202} Wall MP. Predictions of functional performance in community-dwelling people with COPD. \textit{J Nurs Scholash} 2007;39:222-8
may affect the ability of patients to manage their illness. For example, self-management knowledge that patients can achieve when well not infrequently breaks down during severe exacerbations if they have significant tendency to panic\textsuperscript{1204}. A small qualitative study reported that COPD patients supported the use of CDSMPs, but believed that they should be individualized and include strategies for addressing anxiety and depression\textsuperscript{1205}. Dyspnoeic people with COPD who used self-management strategies that focussed on easing dyspnoea during activities (eg controlling overall movement or pacing – n=79) described lower levels of dyspnoea intensity and dyspnoea distress\textsuperscript{1206}. A prospective randomised trial in COPD patients (n=103) comparing dyspnoea self-management (DSM), DSM plus four supervised exercise sessions, and DSM plus 24 supervised exercise sessions found longer duration of exercise training was more effective in controlling dyspnoea, but DSM alone also had positive effects on dyspnoea\textsuperscript{1207}. Using an expensive personalised self-management intervention for 191 patients with moderate and severe COPD, a Canadian multicentre study showed significant reductions in hospital admissions\textsuperscript{1208}, though the main author acknowledges as well that further research is needed\textsuperscript{1209}.

**Home Care**

Although the potential for home care of severe COPD exists, the evidence supporting its benefits is not yet established in randomised controlled trials\textsuperscript{1210,1211,1212}. The CHRONIC Program (developed and evaluated in Spain and Belgium)\textsuperscript{1213,1214} is showing early promising results. Nevertheless, because elderly people disabled by COPD actually receive fewer home supports, such as direct and supportive nursing care and physiotherapy than similar-aged patients with other disabling illnesses including Parkinson's disease, stroke, amputation or arthritis\textsuperscript{1215}, improvements may be more evident when inequities are redressed and specific patients in need


\textsuperscript{1205} Costi S, Brooks D, Goldstein RS. Perspectives that influence action plans for chronic obstructive pulmonary disease. *Can Respir J* 2006; 13:362-368

\textsuperscript{1206} Christenbery TL. Dyspnea self-management strategies: use and effectiveness as reported by patients with chronic obstructive pulmonary disease. *Heart Lung* 2005; 34:406-414


\textsuperscript{1209} Bourbeau J. Disease-specific self-management programs in patients with advanced chronic obstructive pulmonary disease: a comprehensive and critical evaluation. *Dis Manage Hlth Outcomes* 2003; 11:311-319


\textsuperscript{1212} Ram FS, Wedzicha JA, Wright J, Greenstone M. Hospital at home for acute exacerbations of chronic obstructive pulmonary disease. *Cochrane Database Syst Rev* 2003:CD003573


\textsuperscript{1215} Yohannes AM, Roomi J, Connolly MJ. Elderly people at home disabled by chronic obstructive pulmonary disease. *Age & Ageing* 1998; 27:523-525

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are more effectively targeted. This approach, though, needs further careful analysis before it can be recommended for widespread introduction.

A further intervention receiving interest, as technological advances in communication are maturing, is that of the “telephone hotline”. This allows patients from their home to access advice at any time of day or night, and its development has been supported by consumer focus groups. One example (in Western Sydney), was evaluated over a 2-year observational period. There were 675 calls made by 118 patients, 56% of calls being made “after hours”. It is at these times that patients do not have access to their usual family doctor or consultant physician. In 12% of cases hospital presentation was averted by advice given, and there were no adverse effects1216.

Pulmonary Rehabilitation involves a multi-disciplinary team, aims to enhance patient self-efficacy and to involve carers, and should have a clear commitment to quality improvement through feedback and discussion with all people involved in the care of each patient. Despite these intentions, no convincing evidence of better self-management has been shown in studies that have examined this outcome1217,1218,1219,1220, though problems of statistical power and experimental design limit the conclusions. PR and Patient Support Groups, however, are well placed to provide training for patient self-management.

Expert Patients
Another option for SM training is to use lay leaders. The Stanford Model is an example of this (see above). Another, derived from the Stanford Model, is the Expert Patients Program, developed within the UK National Health Service Plan1221. A cost-effectiveness evaluation of the EPP in chronic conditions (mostly endocrine and musculoskeletal problems) has been reported1222. In this program patients self-referred from advertisements in GP surgeries and local media. Patients attended six 2.5 hour group sessions weekly in groups of 8-12 led by patients who already experienced long-term conditions and who had been trained and quality-controlled. Better patient outcomes at slightly lower cost than patients in the six month waiting list control group.

Shared Care
Participation by primary care practitioners and specialist care physicians in providing planned care programs for patients with chronic conditions, enabled by exchange of information has become known as Shared Care. This has been shown effective in diabetes, but has been applied to other conditions as well. There are several models:

1217 Ojanen M, Lahdenso A, Laitinen J, Karvonen J. Psychosocial changes in patients participating in a chronic obstructive disease rehabilitation program. Respiration 1993; 60:96-102
Community Clinics
Specialists attend a clinic in the primary care setting with general practitioners and/or specialist
and/or GP practice nurses. Communication is not systematic, but may include a time for meeting
together to discuss cases.

Basic Shared Care model
Systematic communication is established between specialists and primary care practitioners, each
in their own environment, coordinated by an administrator.

A systematic review of these types of models concluded no recommendations could be made due
to under-powered studies and inconsistent outcomes being reported\textsuperscript{1223}.

Liaison model
Liaison meetings are attended by primary care practitioners and specialists to discuss ongoing
management of registered patients.

Shared Care Record Card
A shared medical record is used by all primary care and specialist practitioners, and
communications made through this (usually patient-held) record.

Computer-Assisted Shared Care
An agreed data set is established to allow collection of common data, and access is provided
through a central repository as required by registered health professionals, and/or new
information additions are notified by email.

These three models were subjected to systematic review, with 19 randomised controlled trials
being identified. There were no consistent benefits in terms of physical or mental health,
disability measures, hospital admissions or satisfaction, but more consistent prescribing
(adherence with guidelines) was clearly evident\textsuperscript{1224}.

4.5 Support Groups for Patients and Carers

In many chronic disease groups communal support (for both the patients and their families or
other carers) has proven helpful. The most common areas researched have been those relating to
cancer and psychosocial problems. Patients attending support groups (SG) scored lower on scales
of stress, confusion, fatigue and maladjusted coping responses and higher on a vigour index than
control group patients\textsuperscript{1225}. As an active psychosocial intervention for cancer, community group
sessions for patients with metastatic breast cancer were evaluated\textsuperscript{1226}. These groups were
educated about coping with their own symptoms and supporting their colleagues. Self-hypnosis
was taught for control of pain, and communication with health professionals or peers about their

\textsuperscript{1223} Gruen RL, Weeramanthri TS, Knight SE, Baillie RS. Specialist outreach clinics in primary care and
\textsuperscript{1224} Smith SM, Allwright S, O’Dowd T. Effectiveness of shared care across the interface between primary
CD004910
\textsuperscript{1225} Spiegel D, Bloom JR, Yalom I. Group support for patients with metastatic cancer: a randomized
outcome study. Arch Gen Psychiatry 1981; 38:527-533
\textsuperscript{1226} Spiegel D, Bloom JR, Kraemer HC, Gottheil E. Effects of psychosocial treatment on survival of
patients with metastatic breast cancer. Lancet 1989; 14:888-891
fears was actively encouraged. This study showed a somewhat surprising significant improvement in longevity as well as quality of life, and the effect has been replicated.\textsuperscript{1227}

Group support has also developed in the fields of Dementia and Alzheimer’s disease, schizophrenia and other mental illnesses, severe arthritis, asthma, cancer, and diabetes mellitus. In many of these fields controlled trials have shown at least short-term benefits. For example, male patients positive for HIV who were regular SG attendees reported lower levels of emotional distress, used more effective coping strategies, and had higher perception of efficacy and control than control group subjects.\textsuperscript{1228} In an alcoholic population, SG attendance was the most powerful predictor of treatment success.\textsuperscript{1229} SG attendance has been found to reduce the number and duration of hospitalisations in mentally ill patients.\textsuperscript{1230} In many studies, however, longitudinal data are not provided, and where such data do exist, they are less supportive of sustained benefit.

In COPD, there are no published randomised controlled trials of benefits from or costs of SGs. A recent pilot study on recently discharged COPD patients found positive health outcomes from a community intervention programme consisting of medical education and community and peer support. There were improvement in symptoms, exercise tolerance, quality of life and of the perceptions of illness, and the authors concluded that the group environment might reduce depression and anxiety by improving self-efficacy or self-esteem through the provision of mutual support.\textsuperscript{1231}

In Australia, the Australian Lung Foundation’s LungNet has been a popular development among its 8,000 or more members, in spite of a lack of efficacy shown in randomised controlled trials. There are published abstracts from several controlled studies in Australia that mirror observations made in other disease populations. These examined the psychological health and handicap of carers of patients with COPD, and of changes in the handicap experienced by carers following their patient’s involvement in PR and in SGs. The results showed similar psychological health problems in caregivers of patients with chronic lung disease as in carers of other disease populations, significant linkages between psychological health of carers and patients, a reduction in their burden of care following PR or SG involvement, and a shift in activities between carers and patients (reflecting a reduction in patient dependence), suggesting that SGs for COPD patients may be useful adjuncts to PR.

\textsuperscript{1230} Lustig SL, Malomane E, Tollman S. A support group for mentally ill people. World Health Forum 1997; 18:319-322
\textsuperscript{1232} Cafarella P, Frith P. Psychological status of COPD Patients and their carers are linked. Respirology 2001; 6 (Suppl):A36
\textsuperscript{1233} Cafarella P, Frith P. Pulmonary Rehabilitation reduces carer strain and psychological morbidity. Respirology 2000; (Suppl): A43
\textsuperscript{1234} Cafarella P, Frith P. Patient completion of pulmonary rehabilitation reduces carer handicap. Respirology 2001; 6 (Suppl):A35
\textsuperscript{1235} Cafarella P, Frith P. Benefits of Lung-Net support group membership. Respirology 2002; 7 (Suppl):A33
\textsuperscript{1236} Cafarella P, Frith P. Carers assessment of patient social adjustment following pulmonary rehabilitation. Respirology 2001; 6 (Suppl):A12
It seems logical to encourage patients and their carers to attend SGs for social support also to receive continued reminders of the benefits of activities and good nutrition. It also appears logical to recommend SG membership as a standard follow-on from attendance at a PR program. These recommendations are to date unsupported by evidence in respiratory disease. If such recommendations are followed, though, attention should be given to aligning the information and activities of the SG with those of the PR program.

### 4.6 Staffing for Pulmonary Rehabilitation

Over the thirty-five years in which formal PR programs have been operating, a range of professionals have contributed to the programs and their evolution. In the US, for example, respiratory therapists were lead professionals, with exercise physiologists and other respiratory scientists, respiratory internists (physicians), specialists nurses, physiotherapists and mental health workers adding expertise in various quanta at different times. It is clear that in Australia physiotherapists have established many programs, initially for exercise training, and often based on cardiac rehabilitation experiences. Specialist nurses have emerged within the past 20 years, and have increasingly played primary roles in PR programs, particularly contributing an education emphasis. Expert assistance has been recruited from respiratory scientists and from other allied health professionals. It has only been in the past 10 years, however, that respiratory physicians have widely acknowledged the value of PR, and many have now assumed either supportive or organisational roles. Community health workers have begun to make a contribution, especially since coordinated and integrated care have become more interesting to system managers. An emerging professional group, especially in cardiac rehabilitation, is from the exercise science stream.

At the outset, it should be said that there is no single best staffing structure. There is essentially no evidence base for recommending any particular craft group’s central role, involvement or exclusion. It is not the intention of this document to provide credentials or the basis of a credentialing process. Indeed, local needs will inevitably dictate local solutions. However, there are some principles that administrators and all staff need to acknowledge, and this Chapter aims to clarify these.

The definitions of PR emphasise the importance of multidisciplinary inputs, integration of services and goals of service provision\(^\text{1237, 1238}\).

The issues that impact on the patient with a chronic respiratory condition, and on the carer, largely dictate the range of services that need to be provided, and the personnel who logically should be involved in delivering the outcomes. Local needs and limitations will influence who can deliver the basic information package and even who supervises exercise training. In a regional centre, for example, a PR program may be coordinated by a community nurse, who may also provide the entire education program, perhaps with help from a local pharmacist, GP and mental health worker. Aboriginal health workers can also provide a culturally-tailored PR program. An exercise training program in the community setting could be organised and


supervised by exercise scientists and/or physiotherapists. Medical knowledge could be delivered by a GP, a respiratory physician, a nurse or respiratory educator, and information on how to use respiratory medications could be delivered by a doctor, pharmacist or respiratory educator.

**Staffing Philosophies**

Whoever establishes and coordinates a PR program, and whatever staff they employ, need to understand the philosophy of PR and the needs of the participants. Above all staff should be enthusiastic, motivated and committed to patient well-being, which is, after all, the prime goal of PR. They should appreciate that chronic respiratory diseases are complex and are associated with an extraordinary range of non-respiratory issues, of medical, psychological and social nature. There is nothing wrong with being excited with an individual patient's achievements arising from their membership of a group, or with being at all times optimistic in the face of apparent failure. Small gains to a therapist can represent enormous accomplishment to a highly disabled patient, or to an over-burdened carer.

It is all too easy for an interdisciplinary program to begin to believe that staff or structure are the reasons for being. It must always be remembered that the program exists for the patient, and that it is part of that patient's continuum of treatment and even of life experience.

Full-time staff and contributing providers should have an understanding of the role of PR in overall disease management, and some appreciation of health economic issues. They need to be committed to performance development and continuous improvement, to be aware of their own roles and responsibilities, the role and responsibilities of their colleagues and the participants, and the overlapping and interacting nature of these roles and responsibilities.

In an ideal interdisciplinary environment the priority should be the team, and professional or personal jealousies are unnecessary. On the other hand, team leaders need to recognise the professional knowledge, experience and skills each team member brings to the program, and team members should acknowledge each other's contributions to the collective knowledge. Communication is essential for good team management and quality improvement, and should be given high priority.

**Structure**

The structure of a PR program team is subordinate to its function and philosophies. However, some structure will be required to sure the function and philosophies are followed.

**Program Director**

Any team needs a captain at the very least. The professional heading the team should have a substantive time commitment to the role, and have sufficient knowledge and experience to understand the special attributes of patients with chronic and complex respiratory disease, their carers, and the therapists on the team. An appreciation of and preferably a role within the overall organisation of respiratory services in the region is also necessary. In large hospitals the Program Director may be a respiratory physician, a nurse manager, or a senior allied health professional. In a community or regional centre, a similar spectrum of staff may aspire to such a position, but a senior administrator may also possess many of the required attributes. The Program Director and Medical Director may be one and the same person.
The Program Director is administratively and professionally responsible for the efficient running of the program. He/she will therefore supervise budgets, staffing issues, plant, equipment, consumables, the setting and reviewing of policies and program goals, communication within the team and from the members of the program, and ensure that the program fits well with other elements of the care continuum.

**Medical Director**
Sometimes the Program Director will also be the Medical Director. The Medical Director is a vital link to the medical profession. He/she is responsible for informing doctors in all health sectors of the benefits, costs and positioning of PR, recommending strategies for patient involvement, ensuring good medical care in continuity with primary care and specialists, maintaining high quality information relating to evidence-based best practice, and ensuring other health professionals understand chronic complex respiratory diseases and their management.

The Medical Director of a Comprehensive PR Program should be a fully qualified Respiratory Physician, with experience in care of patients with chronic complex respiratory diseases, and knowledge of respiratory physiology and exercise physiology.

**Program Coordinator**
A coordinator of activities is required. This may be an administrative/clerical officer or a health professional. The Program Coordinator is responsible for ensuring that patients referred to the program are enrolled for initial assessments, all elements of the program, and follow-up in a timely fashion. Print materials and other educational aids need to be organised. A communication stream between referring professionals or organisations and the PR program needs to be maintained in full working order. The team members need to be informed about team meetings and the times of their sessions in the program. Patient access needs to be facilitated, and carers assisted where necessary. Above all, the Coordinator is often the public face of the program, and needs to be well informed about the program, patient and compassionate.

**Professional Team Members**
As indicated above, there is a wide array of health professionals who may interact with patients and be useful contributors to a PR program. They should all consider themselves to be team members and, as indicated, have a full understanding of and commitment to patient well-being and the philosophies of the Pulmonary Rehabilitation.

The following professionals could be team members:
- Respiratory Physician
- General Physician
- General Practitioner
- Respiratory Nurse
- Community Nurse
- Pharmacist
- Respiratory scientist / technologist
- Exercise scientist
- Physiotherapist
- Occupational therapist
- Psychologist
• Psychiatrist
• Mental health worker
• Behavioural scientist
• Volunteer coordinator
• Community health worker
• Social worker
• Nutritionist
• Dietician
• Speech pathologist
• Continence nurse
• Palliative care nurse of physician
• Chaplain / pastoral care associate
• Vocational rehabilitation counsellor or therapist
• Massage therapist
• Home-care associate

There may be roles for other health or caring professionals as well, according to local custom or availability. While there has been no acknowledgement of a role for volunteers in American guidelines, it is very appropriate that volunteer workers could provide valuable input, especially for carer support such as respite, social outing support, patient support group organisation, fund-raising, and so on.

**Communication**

Members of the team can contribute best to the team approach if they are part of a communication net. This applies equally to management, staff and consumers.

Regular meetings should be held (face-to-face or teleconferenced) which all team members attend, with the prime purpose being review of the program. This may be twice a year. It may suit some programs to have planning days off-site (eg every two years) to re-set goals, priorities, policies, facilities, staffing structures, and other pertinent matters.

Meetings about individual patients or emergent program problems may be required ad hoc, involving any combination of staff relevant to the problem. It may suit some programs to arrange a regular meeting of an "executive group" to ensure problems about individual patients and program matters are resolved in the most expeditious was possible.

All staff members need to maintain a strong commitment to free communication with patients and their carers, both prospective and reactive. A telephone contact point needs to be agreed for these consumers, and this may be the coordinator or one of the team members.

Results of initial assessments and of outcome measurements should be communicated to the referring professional and others involved in the care of the patient as quickly as possible after the results are tabulated. The Medical Director may need to append suggestions about ongoing management. Any Action Planning done with the patient needs to be transmitted to the GP and other vital care members, also in a timely way.
COMPREHENSIVE PULMONARY REHABILITATION
KEY POINTS

1) Comprehensive PR is integrated inter-disciplinary treatment

2) It should include exercise training, psychosocial support, and education directed to behaviour change and self-management

3) Nutritional advice and teaching breathing techniques may be of additional help

4) Comprehensive PR is highly effective and cost-effective for improving functional status, exercise capacity and health related quality of life for people with moderate to severe COPD

5) Clinically significant improvements in dyspnoea, fatigue and mastery occur following programs that include exercise training for at least 4 weeks

6) Family caregivers are adversely affected by their spouse’s COPD, and can be helped by the patient’s involvement in PR

7) Support groups help to improve quality of life, and may improve both patient and family caregiver
5. CLINICAL INDICATORS AND OUTCOME MEASUREMENT

In this section, an attempt is made to provide an understanding of the type, derivation, meaning, validity and application of particular indicators. Where possible, references are made to the uses of each indicator in specific research studies, associations with other indicators and outcome measures and their demonstrated or recommended clinical applications. There are several review documents that provide useful perspectives on biomarkers\textsuperscript{1239}, clinical indicators\textsuperscript{1240}, and clinical outcomes\textsuperscript{1241,1242,1243,1244}, and the important properties of measurement tools to evaluate when deciding what to use\textsuperscript{1245}.

5.1 Respiratory Symptoms

Patients undertaking therapeutic interventions often report changes in symptoms. In COPD the main symptoms are dyspnoea (unpleasant or uncomfortable respiratory sensations, for which there may be multiple descriptors\textsuperscript{1246}), cough, and sputum production (a defining feature of Chronic Bronchitis). Attempts made to standardise reporting of these symptoms have not given much attention to the reproducibility or sensitivity of the instruments, particularly in COPD. The tools usually rely (inevitably) on self-assessment and self-report, with inherent biases. Frequency or severity of coughing, and frequency, amount and colour of sputum are dependent on a range of patient factors, with the psychological status\textsuperscript{1247} and cognitive capacity (notably verbal memory)\textsuperscript{1248} being major variants.

Dyspnoea

Chronic dyspnoea and pain are the two most universally disabling symptoms. They are initiated by a variety of primary pathophysiologies, sensed by peripheral receptors, perceived centrally and interpreted, then expressed behaviourally. In respiratory conditions dyspnoea is the chief symptom, experienced on a daily basis by at least half those with COPD\textsuperscript{1249}, and by virtually all COPD sufferers through any one year of life\textsuperscript{1250}. The inputs to perceived breathing discomfort are legion, and the interpretations of the sensation

\textsuperscript{1240} Jones PW, Agust\textsuperscript{i} AGN. Outcomes and markers in the assessment of chronic obstructive pulmonary disease. *Eur Respir J* 2006; 27:822-832
\textsuperscript{1241} Curtis JR, Martin DP, Martin TR. Patient-assessed health outcomes in chronic lung disease. What are they, how do they help us, and where do we go from here? *Am J Respir Crit Care Med* 1997; 156:1032-1039
\textsuperscript{1243} Sullivan SD, Buist AS, Weiss K. Health outcomes assessment and economic evaluation in COPD: challenges and opportunities. *Eur Respir J* 2003; 21 (Suppl 41);1s-3s
\textsuperscript{1244} Gross NJ. Outcome measures for COPD treatments: A critical evaluation. *COPD 2004*; 1:41-57
\textsuperscript{1245} Jones PW, Kaplan RM. Methodological issues in evaluating measures of health as outcomes for COPD. *Eur Respir J* 2003; 21 (Suppl 41):1s-18s
vary widely\textsuperscript{1251,1252}. The verbal descriptors used by patients for what they mean by dyspnoea are also very individual\textsuperscript{1253,1254}, as is the recall patients have about the severity and frequency of their dyspnoea\textsuperscript{1255,1256}. Consequently, the evaluation of dyspnoea is complex\textsuperscript{1257,1258}. Recent review have summarised these issues\textsuperscript{1259,1260}. Dyspnoea has been widely studied, using simple measures of performance dyspnoea, detailed analyses of baseline and changing dyspnoea, and characterisations of the sensations of dyspnoea both at one time point and longitudinally. Dyspnoea ratings have correlated with well being and HRQoL better than FEV\textsubscript{1}\textsuperscript{1261}. They appear to relate to COPD perceived severity and predict survival better than traditional severity stages based on FEV\textsubscript{1}\textsuperscript{1262,1263}. The most widely used and tested objective measures of dyspnoea are the Medical Research Council (MRC) Dyspnoea Scale, Oxygen Cost Diagram (OCD), Modified Borg Score, visual analogue scales (VAS), Baseline and Transition Dyspnoea Indexes (BDI/TDI), and scores for dyspnoea contained within HRQoL instruments (especially CRDQ – see below). An analysis of outcome measures in an open study of comprehensive PR found that VAS at peak exercise, MRC Grades, CRDQ Dyspnoea, and BDI/TDI functional indexes were highly responsive to change after PR, with SGRQ symptom score being less responsive. However, there were close correlations between the different dyspnoea indexes. The CRDQ and VAS at peak exercise were the most sensitive, while BDI/TDI and MRC Scales were moderately sensitive\textsuperscript{1264}.

**MRC Dyspnoea Scale**

Originally reported in 1960, this scale lists five grades of perceived disablement, taken directly from the sensation of breathlessness felt by an individual during a range of typical daily activities\textsuperscript{1265,1266}.

\begin{footnotesize}
\textsuperscript{1256} Meek PM, Lareau SC, Anderson D. Memory for symptoms in COPD patients: How accurate are their reports? *Eur Respir J 2001; 18:474-481*
\textsuperscript{1262} Hajiro T, Nishimura K, Tsukino M, Ikeda A, et al. A comparison of the level of dyspnoea vs disease severity in indicating the health-related quality of life of patients with COPD. *Chest 1999; 116:1632-1637*
\textsuperscript{1263} Nishimura K, Izumi T, Tsukino M, Oga T. Dyspnea is a better predictor of 5-year survival than airway obstruction in patients with COPD. *Chest 2002; 121:1434-1440*
\textsuperscript{1264} de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. *Chest 2002; 121:1092-1098*
\textsuperscript{1266} Fletcher CM. Standardised questionnaire on respiratory symptoms: a statement prepared and approved by the MRC Committee on the Aetiology of Chronic Bronchitis (MRC Breathlessness Score). *Br Med J 1960; 2:1665*\
\end{footnotesize}
TABLE 5.1. MODIFIED MEDICAL RESEARCH COUNCIL (MRC) DYSPNOEA SCALE

<table>
<thead>
<tr>
<th>MRC Grade</th>
<th>Activity causing breathing difficulty</th>
</tr>
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<tbody>
<tr>
<td>Grade 0</td>
<td>I only get breathless with strenuous exertion</td>
</tr>
<tr>
<td>Grade 1</td>
<td>I get breathless hurrying on the level or walking up a slight hill</td>
</tr>
<tr>
<td>Grade 2</td>
<td>I have to walk more slowly than people my own age because of breathlessness</td>
</tr>
<tr>
<td>Grade 3</td>
<td>I have to stop for breath after walking around 100 metres on level ground or after walking a few minutes on level ground</td>
</tr>
<tr>
<td>Grade 4</td>
<td>I am too breathless to leave the house because of breathing difficulty, or I get breathless when dressing or undressing</td>
</tr>
</tbody>
</table>

The MRC Scale correlates well with the 12-minute walking distance, shuttle walk distance, SGRQ Activity and Impacts Scales, and the CRDQ dimensions of Fatigue, Emotional Function and Mastery Scores, but less well with spirometry ($r=-0.42$). Surprisingly, MRC Grades do not correlate as well with CRDQ Dyspnoea dimension, perhaps because each individual selects his/her own set of activities causing breathlessness in the latter. MRC Grades also correlate with BDI focal score, as well as with each component of BDI ($r=0.61$ to $0.74$), and with the OCD ($r=0.53$ to $0.59$).

This questionnaire is simple for the patient to answer as it is relevant to everyday activities, can be completed in about 30 seconds and has excellent inter-observer agreement. It has been used to grade clinical severity of COPD in rating impact of dyspnoea on HRQoL, and more effectively discriminated prognosis/survival than FEV1 in a five-year observational study of 227 patients with COPD. Subsequently it has been included as the dyspnoea rating tool with body mass index, FEV1 and 6-minute walk distance in the BODE Index, which provides a high correlation with survival in moderate and severe COPD. Although a rather coarse tool, in which a change in Grade by one is highly clinically relevant, it is reasonably responsive to interventions such as PR ($p=0.018$), though less so than VAS after a 6-minute walk test or BDI/TDI. MRC Scale is recommended by NICE and COPD-X guidelines for management of COPD as a cross-sectional indicator of disease severity.

**Oxygen Cost Diagram (OCD)**

This measure was devised in an attempt to equate certain activities to their metabolic requirements. Each stated activity is represented at intervals along a 100 mm line, and the individual is asked to indicate with a mark on the line above the activities that most consistently would cause him/her to be breathless. Like the MRC Scale, therefore the OCD provides an insight into the threshold of activities causing the individual disabling breathlessness. The OCD has not been widely used as a clinical indicator of dyspnoea or as an outcome measure. It does correlate well with MRC Grades ($r=0.53$) and BDI focal score ($r=0.54$).
and sub-elements of BDI (r=0.48 to 0.50), but less well with spirometry (r=0.16 to 0.48). The OCD may require careful explanation before completion, and takes one to two minutes to complete. Its clinical utility has not been established.

**Modified Borg Score**

The development and methodology of this non-linear scale is based on psychophysical principles, and has been widely used in exercise testing since its first description. It allows the patient to match the perceived severity of symptoms or of effort with numbers on the scale, and directly indicates the patient’s perceived dyspnoea (or other symptom) during a specified task. Scores can be indicated at different workloads, though the score at maximum work is the most reproducible. Scoring requires brief (but standardised) explanation before use, and standardised questions should be used each time. Each estimate takes a few seconds. Scores are highly repeatable in the short term, but less so in the longer term. The measure of exercise performance is more repeatable than the Borg rating at load, but Borg Scores correlate well with magnitude of work performed and total ventilation. Responsiveness to interventions like PR is not clear, though if measured at ‘isotime’ (i.e. the same time of serial exercise tests regardless of the maximum load reached) use of tiotropium has been shown to reduce Borg Dyspnoea significantly.

**Visual Analogue Scale (VAS) at peak exercise**

The VAS has been used in a variety of clinical settings since its first description in 1957. Whereas the Borg scale is non-linear and discontinuous, VAS is continuous and linear. It consists of a 100 mm line on which the patient indicates a mark according to perceived breathing discomfort, with anchor points at each end of nil and absolute maximum. It has been adapted for application at rest and end of exercise. Baseline VAS is highly repeatable, but VAS during sub-maximal work is variable within subjects over the medium term. VAS has been validated as a clinical indicator for COPD-related dyspnoea, and as an outcome measure in a recent randomised controlled trial of opiates for dyspnoea, where it was found to be repeatable and responsive to the intervention. Further, VAS at the end of a 6-minute walk test changed significantly after completion of PR in an uncontrolled observational study of 37 patients with COPD.

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1287 de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. *Chest* 2002; 121:1092-1098
1291 de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. *Chest* 2002; 121:1092-1098
**Baseline Dyspnoea Index (BDI) / Transition Dyspnoea Index (TDI)**

The BDI is a complex questionnaire divided into three components\(^{1292}\). These address the degree of “functional impairment” (relating to disability due to breathlessness), magnitude of the task required to produce the breathlessness, and the magnitude of the effort that produces shortness of breath. Each component is divided into five grades. It was proposed that each of the three components contributed different elements to the sensation of dyspnoea\(^{1293}\).

A trained observer asking open-ended questions about symptoms administers the BDI, and then scores each category in turn by interpreting the patient’s responses as a degree of impairment related to dyspnoea for each component. The three ratings (each between 0 and 4) are added to create a “focal score” (0 to 12, with 12 indicating no impairment, and 0 indicating the most severe disability possible). Questioning by experienced observers is takes between 2 and 5 minutes\(^{1294,1295}\). BDI has been extensively validated in a variety of respiratory diseases including COPD, and its reliability and validity are high\(^{1296,1297}\). BDI correlates with severity of airways obstruction (r with FEV1 =0.31 to 0.42), inspiratory muscle strength (r with Pimax=0.43 to 0.49), and maximum oxygen uptake (r with VO2max =0.46), but not with degree of gas trapping (r= -0.14). Good correlations have been shown between BDI and physical functioning, role functioning, health perceptions and social functioning dimensions of the Medical Outcomes Scale (MOS) Short Form (SF) 20-item instrument of generic HRQoL (r=0.36 to 0.70), MRC Dyspnoea Scale (r=0.61 to 0.70), and Oxygen Cost Diagram (r=0.48-0.54).

The Transition Dyspnoea Index (TDI) includes the same three components as the BDI, but the questions posed now relate to a rating of the degree of change from the previous score, ranging from –3 (very marked deterioration), through 0 (no change), to +3 (the greatest possible improvement). In the TDI a score change by 1 or more represents clinically meaningful change, and such changes have been shown to have good face validity (eg in a long-term tiotropium trial\(^{1297}\)). In a prospective uncontrolled study comparing the responsiveness of a range of outcome measures to PR, a clinically significant change in TDI was found in over 50% of patients, with similar percentages showing meaningful changes in VAS at peak

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exercise and in CRDQ\textsuperscript{1308}. The most significant changes seen were in BDI/TDI magnitude of task score (\(p<0.0001\)), and the change in BDI/TDI was most closely correlated with change in CRDQ Mastery Score (\(r=0.65\)) and change in MRC Score (\(r=0.37\))\textsuperscript{1309}.

**Interpretation of Breathing Problems Questionnaire (IBPQ)**

This self-report questionnaire was designed to evaluate the impact of dyspnoea on people with COPD in terms of catastrophising thoughts\textsuperscript{1310}. A short version (IBPQ-S) has been found to have good psychometric properties (internal consistency, Cronbach’s \(\alpha=0.87\); inter-rater reliability, \(k=0.63\); test-retest reliability Wilcoxon matched pairs signed rank test \(p<0.05\)), and related to anxiety triggered by dyspnoea in a comparison with HADS (\(r=0.79\)) in 30 patients with severe COPD\textsuperscript{1311}.

When these issues related to panic need to be considered, this instrument looks to provide reliable insight.

**Pulmonary Functional Status and Dyspnoea Questionnaire (PFSDQ)**

This measure was developed and partly validated to measure both the level of dyspnoea with activities and changes in functional ability\textsuperscript{1312}. It contains 164 items presenting 79 activities of daily living that the patient nominates. The patient nominates the intensity of dyspnoea associated with the activities, as well as any alteration in their functional ability to perform each activity as a result of their COPD. The activities presented are relevant for adults of either gender, reflecting a range of energy requirements, grouped into scales of self care, mobility, eating, home management, social and recreational. Validation shows good validity, stability and reliability for both the dyspnoea and the functional ability domains\textsuperscript{1313}. Changes in dyspnoea do not appear to match declines in lung function over time. Dyspnoea with activities requiring arm elevation showed the sole relationship with rate of FEV1 decline over time.

This tool appears to be useful in research, though no data on its responsiveness to change following interventions have been published. It appears complex and time-consuming and unsuited to routine clinical practice as either an initial assessment or an outcome measure for PR.

**Dyspnoea Management Questionnaire (DMQ-30)**

This instrument was designed to enumerate the behavioural impact of breathing distress and a person’s perceived ability to cope with the dyspnoea\textsuperscript{1314}. It has 30 items that address five dimensions – intensity of dyspnoea, anxiety related to dyspnoea, fearful anxiety avoidance, self-efficacy for activity, and satisfaction with strategy usage. Each question has a 7-point Likert scale. High levels of internal consistency (Cronbach’s \(\alpha = 0.87-0.96\)) and test-retest reliability (intraclass correlation coefficient = 0.71-0.95) have been shown in 85 COPD patients (mainly female). Relevant items correlated well with SOLQ, SF-12 and HADS (see below). Responsiveness to therapeutic interventions and correlations with disease severity as well as other elements of validation still need to be completed, but this instrument looks to have promise as an indicator of the symptom of dyspnoea and its impact at the very least.

\textsuperscript{1308} de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. Chest 2002; 121:1092-1098
\textsuperscript{1311} Gurney-Smith B, Cooper M, Wallace L. Anxiety and panic in chronic obstructive pulmonary disease: the role of catastrophic thoughts. Cognitive Therapy Res 2002; 26:143-155
\textsuperscript{1312} Lareau SC, Meek PM, Roos PJ. Development and testing of the modified version of the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M). Heart Lung 1998; 27:159-168
UCSD Shortness of Breath Questionnaire (SOBQ)

This tool was developed in University of California San Diego, and has been used extensively in one of the foremost PR programs in USA, revised and validated. It appears suited to research if not clinical care\textsuperscript{1315}. It includes 21 activities of daily living covering a range of energy expenditures, and asks patients to rate the severity of dyspnoea they estimate they would experience on a 6-point scale. Three additional questions seek how much limitation there is in their everyday life from (i) shortness of breath, (ii) fear of hurting oneself by over-exerting, and (iii) fear of shortness of breath. Cross-sectional comparisons with FEV\textsubscript{1}, FVC, DLCO, QWB, CES-D, 6MWD, and perceived dyspnoea at the end of a 6MWT showed interesting correlations. Overall health status (QWB) and level of depression (CES-D) correlated significantly, as did most physiological measures, 6-MWD ($r = -0.68$) and Borg dyspnoea ($r = +0.45$). The authors suggest the SOBQ is a reliable and valid measure of dyspnoea, ideally suited to research applications. In a large randomised trial comparing comprehensive PR with an education-alone intervention SOBQ improved in both groups, but significantly more in the comprehensive PR group\textsuperscript{1316}, confirming the responsiveness of the measure. In this same study SOBQ was significantly associated with survival.

The SOBQ has been evaluated for responsiveness alongside other measures, in 164 patients with COPD attending PR. The minimum clinically important difference (MCID) for SOBQ in this study was five units (compared to 0.47 for the CRDQ – in line with previous studies with this instrument – and 0.031 for QWB – also similar to reported levels of significance)\textsuperscript{1317}.

Other measures

HRQoL measures like the CRDQ and SGRQ (described below) can describe the impact of breathlessness on health status. It has been suggested that measures of dyspnoea found in these comprehensive disease-specific health status assessments, notably the Activity dimension of the SGRQ and Dyspnoea component of the CRDQ, may be as useful as the MRC Scale or the BDI\textsuperscript{1318}. In that study, these measures seemed closely inter-related, but there was a distinct difference between Borg at Maximal exercise and other dyspnoea indicators. This difference may relate to the fact that the Borg was measured \textit{at maximal exertion}, while the impact of dyspnoea on activities required the patient \textit{recall their experiences} remotely from the activities.

5.2 Measures of Impairment

Physiological Impairments

Asthma and COPD are characterised by airflow limitation. In asthma there is variability in symptoms and reversibility of airflow limitation following bronchodilator administration, while in COPD the symptoms are more consistent from day to day and bronchodilator responsiveness is incomplete. The measurement of airflow limitation is imperative in all people with respiratory symptoms - as a diagnostic tool, an indicator as severity, and a prognostic indicator.

Spirometry

The most robust test of respiratory impairment is spirometry, from which a large number of variables can be derived. Spirometry requires certain fundamental actions. These include use of a reliable and appropriately calibrated device, adequately trained staff, and assurance of full effort by the patient.

\textsuperscript{1316} Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with chronic obstructive pulmonary disease. \textit{Ann Intern Med} 1995; 122:823-832
\textsuperscript{1317} Kupferberg DH, Kaplan RM, Slymen DJ, Ries AL. Minimal clinically important difference for the UCSD shortness of breath questionnaire. \textit{J Cardiopulm Rehabil} 2005; 25:370-377
For a reliable measurement, the patient must inhale fully to total lung capacity (TLC) then, with lips completely sealed around the mouthpiece, as rapidly and as completely as possible forcibly exhale to residual volume (RV). Efforts should be repeated at standard intervals to ensure consistency of results, and the best effort is taken as the reported measurement. To evaluate bronchodilator reversibility a standard dose of a bronchodilator is administered, with every effort again to ensure optimal inhalation of the dose by the patient. The spirometry test is repeated twenty minutes later. Again the best effort test is used as the reported measurement, and the change from the pre-bronchodilator result is calculated, and then divided by the predicted value to obtain the percent bronchodilator response\textsuperscript{1319}.

Results quote the FEV1 and the FVC, and their change after bronchodilator, as well as the ratio of FEV1/FVC\textsuperscript{1320,1321}. Predictions based on race, gender, age and height are used as reference points. Since FEV1 and VC are reproducible over a long period (Coefficient of Variation, CV <10\%)\textsuperscript{1322}, they can be considered reliable measures in diagnosis, severity rating and response to treatment. That is, they are applicable as clinical indicators and outcome measures. There are several useful checkpoints:

- An FEV1/FVC ratio below 0.70 in adults or below 0.80 in children indicates the presence of airflow limitation.
- In such cases, the level of FEV1 in relation to predicted values is a guide to the grade of severity of the airflow limitation.
- Improvement in FEV1 and/or FVC by more than 15\% and by more than 0.30 litres after bronchodilator is considered a significant bronchodilator response, suggestive of asthma if clinical features are also present.
- An FEV1/FVC ratio above 0.75 in adults with individual values of FEV1 and / or FVC below 80\% predicted suggests the presence of a restrictive disorder. Such findings can also be seen, however, when airflow limitation results in dynamic airway compression and gas trapping. In such cases it is advisable to measure TLC and its subdivisions.

Other measures are also available from the forced expiratory test, especially if the data are electronically derived. Expiratory flow rates at specific lung volumes (eg MEF50), or average flow rate over the middle half of the expiration (eg FEF 25-75 or MMEF), are sometimes used as guides to the presence of early or very mild airflow limitation, especially in small airways. Such measurements are more variable (have wider confidence intervals), and are therefore less robust than the highly repeatable FEV1. The appearance of the expiratory flow-volume curve (Diagram 1) gives an appreciation of the effects of airflow limitation, with reduced peak expiratory airflow in severe cases, a concave expiratory limb, and shifting of the operating lung volumes with gas trapping and hyperinflation.

\textsuperscript{1321} Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories (Crapo RO, Chairman). Standardization of spirometry; 1994 update. Am J Respir Crit Care Med 1995; 152:1107-1136
\textsuperscript{1322} Noseda A, Carpiaux JP, Prigogine T, Schmerber J. Lung function, maximum and submaximum exercise testing in COPD patients: reproducibility over a long interval. Lung 1989; 167:247-257
FIGURE 5.1. SPIROMETRY (VOLUME-TIME PLOT) IN NORMAL PATIENT AND COPD PATIENT

![Spirogram](image)

**Spirogram**

Typical representation of the FVC manoeuvre showing normal and COPD spiromgrams. Note the decreased volume-time slope (i.e. expiratory flow) and prolonged expiratory time to FVC in COPD.

FIGURE 5.2. TYPICAL FLOW-VOLUME CURVES IN NORMAL AND COPD PATIENTS

![Flow-volume curves](image)

**Severe COPD**

Maximal inspiratory and expiratory flow-volume curves in a COPD patient. Note reduced peak expiratory flow and severely decreased flows at 25%, 50% and 75% of VC compared with normal range (vertical bars). There was minimal response to bronchodilator. Absolute values (% predicted) are shown:

<table>
<thead>
<tr>
<th></th>
<th>Pre-BD</th>
<th>Post-BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1</td>
<td>1.1 (44%)</td>
<td>1.2 (47%)</td>
</tr>
<tr>
<td>FVC</td>
<td>3.0 (92%)</td>
<td>3.1 (97%)</td>
</tr>
</tbody>
</table>

**Chronic Asthma**

A patient with substantial but incomplete reversibility. FEV1 increased 46%. Post bronchodilator FEV1 within normal range but mild expiratory flows decreased:

<table>
<thead>
<tr>
<th></th>
<th>Pre-BD</th>
<th>Post-BD</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1</td>
<td>1.0 (35%)</td>
<td>1.4 (52%)</td>
</tr>
<tr>
<td>FVC</td>
<td>1.9 (88%)</td>
<td>2.7 (137%)</td>
</tr>
</tbody>
</table>

MONITORING LUNG DISEASE

KEY POINT

Managing respiratory disease without spirometry and disability measures is similar to diagnosing and treating hypertension diabetes without measuring blood pressure or blood glucose or the impacts of these diseases on the individual.
TABLE 5.2. FEV1 USES AS A CLINICAL INDICATOR AND OUTCOME MEASURE

<table>
<thead>
<tr>
<th>Rationale for FEV1</th>
<th>Usefulness of FEV1</th>
</tr>
</thead>
</table>
| **Diagnosis**<sup>1323,1324</sup> | FEV1/FVC <0.70 indicates airflow limitation  
FEV1 improvement post-bronchodilator > 12% above predicted suggests asthma  
FEV1 fall > 20% post-bronchoconstrictor (e.g. histamine, methacholine, standard exercise) indicates airway hyper-responsiveness, a critical property of asthma |
| **Severity rating**<sup>1325</sup> | Level of FEV1 is an indicator of severity of airflow limitation in asthma and COPD  
Level of FEV1 is used by GOLD to define severity grading for COPD |
| **Prognostic indicator**<sup>1326,1327,1328,1329</sup> | FEV1 predicts all-cause mortality in a general population  
FEV1 predicts outcome from hospital care of COPD exacerbation  
Annual rate of decline in FEV1 predicts survival in COPD  
Annual rate of decline in FEV1 slows after smoking cessation |
| **Outcome measure**<sup>1330,1331,1332</sup> | Test of reversibility with beta-agonist in asthma  
Indicator of reversibility with inhaled corticosteroids in asthma  
Small responses to bronchodilators may occur in COPD  
Response to inhaled corticosteroids in COPD is usually small  
There is minimal response in FEV1 to pulmonary rehabilitation despite improvements in disability measures |

**Complex Lung Function**

Other testing procedures are used to derive static FRC, TLC and other subdivisions of lung volume, gas transfer of carbon monoxide, and a range of other functions (see Introduction)<sup>1333,1334,1335,1336</sup>. These can help understand the effects of airflow limitation (such as gas trapping and hyperinflation) and the efficiency of gas exchange. While they can help to categorise the patient’s physiology and disease severity, they are not useful outcome measures, as they remain essentially unchanged after PR, even when high.

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<sup>1324</sup> Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories (Crapo RO, Chairman). Standardization of spirometry; 1994 update. *Am J Respir Crit Care Med* 1995; 152:1107-1136
<sup>1330</sup> Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories (Crapo RO, Chairman). Standardization of spirometry; 1994 update. *Am J Respir Crit Care Med* 1995; 152:1107-1136
<sup>1334</sup> Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories (Crapo RO, Chairman). Standardization of spirometry; 1994 update. *Am J Respir Crit Care Med* 1995; 152:1107-1136
levels of exercise re-training are included\textsuperscript{1337,1338}. They often do change, on the other hand, after surgical interventions.

**Arterial Blood Gas Measurements**

Blood gas measurements are also performed on blood taken from an artery (usually brachial or radial) to determine the adequacy of oxygenation, gas exchange efficiency, adequacy of ventilation, and acid-base status. These tests do not change after comprehensive PR or any of its components (including exercise training).

**Tests of Static Physiological Impairment**

**Key Points**

Spirometry remains the simplest, most reliable and clinically useful of all physiological tests.

In respiratory disease spirometry is an essential tool for diagnosing airflow limitation, assessing bronchodilator responsiveness, and classifying clinical severity.

Knowledge of arterial blood gases is also vital, as both oxygenation and ventilation (through pCO\textsubscript{2}) can be assessed.

Gas transfer is reduced in the presence of emphysema but not in asthma and this can add to diagnostic specificity.

Lung volume measurements reflect the effects of airflow limitation (distal gas trapping and static hyperinflation).

Spirometry, gas transfer and arterial blood gas analysis are not useful outcome measures in PR because they do not change post-PR, although reduced hyperinflation can occur.

**Exercise impairment**

(a) **Maximal exercise testing**

Maximal (symptom-limited) tests can provide measurement of peak oxygen uptake and a range of other indicators of exercise impairment\textsuperscript{1339}.

**Incremental Exercise Tests**

**ERGOMETER TESTING**

These tests require a carefully calibrated treadmill or cycle ergometer, fast response gas analysers, electrocardiograph, pulse oximeter, and a device to monitor airflow at the mouth. The equipment is

\textsuperscript{1337} Nici L, Donner C, Wouters E, ZuWallack R, et al, on behalf of the ATS/ERS Pulmonary Rehabilitation Writing Committee. American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation. \textit{Am J Respir Crit Care Med} 2006; 173:1390-1413

\textsuperscript{1338} British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation. Pulmonary rehabilitation. \textit{Thorax} 2001; 56:827-834

expensive, the tests are time-consuming for setting-up, conducting and interpreting. Patients often dislike incremental maximal exercise tests because they demand maximal effort and often produce distressing symptoms. However, for accuracy and variety of information about training effects, they are the gold standard. In addition to the physiologic measures it is useful to ask the patient at regular intervals to elect a rating of perceived exertion, breathing difficulty and leg fatigue, using modified Borg scales.

The best form of ergometry is debated. Cycle ergometry is generally considered to provide more reliable results, for several reasons. Quantitation of work performed on a treadmill depends on body weight, stepping cadence, use of arms or shoulder girdle by gripping handrails, and posture (e.g. stooping) can all affect metabolic requirements, and therefore the correlation between apparent level of exercise and actual work performed. Cycle ergometry equipment is cheaper, less space occupying and less noisy. There is greater body stability on the cycle, so ventilation, pulse oximetry and ECG measurements are more stable. For rare patients, however, cycling is impossible and a treadmill is useful. Non-invasive incremental symptom-limited maximal ergometry testing derives the variables shown in Table 5.3. The two parameters derived from exercise testing with least variability over time (CV <10%) in patients with COPD are $V_E$ max and $V_O_2$ max making them useful outcome measures for treatment interventions.

**FIGURE 5.3 CYCLE ERGOMETRY IS HELPFUL IN DETERMINING MAXIMUM EXERCISE CAPACITY AND CLARIFYING CAUSES OF DYSPNOEA**

An important contribution to the understanding of the cause of dyspnoea is dynamic hyperinflation. In people without airflow limitation, there are large reserves in expiratory and inspiratory flows that allow increased ventilation to be achieved without altering operating lung volumes (i.e. higher tidal volume is achieved by increasing flow at iso-volume, reducing tidal end-expiratory volume and increasing tidal end-inspiratory volume). In people with airflow limitation, however, a limit to the expiratory flow and sometimes to inspiratory flow during tidal breathing, either at rest or during exertion, is imposed by airway geometry and lung/airway elastic recoil, and it becomes increasingly difficult to empty the lungs. Increased ventilation can only be achieved by a progressive increase in tidal end-expiratory lung volume, forcing the tidal end-inspiratory volume even higher. In more severe COPD, the static overinflation due to loss of lung elastic recoil with emphysema worsens the dynamic hyperinflation of exercise. By measuring inspiratory capacity (IC) before and during exercise it is possible to observe this dynamic

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hyperinflation\textsuperscript{1342}. Dynamic hyperinflation results in higher work of breathing, as much greater inspiratory pressures are required to overcome the higher elastic recoil for a given change in lung volume\textsuperscript{1343}. This increased work of breathing relates closely to breathlessness\textsuperscript{1344, 1345}.

Several different types of training effects occur after exercise training programs in COPD. The magnitude of these effects is determined by the type and intensity of the exercise undertaken and the duration of the program. For example, strength is built by strength training and endurance training increases endurance in athletes\textsuperscript{1346}, and this probably applies to people with COPD\textsuperscript{1347}. Moreover, the training effects from exercise training are specific to the muscle group exercised\textsuperscript{1348}. In spite of these apparent limitations, other benefits from training have been observed in maximal exercise testing of people with COPD, albeit with some inconsistencies. These include increased work capacity\textsuperscript{1349} and peak oxygen uptake\textsuperscript{1350, 1351}, improved ventilatory function\textsuperscript{1352}, reduced lactate production\textsuperscript{1353} and reduced heart rate response\textsuperscript{1354}. Functional effects perceived by the patient include extended exercise endurance\textsuperscript{1355}, better self-efficacy for exercise\textsuperscript{1356}, less perceived dyspnoea with exertion\textsuperscript{1357}, reduced dependence\textsuperscript{1358}, less depression\textsuperscript{1359}, and better HRQoL\textsuperscript{1360}.

\textsuperscript{1342} O'Donnell DE, Revill SM, Webb KA. Dynamic hyperinflation and exercise intolerance in chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2001; 164:770-777
\textsuperscript{1343} O'Donnell DE, Revill SM, Webb KA. Dynamic hyperinflation and exercise intolerance in chronic obstructive pulmonary disease. \textit{Am J Respir Crit Care Med} 2001; 164:770-777
\textsuperscript{1349} Punzal PA, Ries AL, Kaplan RM, Prewitt LM. Maximum intensity exercise training in patients with chronic obstructive pulmonary disease. \textit{Chest} 1991; 100:618-623
\textsuperscript{1351} Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with chronic obstructive pulmonary disease. \textit{Ann Intern Med} 1995; 122:823-832
\textsuperscript{1356} Ries AL, Kaplan RM, Limberg TM, Prewitt LM. Effects of pulmonary rehabilitation on physiologic and psychosocial outcomes in patients with chronic obstructive pulmonary disease. \textit{Ann Intern Med} 1995; 122:823-832
\textsuperscript{1358} Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, et al. Results at 1 year of outpatients multidisciplinary pulmonary rehabilitation: a randomised controlled trial. \textit{Lancet} 2000; 355:362-368
### Table 5.3. Measurements Derived from Maximal Incremental Exercise Testing

<table>
<thead>
<tr>
<th>Measure</th>
<th>Abbreviation</th>
<th>Definition</th>
<th>Use/Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum work rate</td>
<td>W max</td>
<td>Work rate (watts) achieved at maximal effort</td>
<td>Maximum effort possible. Predicted relates to age, gender, weight</td>
</tr>
<tr>
<td>Heart rate at maximum work</td>
<td>HR max</td>
<td>Highest heart rate (beats per min), usually at maximum effort</td>
<td>Limit of HR response. Predicted relates to age</td>
</tr>
<tr>
<td>Ventilation at maximum work</td>
<td>V̇ e max</td>
<td>Highest ventilation achieved (L per min), usually at maximum effort. Can be compared to maximum voluntary ventilation</td>
<td>Non-limiting in normal, except in elite athletes. May be limiting in respiratory diseases. Breathing reserve at Wmax is usually &gt;25%.</td>
</tr>
<tr>
<td>Maximum voluntary ventilation</td>
<td>MVV</td>
<td>Upper limit of the body’s ability to ventilate the lungs (measured from 12 seconds effort, or calculated from FEV1)</td>
<td>Reduced in respiratory and chest wall disorders</td>
</tr>
<tr>
<td>Breathing Reserve</td>
<td>BR</td>
<td>Gap between V̇ e max and MVV</td>
<td>High when exercise limited by cardiac &amp; vascular disorders or poor effort. Low with lung disorders</td>
</tr>
<tr>
<td>Maximum oxygen uptake</td>
<td>VO₂ max</td>
<td>Highest oxygen uptake (L per min) obtainable despite increasing effort and work. Peak VO₂ may be lower than VO₂max</td>
<td>Predicted relates to age, gender, height, weight, activity levels. Determined by cardiac output, muscle O₂ extraction potential, and ventilation capacity. Reflects maximal cardiac output</td>
</tr>
<tr>
<td>Oxygen pulse</td>
<td>VO₂/HR</td>
<td>Amount of O₂ extracted by body tissues in each cardiac stroke volume</td>
<td>Determined by stroke volume and arterio-venous O₂ content difference. High in fit and beta-blocked patients. Low in cardiac pump disorders</td>
</tr>
<tr>
<td>Anaerobic threshold (AT)</td>
<td>VO₂ AT</td>
<td>Exercise VO₂ above which anaerobic energy production significantly supplements aerobic, with increasing lactic acidosis and accelerated increase in ventilation</td>
<td>Normally &lt;40% pred VO₂max. Low in peripheral vascular, cardiac, pulmonary vascular, respiratory and anaemic disorders</td>
</tr>
<tr>
<td>Oxygen uptake-Work rate relation</td>
<td>ΔVO₂/ΔHR</td>
<td>How much O₂ is utilised by the body for a given level of external work – the coupling of external to cellular respiration</td>
<td>Obese need more VO₂ per unit of work. Reduced slope if reduced O₂ delivery (e.g. cardiovascular or mitochondrial). Increased if anaerobic metabolism or high VO₂ by breathing muscles</td>
</tr>
<tr>
<td>Carbon dioxide output</td>
<td>VCO₂</td>
<td>Output of CO₂ from metabolism (L per min) exhaled from the body</td>
<td>Increased with hyper-metabolic states (e.g. hyperthyroid, obesity)</td>
</tr>
<tr>
<td>Ventilatory equivalent for CO₂</td>
<td>V̇ e/VCO₂</td>
<td>Ratio of V̇ e and VCO₂. Index of dead space ventilation</td>
<td>Declines till ventilatory compensation after AT then increases. Increased (&gt;32) with high dead space (pulmonary vascular, right-left shunt, ventilatory impairment, hyperventilation)</td>
</tr>
<tr>
<td>Ventilatory equivalent for O₂</td>
<td>V̇ e/VO₂</td>
<td>Ratio of V̇ e and VO₂. Reflects ventilation and perfusion matching</td>
<td>Declines till AT then increases. Increased (&gt;28) with high dead space and hyperventilation. Low with chemoreceptor insensitivity</td>
</tr>
<tr>
<td>Oxygen saturation</td>
<td>S_pO₂</td>
<td>Arterial oxygen saturation measured with a pulse oximeter probe on earlobe or finger-tip</td>
<td>Usually above 95%. Significant hypoxaemia may occur with small decrement in S_pO₂. Significant change = 4%; severe desaturation &lt;88%</td>
</tr>
</tbody>
</table>
THE INCREMENTAL SHUTTLE WALK TEST (ISWT)

The ISWT has been more recently developed\textsuperscript{1361} and validated in COPD and heart failure\textsuperscript{1362} as a more tolerable test of impairment that requires little in the way of equipment. It correlates with VO\textsubscript{2}max from incremental ergometry\textsuperscript{1363}. This test has been criticized that it does not reflect normal daily activities (unlike submaximal walking tests – see below), but it is responsive to treatment with medications\textsuperscript{1364} and physical treatments including pulmonary rehabilitation.

The ISWT is walked over a 10-metre "there-and back" circuit, Patients are instructed and guided by cassette tape or compact disc recording to walk at fixed pace so they reach the end of each 10-metre lap at the same time as a "beep". The pace is incremented every minute by 0.17m/sec through 12 increments of speed ("levels"). The test is symptom-limited, and the end of test is judged if the patients does not complete the distance ("lap") in the required time or is too breathless to continue.

\textbf{FIGURE 5.5 INCREMENTAL SHUTTLE WALK TEST OVER A 10-METRE COURSE}

\begin{footnotesize}
\end{footnotesize}
(b) Submaximal Exercise Tests

These tests are generally considered more indicative of disability (see also below). They are usually more closely related to a person's ability to conduct normal activities such as walking, being largely self-paced endurance tests. They are useful for comparing changes over time (e.g. following treatment intervention).

The Six-Minute Walk Test (6MWT)

This was derived from a 12-minute walk test and is conducted in a corridor around 40 to 50 metres long. Patients are instructed to walk at their own pace, though as briskly as they can manage, and to cover as much distance as possible in the time allocated. Usually a pulse oximeter is worn. While the patient is encouraged to persist, rests are allowed for severe breathlessness, leg pain, chest pain, severe fatigue, or severe oxygen desaturation. In addition the patient can be asked to rate the perceived breathlessness and effort using Borg scores.

There has been substantial validation of the 6-minute walk test in different patient populations examining a variety of potential influencing factors. Details of these can be found in a systematic review. Reference equations have been developed for healthy individuals at various ages, and these have been compared and validated in a population of COPD patients. In this study a 6MWD value below 350 metres indicated a worse prognosis, especially in females. The same workers had earlier found that 6MWD appeared at least as good as a prognostic indicator as peak oxygen uptake (VO2max) in people with COPD.

The systematic review also established that the minimum clinically significant change in six-minute walk distance (6MWD), based on its intra-individual repeatability, is 49 metres, although further reliable analysis suggests 54 metres represents the minimum clinically important difference (MCID).

Improvements in 6MWD correlate with changes in dyspnoea ratings after therapeutic interventions. The 6MWT has been compared with the ISWT and cycle ergometry. This study indicates that in the self-paced 6MWT, when the protocol is properly applied, equivalent heart rates and levels of dyspnoea were achieved. Heart increments, however, were linear in the ISWT and ergometry and alinear in the 6MWT, while the dyspnoea increases were linear with time in the 6MWT and alinear in the ISWT and ergometry.

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1367 Solway S, Brooks D, Lacasse Y, Thomas S. A qualitative systematic overview of the measurement properties of functional walk tests used in the cardiorespiratory domain. Chest 2001; 119:256-270
1372 Cote CG, Pinto-Plata V, Kasprzyk K, Dordelly LJ, Celli BR. The 6-min walk distance, peak oxygen uptake, and mortality in COPD. Chest 2007; 132:1778-1785
The 6MWD is an independent predictor of mortality in people with COPD\textsuperscript{1376}, and it has been included in a composite prognostic rating of COPD, known as the BODE Index\textsuperscript{1377}.

**Endurance Shuttle Walk Test (ESWT)**

This test has been carefully validated to determine change from interval to interval\textsuperscript{1378}. It utilizes the same 10-metere course and auditory signals as the ISWT, but the pace is fixed (at 75% to 85% of the maximum level or speed reached in a prior ISWT), and the patient is cued to complete as many laps as symptoms allow (i.e. ‘until they can go no further’). Revill also recommends a time limit of 20 minutes, though the patient is not made aware of this limit. A pulse oximeter can be used to monitor oxygen saturation throughout, and Borg ratings can be obtained, as in the 6MW.

The ESWT has been shown to be responsive to rehabilitation\textsuperscript{1379}, to bronchodilators used in COPD\textsuperscript{1380,1381,1382}. It is a highly adaptable test, not reliant on high technology, and is relevant for activities of daily living.

The likely clinically significant improvement in ESWT is 85 seconds\textsuperscript{1383}.

**Constant Load Endurance Ergometry**

This test involves having the patient exercise on a treadmill or cycle ergometer at a fixed work rate\textsuperscript{1384}. The work rate is generally set at 75% to 85% of the individual’s Wmax established in a previous maximal incremental exercise test, or it can be self-paced. The duration of the test is the primary outcome measure, but Borg ratings of dyspnoea and effort or fatigue, and oxygen saturation can usefully be added.

Endurance walk tests performed on a treadmill compare closely with those performed in a corridor walking test, but measurements are easier to make in a treadmill test\textsuperscript{1385}, and it is not subject to vagaries of traffic flow and ambient conditions that potentially can affect corridor walk tests. On the other hand, treadmills are expensive, space-consuming, and often daunting to patients with severe disease or advanced years. Attempts to compare the two have produced inconsistent results in terms of equivalence of energy expenditure and endurance performance\textsuperscript{1386,1387}.

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\textsuperscript{1376} Pinto-Plata, Cote C, Cabral H, et al. The 6-min walk distance: change over time and value as a predictor of survival in severe COPD. *Eur Respir J* 2004; 23:28-33
\textsuperscript{1382} Brouillard C, Pepin V, Milot J, Lacasse Y, Maltais F. Endurance shuttel walking test : responsiveness to salmeterol in COPD. *Eur Respir J* 2008; 31:579-584
Nutritional Impairments

Patients with severe COPD often lose weight\(^\text{1388}\). In a large (n=1612) uncontrolled cohort study, loss of over 1 unit of body mass index (BMI) was as frequent as 35.3% in females and 27.4% in males in the presence of severe COPD\(^\text{1389}\). A smaller cohort study found the prevalence of under-nutrition was 24.4%\(^\text{1390}\).

Weight under 90% of ideal or weight loss of 5% to 10% of initial body weight are considered indices of malnutrition, and these features have been described in 24% to 35% of patients with moderate and severe COPD\(^\text{1391}\). Low body weight is associated with more severe breathlessness for the same severity of lung function impairment\(^\text{1392}\). Such a relative catabolic state has been shown in a number of uncontrolled cohort or retrospective studies to be an independent risk factor for worse prognosis\(^\text{1393,1394,1395,1396}\). Low body mass index (BMI) is an independent predictor of survival\(^\text{1397}\), and affects mortality due to both COPD and all-causes\(^\text{1398,1399}\). BMI <20 also relates to lung function – FEV\(_1\) and gas transfer – and maximum inspiratory pressure as an indicator of diaphragmatic strength, as well as level of dyspnoea\(^\text{1400}\). An uncontrolled cohort study found that BMI, fat free mass and muscle mass were lowest in COPD patients with chronic hypoxaemia, or in those with severe impairment of FEV\(_1\) (independent of their oxygenation status)\(^\text{1401}\).

Correlates of nutrition (e.g. thigh muscle wasting and hand-grip strength) are also powerful independent prognostic indicators\(^\text{1402}\), but are further strengthened by inclusion of FEV\(_1\) as percent predicted\(^\text{1403}\). Fat-free body mass has been more closely correlated with respiratory muscle strength and functional walking tests than percent ideal body weight\(^\text{1404}\). While peak exercise performance was compromised in


\(^{1402}\) Engelen MP, Schols AM, Baken WG, et al. Nutritional depletion in relation to respiratory and peripheral skeletal muscle function in out-patients with COPD. *Eur Respir J* 1994; 7:1793-1797


underweight people with COPD, neither submaximal exercise performance nor health status were\textsuperscript{1405}. Peak VO\textsubscript{2} has been correlated with fat free mass, BMI and intracellular water\textsuperscript{1406}.

As well as cross-sectional indices of body mass weight loss also has prognostic significance\textsuperscript{1407}. Weight loss is common in COPD patients – up to 32\% of underweight patients had lost >5\% of body weight in the year before study\textsuperscript{1408}. In a prospective study examined post hoc, history of weight loss correlated with decreased survival, and weight gain in both under-nourished and those with normal weight was associated with decreased risk of mortality\textsuperscript{1409}. This latter finding has been replicated\textsuperscript{1410}.

To summarise these observations, weight loss may occur in a third of people with severe COPD, and both absolute weight and weight loss (and their more accurate correlates of nutritional status, BMI, fat free mass and skeletal muscle strength) are strong indicators of mortality. If nutritional status can be improved, survival may improve (along with exercise performance). It is therefore important to assess nutritional status, muscle strength and recent weight loss before PR.

It might appear useful to embark on weight-maintenance early in the course of the disease, since nutritional support later in disease has shown no significant gain in health status or exercise capacity in a meta-analysis that included 277 patients with stable severe COPD\textsuperscript{1411}. Improvements in weight can be achieved with supplementation, as documented in a small randomised controlled trial, though there were no improvements in health status\textsuperscript{1412}. In another intervention study that included repletion and anabolic steroids, body weight increased along with fat free mass, inspiratory muscle strength and decreased risk of early death, without adverse effects\textsuperscript{1413}.

**Nutritional Status**

**Body Mass Index**

Body mass index (BMI) is a function simply of height and weight (weight in Kg / [height in metres]\textsuperscript{2}), and includes fat and fat-free mass. Significant muscle wasting can occur in people with normal or even high BMI. BMI is a strong independent predictor of survival in COPD\textsuperscript{1414,1415}, and gaining weight is associated


\textsuperscript{1409} Schols AMWJ, Slangen J, Volovics L, Wouters EFM. Weight loss is a reversible factor in the prognosis of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1998; 157:1791-1797


\textsuperscript{1413} Schols AMWJ, Slangen J, Volovics L, Wouters EFM. Weight loss is a reversible factor in the prognosis of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1998; 157:1791-1797


with lower mortality\textsuperscript{1416,1417}. As BMI is such a simple measure with such good independent risk prediction properties it has been included in the BODE index, along with other major risk factors for survival\textsuperscript{1418}.

**Fat Free Mass**

Indicators that reflect muscle mass depletion have appeal over BMI, and FFM more closely reflects metabolically active “body cell mass”. FFM appears to be the main component of body mass contributing to the associations with exercise limitation, quality of life and mortality. Patients with COPD whose lean body mass (FFM) is depleted have the greatest impairment of HRQoL\textsuperscript{1419}. Even in COPD patients with normal BMI followed for 7 years in the Copenhagen City Heart Study, FFM was an independent predictor of mortality\textsuperscript{1420}. Some measures are indirect albeit reliable screening tools, while others are more accurate and reliable although requiring significant technological investment.

**Mid-arm muscle area**

MAMA is appealing as it is easily measured, and in a Spanish prospective cohort of 96 male COPD patients, it provided better prognostic information than BMI\textsuperscript{1421}.

**Skinfold thickness**

ST measured at four sites (triceps, biceps, subscapular and supra-iliac) is a time-honoured tool, in which fat-mass is obtained from equations or tables. FFM is body weight minus fat-mass\textsuperscript{1422}.

**Non-Fat Non-Bone Mass**

Dual-energy X-ray absorptiometry (DEXA)\textsuperscript{1423} measures non-fat, non-bone mass. The equipment is the same as that used for Bone Mineral Density measurements, though the computations are different for FFM.

**Bioelectrical Impedance**

Bioimpedance analysis\textsuperscript{1424} measures fat free mass, and new technological tools are becoming less expensive and more widely available, meaning more routine use in respiratory patients is becoming a more realistic possibility.

**Nutritional Screening Measures**

**Patient-Generated Subjective Global Assessment (PG-SGA) Tool**

This tool has been validated in cancer patients\textsuperscript{1425,1426}, and has been used in pulmonary rehabilitation participants. The global rating provides categories of ‘well nourished’, ‘moderate or suspected nutrition deficits’, or ‘severely malnourished’.

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\textsuperscript{1416} Schols AM, Slangen J, Volovics L, Wouters EF. Weight loss is a reversible factor in the prognosis of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1998; 157:1791-1797


\textsuperscript{1421} Soler-Cataluna JJ, Sanchez-Sanchez L, Martinez-Garcia MA, et al. Mid-arm muscle area is a better predictor of mortality that body mass index in COPD. *Chest* 2005; 128:2108-2115

\textsuperscript{1422} Durnin JVGA, Womersley J. Body fat assessed from total body density and its estimation from skinfold thickness: measurements on 481 men and women aged from 16 to 72 years. *Br J Nutr* 1974; 32:77-97


\textsuperscript{1424} Lukaski HC, Johnson PE, Bolonchuk WW, Lykken GI. Assessment of fat-free mass using bioelectrical impedance measurements of the human body. *Am J Clin Nutr* 1985; 41:810-817
malnutrition’ or ‘severely malnourished’, based on a patient-completed series of questions and an observer-completed section.

**Mini Nutritional Assessment (MNA)**

This tool poses a series of questions relating to lifestyle, mobility and other global factors, dietary factors such as protein intake, meal patterns etc, self-perceived nutritional and health status and anthropometric measures, including self-reported weight loss. It has been validated in people aged over 65 years.\textsuperscript{1427,1428}

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**Psychological Impairments**

A wide range of questionnaires has been developed over the past 50 years to measure psychological impairment. Their relative usefulness relates to their validity, reliability, responsiveness, generalisability, and ease of use. Some are generic screening instruments (eg the General Health Questionnaire, Brief Symptom Inventory and Symptom Checklist 90), while others address a range of transient mood states (eg Profile of Mood States, and the Hospital Anxiety and Depression Scale). Yet others focus specifically on personality (eg Minnesota Multiphasic Personality Inventory), tendency to depression (eg Beck Depression Inventory, Centre for Epidemiological Studies Depression Mode Scale, and the Geriatric Depression Scale), denial (Denial Rating Scale) or anxiety disorders (eg State Trait Anxiety Scale).

The impact of the psychological impairment on health status is considered elsewhere, but can be determined from the generic Medical Outcomes Study Short Form surveys (eg SF36 and SF20), the Nottingham Health Profile, or the Quality of Well-Being Scale questionnaires. The impact of psychological status on breathing is addressed in most respiratory disease-specific health status instruments, but other instruments that examine a person's control and coping systems can also be used. These are detailed below (in alphabetical order). The impact of another somatic illness on psychological status can be assessed from the Sickness Impact Profile or Psychosocial Adjustment to Illness Scale. Some health status questionnaires also include psychological or mental health status, and some include components that reflect degree of mastery or self-efficacy.

**Beck Depression Inventory (BDI)\textsuperscript{1429} and BDI-Short Form\textsuperscript{1430}**

A 21-item self-administered questionnaire that takes 5 to 10 minutes to complete. It performs well as a screen for clinically significant symptoms of depression, and has been used in many populations and a variety of settings. When using this scale to assess people with chronic lung disease caution should be exercised in the interpretation of results due to the emphasis on somatic symptoms.

**Brief Symptom Inventory\textsuperscript{1431}**

The BSI is a shorter but psychometrically acceptable derivation from the SCL-90-R. Internal consistency and test-retest reliability are good, and correlations with the symptoms dimension of the SCL-90-R are quite high. There is also high convergence between BSI scales and similar dimensions of the MMPI.
Centre for Epidemiological Studies - Depression Mode Scale (CES-D)\textsuperscript{1432}

This scale may be particularly suited to COPD as it places less emphasis on somatic symptoms of depression, which may be confounded by respiratory impairments. It contains 20 items and takes around 5 to 10 minutes to self-administer. It has been tested in a broad range of populations and clinical settings. It registers depressive symptoms, rather than providing a diagnostic formula for clinical depression. In a large survey in Dutch general practices there was a 2.5-fold higher risk of these symptoms in severe COPD than in age-matched demographically similar controls\textsuperscript{1433}. In a large randomised trial, comprehensive PR and education-only PR had similar benefits on depression scores using this scale\textsuperscript{1434}. Thus, it has sensitivity and responsiveness for depressive symptomatology in COPD.

COPD Self-Efficacy Scale (CSES)\textsuperscript{1435}

Self-efficacy refers to the conviction people have as to whether they can carry out behaviours to achieve certain outcomes. People suffering dyspnoea with activities learn to avoid those activities\textsuperscript{1436}. A lack of confidence in the ability to achieve outcomes from those activities is referred to as low self-efficacy. The CSES is a 34-item questionnaire that takes 5 to 10 minutes of self-completion measures this self-efficacy, specifically related to the limitations perceived as due to COPD. Five factors are identified: negative affect, intense emotional arousal, physical exertion, weather/environmental and behavioural risk factors. The questionnaire is validated in small groups, and its wider reliability and responsiveness to interventions is uncertain.

General Health Questionnaire (GHQ 60, GHQ 30, GHQ 28)\textsuperscript{1437,1438,1439}

The GHQ comes as 60-, 30- and 28-item self-administered questionnaires, which take patients 10, 5 and 5 minutes respectively to complete. It addresses the following domains: Somatic Symptoms, Anxiety and Insomnia, Social Dysfunction, and Severe Depression. It was developed as a screening tool to detect psychiatric disorders among general psychiatric outpatients and those in the community. It focuses on two main areas: inability to carry out normal functions and appearance of new distressing phenomena.

Geriatric Depression Scale (GDS)\textsuperscript{1440}

This 30-item self-administered scale takes 5 minutes to complete, and is well suited to elderly patients (who make up most of the COPD population). A shorter version has also been developed\textsuperscript{1441}. Record of its use in respiratory disease has not been found.

\textsuperscript{1436} Bandura AB. Social learning theory. Englewood Cliffs, NJ: Prentice-Hall, Inc. 1977
\textsuperscript{1438} Goldberg P. The detection of psychiatric illness by questionnaire: a technique for the identification and assessment of non-psychotic psychiatric illness. London: Oxford University Press 1972 (Maudsley Monographs No 21)
**Hospital Anxiety and Depression Scale (HADS)**\(^{1442,1443}\)
This 14-item self-administered questionnaire takes around 5 to 10 minutes to complete, and is a useful screen for clinically significant symptoms or anxiety and depression. It has been utilised in a variety of populations and settings. It is capable of detecting either anxiety or depression in COPD populations and appears responsive to interventions like PR\(^{1444}\).

**Minnesota Multiphasic Personality Inventory (MMPI-2)**\(^{1445}\)
This is a rather daunting but highly validated, reliable and widely used self-administered questionnaire. It has 567 questions that take 90 minutes or so to complete, and addresses a number of domains. There are 8 validity scales with 5 superlative self-presentation subscales, 10 clinical scales with 31 clinical subscales (Harris-Lingoes and Social Introversion subscales), 15 Content scales, 27 Content Component scales, 25 supplementary scales and various special or setting-specific indices. It is used to measure psychopathology across a broad range of client settings, and can help to diagnose personality syndromes as well as psychopathology.

**Multi-Dimensional Health Locus of Control (MHLC)**\(^{1446}\)
Form C of the MHLC is a condition-specific 18-item 5-minute self-administered questionnaire, which has undergone extensive validation in a range of chronic diseases and cancers, showing high levels of concurrent and construct validity as well as reliability and stability. The three scales are internality/personal control, chance, and powerful others/professional control, and appear to be independent\(^{1447}\). Sensitivity in respiratory diseases has not been reported.

**Nottingham Health Profile**\(^{1448,1449}\)
This 38-item questionnaire can be self-administered or interviewer administered, and takes 5 to 10 minutes to complete. The dimensions evaluated are Physical mobility, Pain, Social isolation, Emotional reactions, Energy and Sleep, and there may be some confounding from somatic respiratory problems. It is widely used, has been tested in a wide range of settings, and extensively validated. However, its responsiveness to interventions for COPD is not clearly established.

**Profile of Mood States (POMS)**\(^{1450}\)
This 65-item self-administered questionnaire takes around 5 minutes to complete (yes-no responses), and assesses domains of Tension-anxiety, Depression-dejection, Anger-hostility, Vigour-activity, Fatigue-inertia, Confusion-bewilderment. Surprisingly few studies have examined its responsiveness to interventions in respiratory diseases.

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\(^{1445}\) MMPI-2 Manual for Administration, Scoring, and Interpretation Revised Edition
\(^{1450}\) McNair DM, Lorr M, Dropplemann LF. Profile of Mood States. *San Diego, CA: Educational and Industrial Testing Service 1971*
Psychosocial Adjustment to Illness Scale (PAIS)\textsuperscript{1451}

This questionnaire is answered in a semi-structured clinical interview, and requires a clinical psychologist in attendance. It assesses the psychological and social adjustment of medical patients and/or members of their immediate families to illness. Its reliability and validity have been well tested in a variety of populations and clinical settings, including respiratory disease. Patients entering PR were assessed clinically and with PAIS-Self Report to demonstrate validity, but also to show greater sensitivity for PAIS-SR in detecting the impact of COPD on patients\textsuperscript{1452}.

Sickness Impact Profile (SIP)\textsuperscript{1453,1454,1455}

This is a 136-item questionnaire that can be self-administered or interviewer administered. It takes 20 to 30 minutes to complete. The domains examined are Physical (ambulation, mobility, body care and movement), and Psychosocial (social interaction, communication, alertness behaviour, emotional behaviour, sleep and rest, eating, home management, recreation and pastimes, and enjoyment. It is therefore one of the more comprehensive instruments to evaluate social as well as physical and psychological issues, and has been used in a broad range of respiratory groupings, being suited to COPD, asthma, cystic fibrosis, sarcoidosis and chronic respiratory failure patients. While it is described as responsive, it is relatively insensitive to impacts of mild or moderate COPD.

State Trait Anxiety Scale\textsuperscript{1456}

This self-administered questionnaire examines the dimensions of Anxiety proneness (trait) and Current tension/apprehension (state). It has been tested widely and validated in many populations and settings. It has 40 items and takes most people 10 minutes to complete. Its sensitivity to relaxation therapy reducing anxiety and dyspnoea has been demonstrated\textsuperscript{1457}, and in this study anxiety correlated with dyspnoea at all time points. A randomised controlled study published as a PhD thesis has shown that while hope improved with relaxation and coping training, no effect was seen in anxiety\textsuperscript{1458}. No specific references to responsiveness to PR were found.

Symptom Checklist 90 Revised (SCL-90-R)\textsuperscript{1459}

This is a 90-item self-administered questionnaire with nine primary symptom dimensions and 3 global indices. It is said to take around 15 minutes for the average patient to complete. Reliability and validity have been tested in a wide range of populations and settings. It was designed (and performs well) to screen for a broad range of psychological problems and symptoms of psychopathology. It has shown utility as a primary indicator, an indicator of change over time, and as an outcomes measure following interventions.

\textsuperscript{1451} Derogatis LR. The psychosocial adjustment to illness scale (PAIS). \textit{J Psychosom Res} 1986; 30:77-91
\textsuperscript{1454} McSweeny AJ, Grant I, Heaton RK, et al. Life quality of patients with chronic obstructive lung disease. \textit{Arch Intern Med} 1982; 142:473-478
\textsuperscript{1457} Renfroe KL. Effect of progressive relaxation on dyspnea and state anxiety in patients with chronic obstructive pulmonary disease. \textit{Heart Lung} 1988; 17:408-413
\textsuperscript{1458} Aubuchon BL. The effects of positive imagery on hope, coping, anxiety, dyspnoea and pulmonary function in persons with chronic obstructive pulmonary disease: tests of a nursing intervention and a theoretical model. \textit{Unit Texas Austin 1990 PhD thesis
\textsuperscript{1459} Derogatis LR. SCL-90-R: Administration, scoring, & procedures manual for the revised version. \textit{Baltimore: Clinical Psychometric Research}, 1983
Ways of Coping Check List (WOCCL)\textsuperscript{1460}

This is a 66-item self-administered questionnaire that takes around 10 minutes for most patients to complete. It charts patients into a number of coping styles: confrontive, distancing, self-controlling, seeking social support, accepting responsibility, escape-avoidance, active problem-solving and positive re-appraisal. Its reliability and validity have been well tested in a variety of settings. It has been used in a range of populations, and is useful for the assessment of behavioural and coping strategies used by people in stressful situations.

5.3 Indicators of Functional Disability and Handicap

Functional Exercise Endurance

Tests of respiratory function performed at rest help to provide insight into the degree of airway narrowing or gas exchange impairment, but they give little understanding of the precise cause of a patient's inability to perform activities. In particular, ventilatory requirements with these activities, limitations imposed by cardiovascular impairments, and the role of pulmonary or peripheral vascular abnormalities in functional capacity can only be determined by exercise testing (see above). Ergometry testing with ventilation and gas exchange measurements can provide diagnostic information about exercise impairment\textsuperscript{1461}.

While this information about impairments is valuable, the term impairment refers more to an injury or abnormality occurring at the individual or organ system level representing "any loss or abnormality of psychological, physiological, or anatomic structure or function"\textsuperscript{1462}. Disability, on the other hand, refers more to the effects of the impairments and their interplay and consequences on the individual's functional capacity. Disability is defined as "any restriction or lack (resulting from an impairment of ability to perform an activity in the manner or within the range considered normal for a human being". The WHO definitions also include handicap, which is the "disadvantage for a given individual that limits or prevents the fulfilment of a role that is normal (depending upon age, sex, social and cultural factors) for that individual", though recent revisions now talk about "functional disability" which tends to combine disability and handicap. There is therefore a variety of measurements that can reflect disability and handicap as aspects of functional status, which has been defined as a person’s ability to perform ADLs (comprising psychological, physical and social functioning)\textsuperscript{1463}.

Observations of perceived exertion and dyspnoea\textsuperscript{1464}, pulse and respiratory rate responses and oxygen saturation during an exercise task provide useful insight into functional capacity. The exercise task may be a standardised test (such as a timed walking test, ergometry-based endurance test, or supported and unsupported arm exercise tests), which are standardised and validated, attractive properties for outcome testing. Alternatively, they may grade performance tasks that cover a range of energy expenditures (e.g., washing hands and face, changing bed linen, and heavier housework or gardening)\textsuperscript{1465}. Breathing patterns and task performance can also be assessed\textsuperscript{1466} during these task-related tests.

\begin{thebibliography}{99}
\bibitem{footnote2} Folkman S, Lazarus RS. \textit{J Personality Soc Psychol} 1985; 48:150-170
\bibitem{footnote5} Lareau SC, Breslin EH, Meek PM, et al. Functional status instruments: Outcome measure in the evaluation of patients with chronic obstructive pulmonary disease. \textit{Heart Lung} 1996; 25:212-224
\bibitem{footnote8} Trombly C, Scott AD. Evaluation and assessment. In: Occupational Therapy for Physical Dysfunction. \textit{Baltimore: Williams & Wilkins} 1977
\end{thebibliography}
Functional walk tests have been qualitatively reviewed recently\(^{1467}\). Fifty-two studies of measurement properties were found in the review, most (twenty-nine) relating to the six-minute walk test, with fewer studies of the 2-minute walk test (five), 12-minute walk test (thirteen), shuttle walk test - both incremental and endurance (four), and self-paced walk test (six). The six-minute walk test was favoured as the most applicable to both clinical and research purposes due to its extensive validation and use in these settings. The results are summarised, with the full references to be found in the qualitative review\(^{1468}\).

There are important influences in functional walking tests from encouragement, presence of a learning effect, but not time of day of doing the test\(^{1469}\) (in either COPD or chronic heart failure). For each of the timed walking tests patients should be given at least one trial to learn the test's requirements, with sufficient recovery time between the trials; more than two tests do not appear to be necessary\(^{1470}\). The tests appear valid measures of exercise capacity in various situations - COPD, cystic fibrosis, heart failure, pacemakers, paediatrics, and surgical/pre-operative assessment. Strong to medium correlations have been found in 28 studies between 6MWT and VO2max, maximum work capacity, and a variety of functional and symptom measures\(^{1471}\). These included New York Heart Association functional classifications and oxygen cost diagram. Results in heart failure also suggested some prognostic capacity for predicting likelihood of death or hospitalisation for heart failure. Less clear correlations between 6MWT and health-related quality of life have been found in respiratory conditions. A recent study of 37 patients with severe COPD and who completed a range of outcome measures before and 6 to 8 weeks after outpatient comprehensive PR found a poor correlation between 6MWT and HRQoL results\(^{1472}\), even though each measure showed clinically significant improvement. The 6MWT is responsive to interventions in a variety of settings: correlation between 6MWT and diminished breathlessness after pacemaker insertion, improvement in HRQoL in heart failure treatment, and HRQoL improvement after pulmonary rehabilitation. The endurance shuttle walk test is more responsive to pulmonary rehabilitation than the incremental shuttle walk test\(^{1473}\).

**Functional Disability Questionnaires**

(a) **Activities of Daily Living**

The capacity of people to care for themselves and to actually perform ADL tasks are important aspects of functional disability assessment. In Chronic Heart Failure (CHF), another common cause of chronically disabling dyspnoea in older people, the New York Heart Association (NYHA) classes have wide acceptance. The MRC Scales for Dyspnoea represent a good surrogate for functional disability, couched in graded levels of activity that produce enough dyspnoea to limit the activity. Both basic and instrumental ADL assessment (basic task capacity and performance ability respectively) have been combined in a BADL-IADL, and validated in COPD as well as CHF.

**Basic and Instrumental Activities of Daily Living Questionnaire (BADL-IADL)**

In a multicentre Italian hospital study of 432 patients with CHF, 305 with COPD and 534 with diabetes mellitus, validation was undertaken of a BADL-IADL assessment tool, and significant differences were seen between the three conditions. In COPD a pattern of disablement with specific tasks (IADL) involving

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1467 Solway S, Brooks D, Lacasse Y, Thomas S. A qualitative systematic overview of the measurement properties of functional walk tests used in the cardiorespiratory domain. *Chest 2001; 119:256-270*
1468 Solway S, Brooks D, Lacasse Y, Thomas S. A qualitative systematic overview of the measurement properties of functional walk tests used in the cardiorespiratory domain. *Chest 2001; 119:256-270*
1471 Solway S, Brooks D, Lacasse Y, Thomas S. A qualitative systematic overview of the measurement properties of functional walk tests used in the cardiorespiratory domain. *Chest 2001; 119:256-270*
1472 de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. *Chest 2002; 121:1092-1098*
1473 Solway S, Brooks D, Lacasse Y, Thomas S. A qualitative systematic overview of the measurement properties of functional walk tests used in the cardiorespiratory domain. *Chest 2001; 119:256-270*
mobility and outdoor activity, and practical involvement in household responsibility including money management, with associated dependency was identified, rather than overall BADL. Responsiveness to intervention has not yet been described, but this may a valuable disability indicator with potential for outcome measurement.

**Human Activity Profile (HAP)**
This is a self-report questionnaire addressing 94 hierarchically-arranged VO2-demanding ADLs, designed specifically for use in PR, although little-used in this area. The HAP has good construct validity, being closely associated with VO2max in patients attending PR (r=0.83), and with directly-measured activities from accelerometer over a week (r=0.78). The sequential task-limitation arrangement allows determination of a Maximal Activity Score (MAS), which is the greatest amount of work the patient is currently able to perform (and actually performing at that time). The number of tasks then identified as having been stopped because of dyspnoea is then subtracted from this MAS to provide an Adjusted Activity Score (AAS). The AAS can be used to define low, fair, and average-and-above fitness levels, and has been found to have good construct validity, repeatability and responsiveness to PR.

**Health Status Measures**
There has been considerable research and development activity in the area of health-related quality of life (HRQoL) as a measure of disability and/or handicap in respiratory disease over the past 20 years. In the Introduction section the differences between generic and disease-specific HRQoL were discussed. Briefly, generic instruments classify a broad range of physical and psychological impairments and symptoms in terms of their impact on health status, without reference to the disease causing the impairments or symptoms. Use of such tools allows a comparison between different populations of health status - for example comparing different chronic disease states (such as chronic heart failure, COPD and chronic renal failure) or socio-demographic populations, and often they have been validated and normalised for different age groups or ethno-cultural backgrounds. It has often been stated - and sometimes these statements have been supported by objective research - that these instruments are not as sensitive to change (responsive) as disease-specific measures.

Specific health status measures can be system-specific (eg respiratory disease as a whole) or disease-specific (eg asthma, COPD, lung cancer, cystic fibrosis). It is more difficult to use these tools to compare respiratory patients with cardiac or other patients. Using a system-specific tool it is feasible to compare asthmatics with COPD patients, and so on, while using disease-specific tools reduces the capacity to compare different diseases. On the other hand, it is usually stated that these tools are more responsive to interventions.

**Generic Health Status Measures**

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Medical Outcomes Survey (MOS) Questionnaire\textsuperscript{1481}

This tool is in very wide use in Australia and many other countries. It can be self-administered or interviewer administered (including by telephone\textsuperscript{1482}), and there are computer versions available. It has been validated in many populations at a range of ages, and there are extensive normal values for Australia\textsuperscript{1483}. It has been used in many chronic disease populations\textsuperscript{1484}, including a variety of chronic respiratory conditions\textsuperscript{1485}.

MOS-Short Form 36, 20 and 9 Questionnaires (SF-36, SF-20, and SF-9)\textsuperscript{1486}

These surveys take between 5 and 10 minutes to complete. The SF-20 has been examined alongside BDI and lung function as a cross-sectional indicator of general health status\textsuperscript{1487}. The BDI dyspnoea ratings predicted general health status (SF-20). In another large Japanese cross-sectional study of 194 male patients with stable COPD, there were significant gradations for most SF-36 dimensions across disease severity groupings by ATS (FEV1) criteria, though there were substantial overlaps\textsuperscript{1488}.

Because these instruments were designed to evaluate cross-sectional health status across populations, and patients with COPD have low scores for a range of the dimensions, responsiveness to change is difficult to identify ("floor effect"). In an uncontrolled observational study of patients undergoing comprehensive outpatient PR, significant changes were seen in exercise performance, dyspnoea and mastery, as well as overall HRQoL from the disease-specific CRDQ, but non-significant changes were found in SGRQ and SF-36 (total and all nine health concepts)\textsuperscript{1489}. Other studies have shown no or small improvements in SF-36 or one or more of its components or summary scores\textsuperscript{1490,1491,1492,1493}, though comparison of efficacy of treatments for COPD with interventions in other conditions can be usefully made\textsuperscript{1494}.

Quality of Well-Being Scale (QWB)\textsuperscript{1495}

This is a comprehensive measure of health status, well validated\textsuperscript{1496} in a variety of clinical areas including COPD. The original form is interviewer-administered (as a structured interview with 16 items), and takes

\begin{itemize}
  \item 1481 Ware JF, Sherbourne CD. The MOS 36-Item Short Form Health Survey (SF-36). Conceptual framework and item selection. Med Care 1992; 30:473-483
  \item 1482 Watson EK, Firman DW, Baade PD, Ring I. Telephone administration of the SF-36 health survey: validation studies and population norms for adults in Queensland. Aust NZ J Publ Health 1996; 20:359-363
  \item 1485 Mahler DA, Mackowiak JI. Evaluation of the short-form 36-item questionnaire to measure health-related quality of life in patients with COPD. Chest 1995; 107:1585-1589
  \item 1486 Stewart AL, Hays RD, Ware JE. The MOS short-form general health survey: reliability and validity in a patient population. Med Care 1988; 26:724-735
  \item 1489 de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. Chest 2002; 121:1092-1098
  \item 1491 Boueri FM, Bucher-Bartelson BL, Glenn KA, Make BJ. Quality of life measured with a generic instrument (Short Form-36) improves following pulmonary rehabilitation in patients with COPD. Chest 2001; 119:77-84
  \item 1493 Berry MJ, Rejeski WJ, Adair NE, Zaccaro D. Exercise rehabilitation and chronic obstructive pulmonary disease stage. Am J Respir Crit Care Med 1999; 160:1248-1253
  \item 1494 Boueri FM, Bucher-Bartelson BL, Glenn KA, Make BJ. Quality of life measured with a generic instrument (Short Form-36) improves following pulmonary rehabilitation in patients with COPD. Chest 2001; 119:77-84
  \item 1495 Kaplan RM, Atkins CJ, Timms R. Interday reliability of function assessment for a health status measure. The quality of well-being scale. Med Care 1989; 27:1076-1083
\end{itemize}
around 15 to 20 minutes to complete, but more recent development has led to a self-administered version (QWB-SA). Scores cover symptoms, mobility, physical activity and social activity, and they can also be used to develop utility (as QALYs) for health economic analysis. Responsiveness to intervention has been described for cystic fibrosis and interstitial lung disease populations, though there are conflicting reports of its use as an outcome measure in COPD. In the latter study, a large randomised trial comparing comprehensive PR with education-only with observation over six years, QWB scores at baseline were a strong independent predictor of survival. In the National Emphysema Treatment Trial the SF-36, QWB-SA, SGRQ and SOBQ were evaluated for responsiveness to PR. Both generic and both disease-specific instruments were responsive, and they were interrelated.

(b.ii) Respiratory System Specific Health Status Measures

Air Index
This self-administered 63-item questionnaire usually takes 15 to 20 minutes to complete. It has four dimensions - psychological, physical activity, physical symptoms, and social. It has been validated, but its sensitivity and responsiveness to interventions have not been published.

Airways Questionnaire 20-item (AQ20)
This brief questionnaire takes only 2 to 3 minutes to answer, having a yes/no answer format and only 20 questions, and is just as easy to score. It was developed at St George's Hospital London along similar development lines as the SGRQ. It can be used for both asthma and COPD, and its brevity suggests it could be used more routinely as a clinical tool, as well as being validated for research work. Its responsiveness to intervention has not been published.

Asthma Quality of Life Questionnaire (AQLQ)
The AQLQ was derived along the same lines as the CRDQ for use in patients with asthma. Like the CRDQ it was originally developed for interviewer administration, then as a self-administered questionnaire. There are 32 items, which take around 10 to 15 minutes to complete, and covers symptoms, emotions, exposures to environmental triggers, and activity limitation. It is available in a variety of languages. It has been extensively validated, and is responsive to intervention.

**Asthma Quality of Life Questionnaire (Marks)**

This simple questionnaire, developed in Australia and extensively validated, takes around 5 minutes for patients to complete the 20 questions. It covers breathlessness and physical restrictions, mood disturbance, social disruption, and personal concerns for health. It appears responsive to changes in asthma status.

**Breathing Problems Questionnaire (BPQ)**

This self-administered 33-item or 10-item (Short-version) questionnaire is available in a variety of languages and takes around 3 to 10 minutes to complete. It has 13 domains, scored in two constructs - health knowledge and health appraisal. It appears responsive to change after PR.

**Chronic Respiratory Disease Questionnaire (CRDQ)**

The CRDQ was developed to determine effects of respiratory disease on health status, and its change following interventions. It was originally designed for interviewer administration, and is therefore rather resource intensive, though recent adaptations have been made that allow self-administration. It is available in several languages, and has been validated in them all. It is really a system-specific instrument rather than disease-specific, and has been used in COPD, asthma, and cystic fibrosis.

There are 123 questions that relate to health status over the past two weeks, measured on a 7-point Likert scale, which contribute to four component scores: Dyspnoea, Emotional Function, Fatigue and Mastery, but the four components can be summed to provide a total score of 20 to 140. In answering the Dyspnoea component the patient is asked to identify the five tasks or activities important to their everyday life that make them feel breathless, then indicate how severely breathless they are with each activity. When answering a follow-up questionnaire, the patient is reminded of their first score for each question, so they can more clearly indicate a direction of change. Because each patient chooses his/her own dyspnoea-causing activities, he/she cannot be compared to other patients.

This instrument has been used to define a population's health status related to respiratory disease, in which circumstance it performs in a similar way to other health status measurements. For example, when compared with SGRQ and several dyspnoea measures in 160 male Japanese patients with mild to severe COPD, the Dyspnoea component grouped with the specific dyspnoea measures and SGRQ Activities dimension in factor analysis. On the other hand, the CRDQ Emotional function component did not group with HADS but with "other HRQoL" (together with CRDQ Fatigue and Mastery, and SGRQ Symptom dimensions)

In another study of 100 UK patients with COPD, the Dyspnoea component score showed poor correlation with MRC Dyspnoea Grade, while the other components related closely with SGRQ, and there were significant differences between MRC Dyspnoea Grades for Fatigue and Mastery components. A comprehensive controlled study in elderly men with COPD (n=96) compared to 55 older men with normal lung function. Both the BPQ and the CRDQ were repeatable, but BPQ was more

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1507 Marks GB, Dunn SM, Woolcock AJ. A scale for the measurement of quality of life in adults with asthma. J Clin Epidemiol 1992;45:461-472
1508 Marks GB, Dunn SM, Woolcock AJ. An evaluation of an asthma quality of life questionnaire as a measure of change in adults with asthma. J Clin Epidemiol 1993; 46:1103-1111
sensitive than CRDQ in these older British men. The most important determinants of CRDQ were activities of daily living (NEADL) and emotional status in this study. Depression scores, exercise limitation and dyspnoea-related limitation were the main factors accounting for level of HRQoL in CRDQ\textsuperscript{1516}.

The CRDQ was designed to be responsive to intervention, and it has performed well in demonstrating changes following PR, as a total HRQoL score and as individual component scores\textsuperscript{1517,1518,1519,1520}. Indeed, in a small prospective study of PR, CRDQ was one of three most responsive objective outcome measures (with BDI/TDI and 6MWD)\textsuperscript{1521}. Given these discriminant properties, the CRDQ should be highly recommended for use as an outcome measure for both research and routine clinical purposes. The drawback of requiring a trained interviewer for each patient appears to have been surmounted with a self-completion form, which has been found to be as sensitive to change with PR as the interview-based form\textsuperscript{1522}.

**Living With Asthma Questionnaire (LWAQ)\textsuperscript{1523}**

Hyland described this 68-item questionnaire in 1991. Its length may be a deterrent to more widespread use - it takes around 20 minutes to complete, either self-administered or conducted by a trained interviewer. Its validity, reliability and responsiveness have been demonstrated. There are many dimensions addressed, including sport, social/leisure, holidays, sleep, mobility, work/other activities, colds, effects on others, sex, medication usage, and dysphoric states and attitudes.

**Maugeri Foundation Respiratory Failure Questionnaire (MRF28)\textsuperscript{1524}**

This 28-item questionnaire was designed for use in chronic respiratory failure in people with COPD or kyphoscoliosis. It is available in several languages, takes about 10 minutes to complete (self-administered), and evaluates daily activities, cognitive and emotional status, invalidity, perceptions of health, and respiratory health. It discriminates well between different stages of severity of disease, and is the only validated instrument for evaluating these issues in people with chronic respiratory failure.

**Pulmonary Function Status and Dyspnoea Questionnaire (PFSDQ)**

This measure has been validated to measure breathlessness with activities and changes in functional ability\textsuperscript{1525}. It has 164 items, presenting 79 activities of daily living that the patient nominates intensity of dyspnoea associated with them as well as any alteration in their functional ability to perform them as a result of their COPD. It does rely on patient memory, as it seeks their experiences over the past 30 days. Activities are relevant for adults of either gender, reflecting a range of energy requirements, grouped into scales of self-care, mobility, eating, home management, social and recreational. Validation shows good

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\textsuperscript{1516} Engstrom CP, Persson LO, Larsson S, Sullivan M. Health-related quality of life in COPD: why both disease-specific and generic measures should be used. *Eur Respir J* 2001; 18:69-76


\textsuperscript{1520} Green RH, Singh SJ, Morgan MDL. A randomised controlled trial of four weeks versus seven weeks of pulmonary rehabilitation in chronic obstructive pulmonary disease. *Thorax* 2001; 56:143-145

\textsuperscript{1521} de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. *Chest* 2002; 121:1092-1098

\textsuperscript{1522} Williams JEA, Singh SJ, Sewell L, Morgan MDL. Health status measurement: sensitivity of the self-reported Chronic Respiratory Questionnaire (CRQ-SR) in pulmonary rehabilitation. *Thorax* 2003; 58:513-518

\textsuperscript{1523} Hyland ME. The living with asthma questionnaire. *Respir Med* 1991; 85:13-16


\textsuperscript{1525} Lareau SC, Meek PM, Roos PJ. Development and testing of the modified version of the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M). *Heart Lung* 1998; 27:159-168
validity, stability and reliability of both the dyspnoea and the changes in functional ability domains\textsuperscript{1526}. Changes in dyspnoea do not appear to match declines in lung function over time. Dyspnoea with activities requiring arm elevation showed a positive relationship with rate of FEV1 decline.

This may be a useful research tool, though no data on its responsiveness to change following interventions has been found. It appears rather complex and time-consuming for routine clinical practice.

**Pulmonary Functional Status Scale (PFSS)\textsuperscript{1527}**

This instrument was designed to give strong emphasis to the psychological impact on functional capacity to perform tasks and allows for tasks not undertaken because of non-pulmonary reasons. It also suits the older population affected by COPD. It is a self-report questionnaire, which has been refined from 64 items to 35, with several patterns of response required. It takes around 20 minutes to complete, and yields three main factors - daily activities/social functioning, psychological functioning, and sexual functioning. Its total score correlates well with SIP, 12-minute walk test and the psychological functioning subscale. It has been well-validated, and is said to be responsive to intervention\textsuperscript{1528}.

**Quality of Life Index (QLI) - Pulmonary Version III\textsuperscript{1529}**

The QLI-III is designed for use in patients with COPD. It is a self-administered 70-item questionnaire that takes around 10 to 15 minutes to complete, and covers the dimensions of health and functioning, psychological/spiritual, social and economic, and family. It has been studied in a variety of populations, and has been shown to be sensitive and responsive to cardiopulmonary rehabilitation\textsuperscript{1529,1530}.

**St George Respiratory Questionnaire (SGRQ)**

This measure was described in 1992\textsuperscript{1532}, and has been extensively validated in several languages. It has become widely used in bronchodilator and other medication studies in COPD. There are 50 questions, with 76 responses, and takes about 15 minutes for self-completion.

The SGRQ has four dimensions: Symptoms (frequency and severity), Activity, and Impact (social functioning, psychological disturbances). With weighting of responses there is some difficulty with scoring, though computerised versions have recently become available (including one developed at the Prince of Wales Hospital, Sydney). A total score is calculated by combining the three dimension scores (total score - 0 to 100%, with 100% being maximal disability).

The SGRQ is reliable, reproducible, sensitive to change over time, responsive to interventions\textsuperscript{1533}, and can be used in both COPD and Asthma\textsuperscript{1534}. SGRQ total scores correlate well with SIP ($r=0.65$, $n=41$) and HADS Anxiety ($r=0.50$), and SGRQ total score and both Symptoms and Impacts (but not Activity) were...
significant covariates with severity of hypoxaemia \((p<0.002)\)\textsuperscript{1535}. Total SGRQ correlates with VO\textsubscript{2}max in mild COPD (but not moderate or severe), with \(r = -0.67\)\textsuperscript{1536}. Distinct differences have been shown between grades of COPD severity as measured by MRC Dyspnoea Grade\textsuperscript{1537}. Activity in SGRQ reflects the same factor as MRC Dyspnoea, BDI, OCD, and Dyspnoea in CRDQ. Symptoms and Impacts appear to be distinct entities, with Symptoms reflecting the same factor as CRDQ Fatigue, Emotional Function and Mastery. As an outcome measure the SGRQ performs variably. There were non-significant changes seen in total SGRQ and its three dimensions in the prospective uncontrolled trial of PR\textsuperscript{1538}. The MCID for total SGRQ score following intervention is currently considered to be 4 units\textsuperscript{1539}.

### Seattle Obstructive Lung Disease Questionnaire (SOLQ)\textsuperscript{1540}

This was designed to be self-completed, and to be computer scannable. It was modelled on the CRDQ, then evolved to a 29-item tool that was validated against CRDQ, CSES satisfaction and physiology measures. There are three dimensions of health and one of treatment satisfaction. The physical function scale was loosely based on SF-36, and assesses degree of dyspnoea and the extent of physical limitation. The coping scale reflects self-efficacy. The other health scale is emotional function, reflecting the impact of the respiratory condition on psychological well being. It is reliable, valid and responsive, and is simple to use and to score. It takes most patients 5 to 10 minutes.

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\textsuperscript{1535} Okubadejo AA, Jones PW, Wedzicha JA. Quality of life in patients with chronic obstructive pulmonary disease and severe hypoxaemia. \textit{Thorax} 1996; 51:44-47

\textsuperscript{1536} Hajiro T, Nishimura K, Tsukino M, et al. Stages of disease severity and factors that affect the health status of patients with chronic obstructive pulmonary disease. \textit{Respir Med} 2000; 94:841-846


\textsuperscript{1538} de Torres JP, Pinto-Plata V, Ingenito E, Bagley P, et al. Power of outcome measurements to detect clinically significant changes in pulmonary rehabilitation of patients with COPD. \textit{Chest} 2002; 121:1092-1098

\textsuperscript{1539} Jones PW. Interpreting thresholds for a clinically significant change in health status in asthma and COPD. \textit{Eur Respir J} 2002; 19:398-404

<table>
<thead>
<tr>
<th>Questionnaire names</th>
<th>Respiratory population</th>
<th>No. of items</th>
<th>Time to complete</th>
<th>Domains assessed</th>
<th>Administration format</th>
<th>Key Features/ Remarks</th>
<th>Key references</th>
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<tbody>
<tr>
<td>Medical Outcomes Study Short Form 36 (MOS SF-36)</td>
<td>COPD, Asthma, Cystic Fibrosis, Rhinosinusitis, Interstitial Lung Disorders</td>
<td>36</td>
<td>5 mins</td>
<td>Physical functioning; role limitations due to physical health problems; bodily pain; social functioning; general mental health; role limitations due to emotional problems, vitality, energy or fatigue; general health perceptions.</td>
<td>Self or interviewer administered</td>
<td>Validity and reliability widely tested, used with many populations, good discriminatory potency in interstitial diseases, In COPD outpatients, floor and ceiling effects have been noted, questioning sensitivity to change following pulmonary rehabilitation</td>
<td>Ware, Sherbourne; Stewart; Benzo; Boueri; Mahler, Mackowiak; Prieto; Harper; Berry.</td>
</tr>
<tr>
<td>General Health Questionnaire (GHQ-60, 30 &amp; 28)</td>
<td>COPD, Asthma</td>
<td>60, 30 and 28</td>
<td>10 mins (GHQ60) 5 mins (GHQ30 &amp; GHQ28)</td>
<td>somatic symptoms; anxiety and insomnia; social dysfunction; severe depression</td>
<td>Self-administered</td>
<td>Screening tool to detect psychiatric disorders among general psychiatric outpatients and those in the community. Focuses on 2 areas: inability to carry out normal functions; appearance of new distressing phenomena.</td>
<td>Goldberg.</td>
</tr>
<tr>
<td>Beck Depression Inventory (BDI)</td>
<td>COPD, Asthma</td>
<td>21</td>
<td>5-10 mins</td>
<td>Depression</td>
<td>Self-administered</td>
<td>Screen for clinically significant symptoms of depression, utilised with many populations and in many setting</td>
<td>Beck.</td>
</tr>
</tbody>
</table>

1544 Boueri FM, Bucher-Bartelson BL, Glenn KA, Make BJ. Quality of life measured with a generic instrument (Short Form-36) improves following pulmonary rehabilitation in patients with COPD. *Chest* 2001;119(1):77-84
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<th>Key references</th>
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<tr>
<td>Hospital Anxiety and Depression Scale (HADS)</td>
<td>COPD, Asthma</td>
<td>14 items</td>
<td>5-10 mins</td>
<td>Anxiety, Depression</td>
<td>Self-administered</td>
<td>Screen for clinically significant symptoms of anxiety and depression, utilised in many populations and settings</td>
<td>Zigmond, Snaith1551, Bjelland1552</td>
</tr>
<tr>
<td>Centre for Epidemiological Studies – Depression Mode Scale (CES-D)</td>
<td>COPD</td>
<td>20</td>
<td>5-10 mins</td>
<td>Depression</td>
<td>Self-administered</td>
<td>Useful because items place less emphasis on somatic symptoms of depression, utilised in many populations and settings</td>
<td>Radloff1553</td>
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<tr>
<td>Multi-dimensional Health Locus of Control (MHLOC)</td>
<td>COPD, Asthma</td>
<td>18</td>
<td>5 mins</td>
<td>Internality; chance externality; powerful others externality (replaced with doctors; and other people in Form C)</td>
<td>Self-administered</td>
<td>Form C is condition specific</td>
<td>Wallston 19941554, Wallston 19781555</td>
</tr>
<tr>
<td>Nottingham Health Profile</td>
<td>COPD, Cystic Fibrosis</td>
<td>38</td>
<td>5-10 mins</td>
<td>Physical mobility, pain, social isolation, emotional reactions, energy, sleep</td>
<td>Self or interviewer administered</td>
<td>Reliability and validity tested widely, responsiveness to interventions for COPD not clearly established</td>
<td>Hunt1556, Prieto1557</td>
</tr>
<tr>
<td>Profile of Mood States (POMS)</td>
<td>COPD, Asthma</td>
<td>65</td>
<td>5 mins</td>
<td>Tension-anxiety, depression-dejection, anger-hostility, vigour-activity, fatigue-inertia, confusion-bewilderment.</td>
<td>Self-administered</td>
<td>Reliability and validity tested widely, utilised in many populations and settings</td>
<td>McNair1558</td>
</tr>
<tr>
<td>Symptom Checklist 90 Revised (SCL-90-R)</td>
<td>COPD, Asthma</td>
<td>90</td>
<td>15 minutes</td>
<td>9 Primary Symptom Dimensions 3 Global Indices</td>
<td>Self-administered</td>
<td>Reliability and validity tested in many populations and settings. Screens for a range of psychological problems and symptoms of psychopathology. Useful as a progress or outcomes measurement instrument.</td>
<td>Derogatis1559</td>
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<tr>
<td>State-Trait Anxiety Inventory (STAI)</td>
<td>COPD, Asthma, CRF, CF</td>
<td>40</td>
<td>10 minutes</td>
<td>Anxiety proneness (trait) and current tension/apprehension (state)</td>
<td>Self-administered</td>
<td>Reliability and validity tested widely, utilised in many populations and settings, specific versions available for adults and children</td>
<td>Spielberger1560</td>
</tr>
<tr>
<td>Ways of Coping Questionnaire</td>
<td>COPD, Asthma</td>
<td>66</td>
<td>10 minutes</td>
<td>confrontive coping, distancing, self-controlling, seeking social support, accepting responsibility, escape-avoidance, active problem-solving, positive reappraisal.</td>
<td>Self-administered</td>
<td>Reliability and validity tested widely, used in many populations and settings, useful for assessing behavioural and coping strategies used by patients in stressful situations</td>
<td>Folkman, Lazarus1561</td>
</tr>
<tr>
<td>Minnesota Multiphasic Personality Inventory (MMPI)-2</td>
<td>COPD, Asthma</td>
<td>567</td>
<td>60-90 minutes</td>
<td>8 Validity Scales; 5 Superlative Self-Presentation Subscales; 10 Clinical Scales; 31 Clinical Subscales (Harris-Lingoes and Social Introversion Subscales) 15 Content Scales; 27 Content Component Scales; 25 Supplementary Scales; various special or setting-specific indices</td>
<td>Self-administered</td>
<td>Used to measure psychopathology across a broad range of client settings. Diagnoses personality syndromes &amp; psychopathology Reliability and validity tested widely, utilised in many populations and settings</td>
<td>MMPI-2 Manual1562</td>
</tr>
<tr>
<td>Psychosocial Adjustment to Illness Scale (PAIS)</td>
<td>COPD, Asthma</td>
<td>46</td>
<td>20-25 minutes</td>
<td>Health Care Orientation, Vocational Environment, Domestic Environment, Sexual Relationship, Extended Family Relationship, Social Environment, Psychological Distress.</td>
<td>Semi-structured clinical interview, self-report version available (PAIS-SR)</td>
<td>Assesses the psychological and social adjustment of medical patients (and/or members of their immediate families) to illness, Reliability and validity tested widely, utilised in many populations and settings</td>
<td>Derogatis1563</td>
</tr>
</tbody>
</table>

1562 MMPI-2 Manual for Administration, Scoring, and Interpretation Revised Edition
1563 Derogatis L.R. The psychosocial adjustment to illness scale (PAIS). J Psychosom Res 1986;30(1):77-91
<table>
<thead>
<tr>
<th>Questionnaire names</th>
<th>Respiratory population</th>
<th>No. of items</th>
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<th>Administration format</th>
<th>Key Features/ Remarks</th>
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<tbody>
<tr>
<td>Sickness Impact Profile (SIP)</td>
<td>COPD, Asthma, Cystic Fibrosis, Sarcoidosis, CRF</td>
<td>136</td>
<td>20-30 minutes</td>
<td>Physical: ambulation, mobility, body care, movement. Psychosocial: social interaction, communication, alertness behaviour, emotional behaviour; sleep and rest, eating, home management, recreation and pastimes, employment.</td>
<td>Self or interviewer administered</td>
<td>Described as responsive but some studies have shown it to be relatively insensitive to mild or moderate disease in COPD patients</td>
<td>McSweeny1564, White1565.</td>
</tr>
<tr>
<td>Quality of Well-Being Scale (QWB)</td>
<td>COPD, Cystic Fibrosis</td>
<td>16</td>
<td>12-20 minutes</td>
<td>Symptoms, mobility, physical activity, social activity.</td>
<td>Interviewer administered (Structured)</td>
<td>Scores can be translated into economic evaluation for cost-effectiveness studies or quality of adjusted life years (QALYs), no evidence of sensitivity to change associated with pulmonary rehabilitation, sensitivity reported with Cystic Fibrosis interventions</td>
<td>Anderson1566, Chang1567, Guyatt1568</td>
</tr>
<tr>
<td>Geriatric Depression Scale</td>
<td>COPD, Asthma</td>
<td>30</td>
<td>5 minutes</td>
<td>Depression</td>
<td>Self-administered</td>
<td>Appropriate for elderly patients</td>
<td>Yesavage1569, Wigal1570</td>
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<tr>
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</thead>
<tbody>
<tr>
<td>St. George’s Respiratory Questionnaire (SGRQ)</td>
<td>COPD, Asthma</td>
<td>50</td>
<td>10-15 minutes</td>
<td>Symptoms (frequency &amp; severity); Activity; Impact (social functioning, psychological disturbances)</td>
<td>Self-administered</td>
<td>Sensitive to change, many languages available, reliability and validity widely tested</td>
<td>Jones, 19921571, Jones, 19971572, Lahdensuo, 19961573</td>
</tr>
<tr>
<td>Chronic Respiratory Questionnaire (CRQ)</td>
<td>COPD, Cystic Fibrosis, Asthma</td>
<td>123</td>
<td>15-30 minutes</td>
<td>Dyspnoea, Fatigue, Emotional Function, Mastery of Disease</td>
<td>Interviewer administered</td>
<td>Sensitive to change, resource intensive (not self-administered), reliability and validity widely tested, many languages available, a new self-report version recently developed</td>
<td>Guyatt, 19871574, Wijkstra, 19941575, Goldstein, 19941576, Griffiths, 20001577, Lacasse, 19971578, Green, 20011579</td>
</tr>
<tr>
<td>Quality of Life Index (QLI) - Pulmonary Version III</td>
<td>COPD</td>
<td>70</td>
<td>10 minutes</td>
<td>health and functioning, psychological/spiritual, social and economic, family</td>
<td>Self-administered</td>
<td>Utilised with many populations and in many settings, responsive and sensitive to change in the one study with a cardiopulmonary rehabilitation program</td>
<td>Ferrans, 19921580, McEntee, 20001581, Scherer, 19941582</td>
</tr>
<tr>
<td>Pulmonary Function Status and Dyspnea Questionnaire (PFSDQ)</td>
<td>COPD</td>
<td>158</td>
<td>15 minutes</td>
<td>daily activities/ social functioning, psychological functioning, sexual functioning</td>
<td>Self administered</td>
<td>Focus on dyspnoea and functional status, responsive to pulmonary rehabilitation interventions, validity and reliability tested, thorough assessment of dyspnoea</td>
<td>Lareau, 19941583, Lareau, 19981584</td>
</tr>
</tbody>
</table>

1572 Jones PW, Bosh TK. Quality of life changes in COPD patients treated with salmeterol. Am J Respir Crit Care Med 1997;155:1283-1289
1578 Lacasse Y, Wong E, Guyatt G. A systematic overview of the measurement properties of the Chronic Respiratory Questionnaire. Canad Respir J 1997; 4:131-139
1584 Lareau SC, Meeck PM, Roos PJ. Development and testing of the modified version of the Pulmonary Functional Status and Dyspnea Questionnaire (PFSDQ-M). Heart Lung 1998; 27:159-168
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<tbody>
<tr>
<td><strong>Seattle Obstructive Lung Disease (SOLQ)</strong></td>
<td>COPD</td>
<td>29</td>
<td>10 minutes</td>
<td>physical function, emotional function, coping skills, treatment satisfaction</td>
<td>Self-administered</td>
<td>efficiently measures the functional status impairments specifically due to COPD, data for stable vs unstable disease, promising validity, reliability and responsiveness</td>
<td>Tu, 1997&lt;sup&gt;1585&lt;/sup&gt;</td>
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<tr>
<td><strong>Living With Asthma Questionnaire (LWAQ)</strong></td>
<td>Asthma</td>
<td>68</td>
<td>20 minutes</td>
<td>social/leisure, sport, sleep, holidays, work and other activities, colds, mobility, effects on others, medication use, sex, dysphoric states and attitudes</td>
<td>Self-administered</td>
<td>Subscales of functional limitation and distress Useful for individual patient management and clinical trials, responsive but sensitivity unclear</td>
<td>Hyland, 1991&lt;sup&gt;1586&lt;/sup&gt; Hyland, 1991a&lt;sup&gt;1587&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Pulmonary Functional Status Scale (PFSS)</strong></td>
<td>COPD</td>
<td>161</td>
<td>15-30 minutes</td>
<td>ADLs: self-care, transportation, household tasks, grocery shopping, meal preparation, daily activities, relationships, dyspnoea anxiety, depression</td>
<td>Self-administered</td>
<td>Focus on dyspnoea and ADLs, not widely tested, face and concurrent validity with SIP</td>
<td>Weaver, 1992&lt;sup&gt;1588&lt;/sup&gt; Mercer, 1997&lt;sup&gt;1589&lt;/sup&gt; Votto 1996&lt;sup&gt;1590&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Maugeri Foundation Respiratory Failure Questionnaire (MRF28)</strong></td>
<td>CRF, COPD</td>
<td>28</td>
<td>10 minutes</td>
<td>daily activity, cognitive function, emotional status, invalidity, perception of general health, respiratory health</td>
<td>Self-administered</td>
<td>specifically designed for patients with chronic respiratory failure, due to COPD or kyphoscoliosis, either on LTOT or NIPPV, many languages available, good discriminatory potency between different levels of impairment of CRF patients</td>
<td>Carone 1999&lt;sup&gt;1591&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>1586</sup> Hyland, ME The living with asthma questionnaire: Respir Med 1991; 85 (Suppl B):13-16
<sup>1588</sup> Weaver TE, Narsavage GL. Physiological and psychological variables related to functional status in chronic obstructive pulmonary disease. Nurs Res 1992; 41:286-291
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<tbody>
<tr>
<td>Airways Questionnaire</td>
<td>COPD</td>
<td>30</td>
<td>3 minutes</td>
<td></td>
<td>Self-administered</td>
<td>Many languages available</td>
<td>Barley, 19981592</td>
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<tr>
<td>COPD Self-Efficacy Scale (CSES)</td>
<td>COPD</td>
<td>34</td>
<td>5-10 minutes</td>
<td>Negative affect, intense emotional arousal, physical exertion, weather/environmental, behavioural risk factors</td>
<td>Self-administered</td>
<td>Self-efficacy measured in terms of confidence to achieve a physical activity, not a QOL index</td>
<td>Wigal, 19911593</td>
</tr>
<tr>
<td>Asthma Quality of Life Questionnaire</td>
<td>Asthma</td>
<td>32</td>
<td>10-15 minutes</td>
<td>Symptoms, emotions, exposure to environmental stimuli, activity limitation</td>
<td>Self or interviewer administered</td>
<td>Many languages available, reliability and validity widely tested, responsiveness and sensitivity tested, minimally important difference developed, widely used</td>
<td>Juniper, 19931594</td>
</tr>
<tr>
<td>(AQLQ)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Juniper, 19921595; Boulet, 19951596; Gibson PG, Talbot PI, Toneguzzi, 19951597</td>
<td></td>
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<tr>
<td>Asthma Quality of Life Questionnaire</td>
<td>Asthma</td>
<td>20</td>
<td>5 minutes</td>
<td>Breathlessness and physical restrictions, mood disturbance, social disruption, concerns for health</td>
<td>Self-administered</td>
<td>Validity and reliability reported, developed in Australia</td>
<td>Marks, 19931598; Marks, 19921599</td>
</tr>
<tr>
<td>(Marks)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Manchester Respiratory Activities of</td>
<td>COPD</td>
<td></td>
<td></td>
<td></td>
<td>Self or interviewer administered</td>
<td>Composite of questions from the Nottingham Extended ADL Questionnaire (NEADL) and Breathing Problems Questionnaire (BPQ). Sensitive to PR interventions, useful for older populations, respiratory specific ADL index</td>
<td>Yohannes, 20001600</td>
</tr>
<tr>
<td>Daily Living Questionnaire (MRADL)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
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1599 Marks GB, Dunn SM, Woolcock AJ. A scale for the measurement of quality of life in adults with asthma. *J Clin Epidemiol* 1992;45:461-472
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</tr>
</thead>
<tbody>
<tr>
<td>Air Index</td>
<td>Asthma</td>
<td>63</td>
<td>15-20 minutes</td>
<td>Psychological, Physical Activity, Physical Symptoms, Social</td>
<td>Self-administered</td>
<td>Validity and reliability established, responsiveness and sensitivity not established</td>
<td>Letrait, 1996&lt;sup&gt;1601&lt;/sup&gt;</td>
</tr>
<tr>
<td>Breathing Problems Questionnaire (BPQ)</td>
<td>COPD, Asthma</td>
<td>33 (Long Version), 10 (Short Version)</td>
<td>3-10 minutes</td>
<td>Walking, Bending or reaching, Washing and bathing, Household chores, Social interactions, Effects of weather or temperature, Effects of smells and fumes, Effects of colds, Sleeping, Medicine, Dysphoric states, Eating, Excretion urgency Also can calculate scores based on two constructs: health knowledge and health appraisal</td>
<td>Self-administered</td>
<td>Available in other languages, responsive to changes following pulmonary rehabilitation</td>
<td>Hyland, 1994&lt;sup&gt;1602&lt;/sup&gt;, Hyland, 1998&lt;sup&gt;1603&lt;/sup&gt;</td>
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APPENDIX 1
Pulmonary rehabilitation programs in Australia

A.1.1. ALF Better Breathing Program
Survey of Patient Perspectives of Pulmonary Rehabilitation

The Australian Lung Foundation commissioned an evaluation in 1999 of patient perspectives of Pulmonary Rehabilitation (PR) in an attempt to identify the critical factors for success, the "core elements" required, and current referral systems.

The evaluation had an initial small-scale qualitative phase, which was followed by a more comprehensive quantitative phase. The former comprised face-to-face interviews with patients in their homes. Eight patients who had been in three different programs were interviewed in March 2000. The sample covered patients who completed a PR program and joined a patient support group (PSG), patients who only completed a PR program and did not join a PSG, and patients who did not complete their full PR program. From the responses a range of questions were developed for the quantitative phase.

Description of quantitative survey
The structured questionnaire for telephone interviews was piloted before being used in the active quantitative survey. Interviews were conducted by phone over an average time of 40 minutes. There were 151 interviews conducted, over May and June 2000. The patients interviewed were selected by ballot from patient lists provided by hospitals and program volunteers. They covered a wide span of ages, and they represented 24 PR programs across different cities, regional and rural as well as urban. As in the earlier phase, patients selected represented those completing PR and joining PSGs (46%), those completing PR but not joining PSGs (44%), and those who did not complete PR (9%). The structured interviews were coded for a range of patient characteristics, location of program, program characteristics, patient expectations and ratings of program characteristics and outcomes, and issues about PSGs. These data were computer processed along with patient psychographic measures, and analysed.

Patient characteristics
Two-thirds of programs were city-based. State-distribution of patients were: 30% New South Wales, 21% each Victoria and South Australia, 12% Western Australia, 10% Queensland, and 7% Tasmania. The gender ratio was 59% male, 41% female. The majority were aged more than 60 (30-49 = 1%, 50-59 = 13%, 60-69 = 30%, 70-79 = 47%, 80-plus 10%). Respiratory diagnoses coded included emphysema (75%), asthma (42%), chronic bronchitis (13%), COPD/COAD (13%), and bronchiectasis (10%). Non-respiratory conditions were also often coded - especially arthritis (41%), hypertension (25%) and osteoporosis (23%). Most patients (92%) did not attend with a carer or family member, and 40% actually lived alone. The majority appeared to be in
mild to moderate disability, as 79% felt comfortable walking outside, and 5% were still in paid employment. Most (86%) had been smokers in the past, and only 9% had never smoked. Word of mouth, rather than advertisements, was the most common source of awareness about the programs (96%), and Specialists were the most usual source of referral (49%). For the 17 patients who did not attend all sessions and the 14 who dropped out of their program, sickness was the most common limiting factor.

**Expectations and Perceived outcomes**

Most participants expected improvements in breathing (30%) and exercise capacity (21%), but there was a range of other expectations. Overall program ratings averaged between highly beneficial (32%) and extremely beneficial (54%), though 4% rated their program as "not at all beneficial". Perceived benefits were related to achievement of or exceeding expectations in exercises, breathlessness and fitness. Low ratings of benefit came especially from the oldest clients and from respondents who did not complete the program. Some felt they were pushed too hard, while others felt they did not reach their expectations of gain in fitness. After completion of the program most patients continued some form of exercise, mostly walking (82%), while a minority used gym equipment (33%) and/or weights (1%), predominantly at home (89%). Almost 60% felt their fitness was greater after the program than before, although respiratory problems had interfered with exercise in almost half the survey respondents. Knowledge and awareness were perceived as slightly more beneficial than fitness and general wellbeing, yet rather paradoxically, in programs offering the greatest amounts of formal education the perceived long-term fitness subsequently was less. The information deemed to be of greatest interest/benefit covered use of medications (41%), breathing techniques (35%), physical exercise (30%) and nutrition (25%), though there was substantial variance across programs, probably depending on the emphasis and available personnel.

**Access**

Most respondents (82%) had no access difficulties, though it must be acknowledged that poor access would have a selection bias. Distance from the program and parking were the most prevalent access complaints. Most (81%) had to travel less than 30 minutes to attend, but city respondents and women reported longer travelling times. Most travelled by car (75%), especially in regional and rural areas, though women were more likely to travel by public transport. Most patients (83%) waited less than 3 months to start their PR participation.

**Course characteristics**

Physiotherapists coordinated 56% of programs, and 29% were run by respiratory nurses. There was a high degree of satisfaction with program coordinators. Most courses lasted from 6 to 8 weeks, and most participants attended only one session per week (57%). Group sizes ranged from a few as 4 to as many as 30 (median = 10). Socialisation occurred in two-thirds of programs, and most (75%) patients felt this was important time for them. Most patients (88%) received reference material while in the program, and 95% of those receiving such material found it useful, especially to refer to later. Sessions were usually 90 to 120 minutes (61%), and most (89%) included exercise. When exercise training was included there was a high participation rate in the exercises (88%), and the sessions were most likely to be an hour or more (58%). Those patients attending exercise training perceived greater long-term benefit, and those attending for longer times gained greater enjoyment and perceived greater fitness gains. A variety of exercises was employed, with gym equipment and weights being commonly utilised (88% each). Most participants also did exercises at home during the program (79%), almost half on at least 6 occasions per week (49%), 30% of them for more than 30 minutes.
Follow-up and Patient Support Groups
Follow-up contact between patient and program staff was common (68%), especially in those joining PSGs (84%), and especially males (75%). This contact was highly valued, although those who did not have follow-up contact actually preferred it that way. Three-quarters of all participants expressed interest in repeating their program, and 41% remained in PSGs after their participation in PR. There were many reasons why people wanted to repeat their participation, and equally many for those not wanting to repeat – however no consistent message was apparent. PSG membership was not taken up by 58% of respondents, 17% of whom had never heard of them, 13% lived too far away, 7% were too busy, while cumulatively 24% had their own support network, found their doctors provided enough, participated in other service groups, or preferred to help themselves. PSGs were valued for their capacity to provide social contacts (56% of respondents), more than for formal lectures (26%) or information updates (11%).

Conclusions
1. 85% rated their PR programs positively.
2. The main benefits related to better breathing, better fitness and greater knowledge of exercises and breathing techniques.
3. Long-term benefits were often perceived.
4. Benefit did not relate to length or intensity of program.
5. Establishing and extending physical limits appeared to provide confidence to exercise more at home.
6. Components valued highly were exercise training, formal education, resource materials, and informal social contacts.
7. A balance needs to be established between education and exercise training inputs.
8. Little emphasis has been put on specific behaviour change strategies.
9. Heterogeneity of disease, severity of disability, program, and group size were not considered important influencing factors.
10. Follow-up was important especially for those who are less well.
11. Many patients would wish to repeat PR.
12. Continuation exercise was highly valued.
13. Access created difficulties for women in particular.
A.1.2. ALF Better Breathing Program
Survey of Pulmonary Rehabilitation Programs in Australia

This project was conducted in 2000 under the supervision of Sue Jenkins (physiotherapist coordinator of a PR program) for the ALF. Submissions from organisations and individuals on an ALF register (PR Network) were invited. Fifty-three Australian PR programs were identified as being current, and a representative from each was surveyed by structured telephone interview. Another 14 had made submissions previously but their funding had failed, or they were still in a set-up phase. Of the fifty-three, 38 were based in major teaching hospitals, regional base hospitals, or smaller private hospitals, and 15 were run from community centres. All states were represented: Victoria (12), New South Wales (11), Queensland (9), Western Australia (9), South Australia (6), Tasmania (4) and Australian Capital Territory (2). A range of characteristics was surveyed, from referral patterns, through personnel involved, program components, assessment tools, outcome measures and follow-up.

Patient throughput
Nationally 2,554 patients completed PR in 1999. Six programs reported throughputs of over 100 patients in the year, while the median number per site per year was 35. Most patients had COPD, though the proportion with COPD ranged from 30% to 100% (median 85%). Thirty-two programs catered for pre and post surgical candidates (LVRS and transplantation). Most programs included carers, and over two-thirds (68%) provided some form of maintenance sessions. Half the programs had waiting lists, from 2 to 7 months.

Referral patterns, and links with GPs
Most referrals were from respiratory specialists (83%), GPs (71%) and thoracic surgeons (67%). Twenty-two percent of programs accepted self-referrals. Strong links with GPs were reported from 9 centres (including two linked to coordinated care programs), but the majority reported weak (39) or non-existent (5) links to GPs. Hospital inpatients (32%) and physiotherapists (28%) were important referral sources. Only 7.5% had referrals from patient support groups.

Program components
Four programs provided only education sessions, while 11 provided only exercise training (though two of these also provided information on smoking, infections, stress management and community resources). The remaining 38 provided education and exercise. In the 42 programs providing education, a wide range of topics was offered. Most commonly this related to exercise (90.5%), breathing exercises (90.5%), and activities of daily living and energy conservation (73.5%). Stress management and coping were addressed by 83%, relaxation was taught in 64%, and psychological issues were addressed by 69.8%. Information was provided about medications by 81%, inhalation devices by 75.5%, prevention of infections by 60%, oxygen therapy by 58.4%, and community resources by 71.6%. Smoking was specifically addressed in only 49%, while information about lung function (52.8%), nutrition (81%), and support groups (58.5%) were more often programmed. Incontinence (26%) and sexuality/relationships (16.9%) were uncommon components. Carer issues were addressed by 49% of programs.
Staffing
Most programs (72%) were coordinated by physiotherapists, while 24.5% were coordinated by nurses. One occupational therapist and one psychologist were listed as coordinators. Patient information sessions were provided by physiotherapists in all but one program and by nurses by 62%. Occupational therapists (75.4%), dieticians (73.5%), pharmacists (66%), and social workers (62%) were highly represented presenters. Other contributors were psychologists (30%), mental health nurses (11%), respiratory scientists/technicians (16.9%), respiratory physicians (41.5%) and GPs (13.2%).

Assessments
Patients underwent formal assessments in all programs, all but four recording a medical history and well under half recording lung function (40%). Some form of exercise performance assessment was made in 87% (the most common was a 6-minute walk test). At least one form of quality of life assessment was made in 60% (the disease-specific Chronic Respiratory Questionnaire in 32% and St George’s Respiratory Questionnaire in 26.4%, and the generic SF36 in 8%). No programs recorded measurement of specific psychological measures, though self-efficacy, locus of control or self-esteem were assessed in two. Health care utilization indexes (hospitalization etc) were recorded routinely by only one program.

Post-program assessments were undertaken in all 53 programs. The outcome measures were: exercise performance (85%), quality of life (55%), lung function (38%), and patient satisfaction (13%).

Follow-up
Some form of follow-up monitoring assessment was made at 3 months by 32% of programs, at 6 months by 56.6%, at 9 months by 15%, and at 12 months by 35.8%. Referrals were made to patient support groups from 90.5% of the 53 PR programs.

Conclusions
1. People with moderately severe and severe COPD represented the main clientele of PR programs in Australia in 1999.
2. A small minority (less than 1%) of the estimated half-million Australians with symptomatic COPD are able to access current programs.
3. The most common sources of referrals in 1999 were respiratory physicians and GPs, though links to GPs were considered very weak.
4. Most programs provided both education and exercise training, with a high level of attention reported to stress management as well as breathing exercises.
5. Areas of specific information deficiency were continence and sexuality, and smoking.
6. Only half of the programs addressed carer issues specifically, despite most encouraging carers to attend.
7. Physiotherapists and nurses were highly represented as information providers, with doctors, mental health workers and pharmacists being less frequently involved.
8. Lung function was not widely used as an initial assessment tool (or outcome measure).
9. Exercise performance was almost universally assessed initially and as an outcome, most often with a 6-minute walk test.
10. Quality of life was measured in only 40% of programs (disease-specific the most usual), and psychological measures were rarely assessed.
11. Eighteen of the 53 programs did not have any follow-up visits programmed, although all but one of these recommended or referred patients to support groups.
A.1.3. ALF Patients Needs Analysis

A Patient Needs Analysis was undertaken in 1999 by Pieter Walker (respiratory psychologist) for the ALF, utilising both questionnaires and focus groups with structured discussion and analysis. Patients who were members of LungNet Patient Support Groups were invited to participate.

**Patient demographics**

There were 576 respondents, with an average age of 66.6 years, and a male : female ratio of 53% to 47%. There was a representative mix of diagnoses – 56% emphysema, 37% asthma, 22% bronchitis, and 37% “other respiratory diagnoses”. Over 70% had a smoking history. Patients were on average severely disabled, with 86.4% of them perceiving their condition as at least moderately severe, 41% of them were using long term oxygen therapy, and almost half had been admitted to hospital at least once in the past year. The average number of respiratory medications used by them was 3.5.

**Impacts on Quality of Life**

Questionnaire analysis showed functional status was the main contribution to poor quality of life. This included limits to leisure activities, physical mobility and household activities. Other factors contributing to poor quality of life included (in order) lack of knowledge, poor community awareness and understanding of lung diseases, costs of their illness (medications, visits to health professionals, and foregone employment), poor communication from their doctors, and social stigma and isolation. In the focus groups, psychological impacts such as anxiety, depression and low self-esteem were identified as the most significant factors in poor quality of life.

**Services and Information**

The most frequently accessed health services were (in order) GPs, pharmacy, support group and respiratory physician. There was a high level of satisfaction with GP care, though patients recognized that GPs needed better training about chronic lung disease management, and about communication with patients. Focus groups rated support groups and rehabilitation highly, but reported that access to rehabilitation and counseling was currently inadequate. They also felt more information about support services, diseases and medications was required. Services such as district nursing, domiciliary care and meals on wheels were under-utilised. Further, access to and availability of medications, and inadequacy of medication information (especially drug side effects) were identified as problematic. Of the information they received, 76% came through respiratory specialists and 74% through GPs or other doctors, most commonly verbally (87%). Only 47% recalled receiving printed information, and there was essentially no use of audio-visual or computer educational aids reported.

**Conclusions**

1. Quality of life was adversely affected by psychological factors.
2. However, access to counseling, rehabilitation and other support services was sub-optimal.
3. Patients want better access to clear information about medications and their side effects.
4. An independent central resource (ALF) for information about disease management was highly valued, above pharmaceutical company patient information.
5. Telephone counseling and help-line services were reported as highly desirable.
6. Self-management aids, client-held records, and action plans were considered important.
A,1.4. Pulmonary Rehabilitation Survey, 2007

A Market Research Survey was undertaken for ALF by StollzNow, and reported in July 2007. A total of 137 PR coordinators completed questionnaires, in 96% of cases at a time when a PR program was in existence on site. The survey covered rural and metropolitan areas, in all states and territories. Several main themes were addressed.

Program Aspects
71% of programs were conducted as regular group courses over a specific time-frame, with 27% running as continuous ‘rolling’ programs.

Course characteristics
- The national average for participants attending is 1.8 times per week
- The national average for duration is 9 weeks
- The national average number of participants is 8.4 per group
- Referral sources are mostly specialists (43.7%), with primary care is the source for 33.9%
- There are specific entry criteria for 45% of programs, mostly applying diagnostic groups (86%), but in 33% severity is a lead criterion

Waiting lists
- The national average for patients on a waiting list is 13.5 patients
- 17% of programs have waiting times ‘more than 8 weeks’
- The national averaging waiting time to enter a program is 5.9 weeks beyond the start of the next program

Challenges and Barriers
52% of programs identified a variety of challenges, mainly related to patient transport (56%), patient drop-out (51%) and uncertain funding (47%).
Other important challenges were staff attraction and retention (37%), lack of support from the hospital (35%) and adequacy of referrals (21%).
96% were sure there are patients not attending who could gain benefits by being referred.

Funding sources
Of the many identified funding sources, ‘within hospital funding’ was the most common (51%), followed by specific ‘state funding’ (35%).

Barriers to attendance
- lack of awareness by primary care (74% - 84% in rural areas)
- transport difficulties (65% - 56% in rural areas)
- lack of acceptance by patients (52%)
- lack of awareness among specialists (40%)
- lack of funding (38%)
- lack of parking (37% - 29% in rural areas)

Maintenance
82% of PR coordinators indicated they refer their patients for maintenance courses following completion of the PR course. In 66% these are ‘community based’, though in NSW 62% were
based in hospitals. Very few were conducted in a gym or at home. The 18% who did not refer on were not aware of maintenance programs available in the vicinity.

**Support groups and ALF resources**
62% of PR coordinators refer patients on to support groups. The remainder were unaware of local support groups.
Important linkages between programs and the ALF were identified. 70% of programs provided information about ALF supports during lectures, and 68% provided ALF literature.
There was strong interest in the ALF providing information about PR programs – effective methods considered were GP posters (76%), hospital posters (74%), letters and information to primary care (69%) and letters and information to specialists (62%)
Media campaigns were thought to be probably ineffective.

**Conclusions**
1. PR programs are available in all states and territories (with fewest being available in ACT). Distribution according to population and geography was not documented.
2. Most courses have twice-weekly attendance, with around 10 patients per group, running for an average of 9 weeks. These match guidelines satisfactorily
3. Only one-third of programs received GP referrals.
4. On average there are over 10 patients on waiting lists per program, and these patients on average wait for around 6 weeks after the next group starts (i.e. for up to 13 weeks).
5. Program funding and patient access difficulties are the major challenges in keeping programs running.
6. Lack of awareness of PR by both GPs and specialists, lack of acceptance by patients of the role and benefits of PR, and transport difficulties are major barriers for delivering PR.
7. Maintenance program availability is an important ‘missing link’ between evidence and practice.
A.1.5. Comprehensive Pulmonary Rehabilitation.

A Sample Program

This example should not be seen to be the paragon of Pulmonary Rehabilitation. There are more extensive details to be found in the ALF/APA Pulmonary Rehabilitation Toolkit, which can be accessed through http://www.pulmonaryrehab.com.au.

**Education Course**

A comprehensive education package, including:

- Training in partnership self-management
- Anatomy and physiology of the lung and lung mechanics
- Sputum clearance, bronchial hygiene and breathing techniques
- Benefits of exercise
- Dealing with stress / anxiety and depression
- Respiratory medications (pharmacy)
- Use of respiratory devices / and O2
- Weight maintenance and good nutrition
- Difficult issues (sex, relationships, continence, end-of-life, palliation)
- Activities of daily living / task simplification
- Social, family and community supports

Experience has suggested:

- Group sizes of 6 to 12 patients work best (with additional significant others).
- Classes are led by a relevant specialist allied health / nursing / medical worker.
- Training classes should encourage full participation of patients and their spouse / carer.
- Therapists should stress the importance of enjoyment and provide leadership on developing self-confidence to communicate with doctors and other health workers, enabling a capacity to self-monitor and self-manage.
- The duration of the course depends on local practicalities and the ability of the participants to attend multiple times. On average 2 hours per week for 8 weeks should cover most aspects.

**Exercise Training Program**

Participants attend a supervised and monitored exercise program in a gymnasium, involving:

- Upper and lower limb training
- Focus on improving endurance, muscle strength and flexibility
- General exercise program
- Interesting activities
- Learning how to do it at home
- Breathing exercises.

Experience and the medical literature have suggested:

- Participants should perform exercise at least 3 times a week for at least 45 minutes to achieve training over 6 to 8 weeks.
- Exercise classes are limited to small numbers (less than 15) so that safe, individualised attention can be given.
Where the subject’s pO2 is less than 55mmHg or the SpO2 is less than 87%, supplemental oxygen is provided and the participant monitored carefully in each early session. This helps to reassure the therapist, patient and carer about setting safe limits for ongoing exercise.

In addition, participants are encouraged to undertake regular home exercises.

They may be issued with a booklet (containing pictures of the exercise to be done at home), sometimes a pedometer or similar activity monitor, and a behavioural diary.

**Psychosocial Supports**
Participants are encouraged to enrol in a patient support group, and they receive advice on the community network of social programs and supports.

- Through the course, if patients want individual advice, or a therapist identifies a need for such advice, counseling should be made available.
- Notable areas are anxiety or depression, stress management, sex/relationship counseling, nutrition advice, terminal care issues, incontinence, etc.

**Patient Screening Evaluations**
The aims of initial patient assessment are numerous. They include introducing patients to key staff and facilities and characterising their medical conditions and comorbidities. Specific issues include determining the severity of the respiratory impairment, degree of reversibility, and functional performance, documenting what medications are actually taken (and alerting managing doctors to potential problems), highlighting mobility, nutritional and psychosocial issues that need to be addressed, and providing baseline reference values for outcome measures.

**Demographics**
- age, race, gender
- smoking history (current habit, date of quitting (if relevant), average consumption over years)
- main respiratory diagnoses (eg chronic bronchitis, asthma, emphysema, bronchiectasis, pulmonary fibrosis) and their duration
- use of domiciliary oxygen (dose, duration of use, and date of starting),
- other medical conditions currently relevant or contributing to disablement
- current medications actually used (and those prescribed), including "adjunct", "alternative", and "herbal" products.

**Carer status**
- presence of an immediate carer at home
- well-being of the carer

**Lung Function**
- forced expiratory volume in 1 second (FEV1), forced and slow vital capacity (FVC & SVC) and inspiratory capacity (IC) pre and post bronchodilator (for severity of respiratory impairment and reversibility)
- arterial blood gas analysis (ABG) for PaO2 and PaCO2 (for degree of hypoxaemia, and presence of acute or chronic respiratory failure)
- static lung volumes and gas transfer factor (for degree of hyperinflation and gas transfer impairment)
• functional exercise capacity with perceived distress (eg Borg for fatigue and dyspnoea) and oximetry

**Psychology**

• Overall psychological health (eg GHQ28)
• Specific psychiatric diagnoses (eg HADS)
• Cognitive status (eg MMS)
• Mood disturbance (eg POMS)

A report of findings should be provided for referring practitioners and other health workers involved in the patient's care.

**Primary Outcome measures**

• Functional exercise capacity (eg 6-minute walk test or endurance shuttle walk test)
• HRQoL Questionnaires (eg SGRQ, CDQ, SF36)
• Other focussed questionnaires (eg coping, self-efficacy, etc)
• Health care utilisation (eg number of hospital attendances, length of stay in hospital admissions, programmed and urgent visits to GPs and specialists, actual out-of-pocket expenditure by patient and carer)

A report of progress following the main program should be provided for referring practitioners and other health workers involved in the patient's care.
APPENDIX 3

Submissions to ALF

The Australian Lung Foundation sponsored the preparation of this document, and as part of that sponsorship invited expressions of interest in developing Standards for PR from all organisations and individuals on their PR Network database in December 2001. Submissions were received from the following:

AUSTRALIAN PHYSIOTHERAPY ASSOCIATION. The National Cardiothoracic Special Group of the Australian Physiotherapy Association, written by Dr Marie Williams, Chairperson, and Ms Kathy Mecca, Victoria Representative, National Cardiothoracic Special Group, Australian Physiotherapy Association.

THE ALFRED HOSPITAL MELBOURNE. Prue Munro, Senior Clinician Physiotherapist, Lung Transplantation Unit; and Anne Holland, Senior Physiotherapist, Pulmonary Rehabilitation Program, The Alfred Hospital, Melbourne, VIC

AUSTIN & REPATRIATION MEDICAL CENTRE MELBOURNE. Catherine Hill, Senior Physiotherapist, Pulmonary Rehabilitation, Austin & Repatriation Medical Centre, Prahran, VIC

ROYAL BRISBANE HOSPITAL PERTH. Cherie Hearn, Senior Physiotherapist, LATTICE team, Royal Brisbane Hospital, QLD

CONCORD HOSPITAL SYDNEY. Andreas Heidemann, Pulmonary Rehabilitation, C 31 Respiratory Unit, Concord Hospital, NSW

PRINCESS MARGARET HOSPITAL FOR CHILDREN PERTH. Kylie Johnstone, PhD student, Curtin University of Technology, Clinical Specialist Physiotherapist (Cardiopulmonary), Princess Margaret Hospital for Children, Perth, WA

MID NORTH COAST AREA NSW. Kempsey District Hospital and the Mid North Coast Area Health Service, NSW. Chris Hanna, Project Officer, Priority Health Care Programme, Health Service Development Unit, Port Macquarie Health Centre, Port Macquarie, NSW

PRINCE OF WALES HOSPITAL SYDNEY. Cynthia Ashley, Health Professional involved with PR Programs, Prince of Wales Hospital, Randwick, Sydney, NSW

ROYAL PERTH HOSPITAL. PERTH. Kylie Hill, (Senior respiratory physiotherapist) and Peta Winship (Senior cardiothoracic physiotherapist), Royal Perth Hospital, WA

ROYAL PRINCE ALFRED HOSPITAL SYDNEY. Pulmonary Rehabilitation Unit, Department of Physiotherapy, Royal Prince Alfred Hospital, Submitted by Jenny Alison and Lissa Spencer, Sydney, NSW.
SHOALHAVEN REGION. Submitted by Tod Adams, CNC Chronic and Complex Care, CVA & CAL Coordinator, Nowra, NSW

ST VINCENTS HOSPITAL MELBOURNE. Pulmonary Rehabilitation Coordinator, Amanda Kochevatkin, Senior Physiotherapist, St Vincents Hospital, Melbourne, VIC

WHITEHORSE COMMUNITY HEALTH SERVICE VIC. WCHS Pulmonary Rehabilitation Program (PRP), Edward Chan (physiotherapist) and Olive Aumann (community health nurse) with input from participants (and their carers) and the Whitehorse Respiratory Support Group; from the Whitehorse Community Health Service, Box Hill, VIC.

THE NORTHERN HOSPITAL MELBOURNE. David Berlowitz, PhD student (Physiotherapy), University of Melbourne, and Coordinator, Cardiovascular and Respiratory Medicine Research Program, The Northern Hospital, Melbourne, VIC.

SIR CHARLES GAIRDNER HOSPITAL PERTH. Dr Sue Jenkins and Nola Cecins, Pulmonary Rehabilitation Physiotherapists, Physiotherapy Department, Sir Charles Gairdner Hospital, Nedlands, WA 6009

THE WESLEY HOSPITAL BRISBANE. The Introduction of a Pulmonary Rehabilitation Program, Submitted by Elizabeth Egan, The Wesley Hospital, Brisbane, QLD

EPWORTH HOSPITAL MELBOURNE. Caroline Nicolson, Physiotherapist, (including Business Plan and Audit Results), Epworth Hospital, Bridge Road, Richmond VIC

Pulmonary Rehabilitation at Grace McKellar Centre. Submitted by Bonita Emsley, Pulmonary Coordinator, North Geelong Community Rehabilitation Centre, Barwon Health, Ballarat Road, North Geelong, VIC

GREENSLOPES PRIVATE HOSPITAL BRISBANE. Respiratory Rehabilitation at Greenslopes Private Hospital, submitted by L Molloy, Program Coordinator, Brisbane, QLD

REPATRIATION GENERAL HOSPITAL ADELAIDE. Pulmonary Rehabilitation Annual Report, Peter Frith, Department of Respiratory Medicine, Repatriation General Hospital, Daw Park, SA

‘Personal Expressions of Interest’

Dr John Booth, Exercise Physiologist, Wollongong, NSW

Ms Vicki Neale, Post-Lung Transplant patient, South Plymptom, SA

Consumer at Royal Prince Alfred Hospital Pulmonary Rehabilitation program, by Virginia Northwood, President, LAM Australia Inc, LEICHHARDT, NSW

Research and Development Papers

Preliminary outcome of COAD Rehabilitation, Submitted by Maria Podger, Ipswich Hospital, QLD
EVALUATION OF AN OUTPATIENT PULMONARY REHABILITATION PROGRAMME. Submitted by Vanessa McDonald, Clinical Nurse Consultant, Respiratory Medicine, John Hunter Hospital, Newcastle, NSW

Evaluation & Progress Report of Programmes for Chronic Airways Limitations Disease, May to July 2001. Manning Base Hospital, Mid North Coast Area Health Service. By Karyn Jarvie, Port Macquarie, NSW

Grant Submission for "Breathing Easier in East Gippsland - An Evidence Based Pulmonary Rehabilitation Program", from Chris Shoemaker, Bairnsdale Regional Health Service, VIC

"Clinical Pharmacy Input into a Respiratory Rehabilitation Program." Aust J Hosp Pharm 1998; 28:181-184, submitted by Christopher Alderman, Chief Pharmacist, Repatriation General Hospital, Adelaide, SA

a) Australian surveys and guidelines
   I  Best Practice Guidelines for Cardiac Rehabilitation, Victoria
   II NSW Policy Standards for Cardiac Rehabilitation
   IV  COPD Case Statement, ALF 2000
   V  Australian and New Zealand Guidelines for Diagnosis and Management of Chronic Obstructive Pulmonary Disease (2003 and updated 2006)

b) International surveys and guidelines
   I  American Pulmonary Rehabilitation Guidelines 1995
   II ERS Task Force Position Paper 1997
   III BTS Statement on Pulmonary Rehabilitation 2001
   IV Other Systematic Reviews (eg Lacasse et al 1997, 2003)
   V GOLD Workshop Report and Executive Summary (2001 and updates to 2006)

1.1. Regional physiotherapy (Veronica Brydon)
1.2. Bankstown Hospital (Regina Leung)
1.3. Queensland COPD Interest Group
1.4. Western Hospital Melbourne Research Proposal
1.5. Perth/Adelaide Health Economics Research Proposal