

**Effectiveness of a Patient Mediated
Intervention in Increasing the Use of
Cochrane Reviews of Evidence in Clinical
Practice: A Controlled Clinical Trial in COPD**

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ABSTRACT

Interventions are needed to improve health outcomes by increasing the practice of evidence based medicine (EBM). Patient mediated interventions have been little studied but hold promise: they target identified barriers to EBM and particular types of patient mediated intervention have shown success. Furthermore, consumers are now being given information about evidence but the effects of this on EBM have yet to be properly assessed.

The aim of this study was to show whether informing patients about research evidence leads to improved application of that evidence in their medical care. The study trialed a relatively low cost manual, developed using current best practice, which summarised Cochrane Reviews of evidence. The study focused on chronic obstructive pulmonary disease (COPD), a high-cost, high-burden chronic disease, showing a large gap between evidence and clinical practice.

The study comprised a controlled before-and-after trial and a process evaluation. The trial assessed the success of this manual in changing medical practice for three indicator treatments (influenza vaccination, bone density testing and pulmonary rehabilitation) and in changing patient quality of life, knowledge, communication with doctor, satisfaction with information and anxiety. Results were analysed by median split of socioeconomic disadvantage. At 3 months the manual was associated with lower anxiety for participants with lowest socioeconomic disadvantage. At 12 months the manual was associated with higher pulmonary rehabilitation enrolment for participants with greatest socioeconomic disadvantage. Other outcome measures showed no significant change. Limitations included loss of power from unexpectedly good baseline care and adjustments for baseline differences. The process evaluation showed that the manual was read more than a control pamphlet at both 3 and 12 months but a minority of manual recipients reported talking to their doctor about topics from the manual. Very little treatment change was reported. Patient attitudes

to evidence and doctor/patient communication norms appeared to be barriers for this patient group.

New protocols for the design of behavioural interventions provide a framework for overcoming these barriers in future interventions.

DECLARATION

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person except where due reference has been made in the text.

I give consent to this copy of my thesis, when deposited in the University Library, being available for loan and photocopying.

Signed

Date.....

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Many individuals contributed to the development of *Talking to your doctor about COPD*. I am grateful to them all, including those not named below. Health professionals and patients who contributed to the resource are acknowledged in an appendix, but I thank them here also. An early conversation with Dr Anne Johnson of Flinders University provided me with an invaluable orientation to current thinking on informing patients. Mr Danny Stevens of Drug & Alcohol Services South Australia kindly outlined advantages and disadvantages of a range of possible presentation formats for *Talking to your doctor about COPD*. Final editorial scanning and formatting were provided by In Writing. WestAir members and Pam Selim helped arrange for photographs which were taken by Alan Hoare and Basil Popowycz. Ms Beth Chandler very kindly donated a professionally produced diagram of the lungs and Dr Bronnie Veale gave advice on methods for piloting.

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LIST OF ABBREVIATIONS

COPD	Chronic obstructive pulmonary disease
CRQ	Chronic Respiratory Questionnaire
EBM	Evidence based medicine
GP	General practitioner
PIM	Patient information material
QoL	Quality of life

PUBLICATIONS AND PRESENTATIONS

To date, the following peer reviewed publications, conference presentations and awards have resulted from work described in this thesis.

JOURNAL ARTICLES

Harris M, Smith B, Veale A. (2005) Printed patient education interventions to facilitate shared management of chronic disease: a literature review. *Internal Medicine Journal*. **35** (12): 711-5.

Harris M, Smith B, Veale A. (2005) Engaging patients in evidence based medicine: development of a resource for people with chronic obstructive pulmonary disease. *Chronic Illness* **1** (4): 330-336.

Harris M, Smith B, Veale A. Providing patients with reviews of evidence about COPD treatments: a controlled trial of outcomes. *Chronic Respiratory Disease*. IN PRESS (accepted 07/10/2005 for publication).

CONFERENCE PRESENTATIONS

Harris M, Smith B, Veale A, Esterman A, Frith P, Selim P. Informed consumers as drivers of evidence based medicine: a trial. *X111 Cochrane Colloquium* October 2005 Melbourne. (Oral presentation)

Harris M, Wildgoose D, Veale A, Smith B. Patient mediated interventions to increase adoption of evidence: aids and barriers to an intervention in chronic obstructive pulmonary disease (COPD). *X111 Cochrane Colloquium* October 2005 Melbourne. (Oral presentation)

Harris M, Smith B, Veale A. Print interventions to facilitate shared management of chronic disease: a literature review. *Australasian Epidemiological Association Annual Conference*, October 2004 Adelaide. (Poster presentation)

Harris M. The importance of informal learning for health professionals. *Annual Conference of ANZAME: The Association for Health Professional Education* June 2004 Adelaide. (Oral presentation)

Harris M, Smith BJ, Veale A, Heard A. Dissemination of reviews to consumers: best-practice development of a Cochrane-based booklet on COPD. *Annual Scientific Meeting of the Thoracic Society of Australia and New Zealand* April 2003 Adelaide. (Oral presentation)

Harris M, Smith BJ, Heard A. COPD: Informed patients as best-practice drivers. *Public Health Association of Australia Annual Conference*. 2002 Adelaide. (Poster presentation)

AWARDS FOR MELANIE HARRIS

Winner of the Student/Health Professional in Training category award for the 2004 National Institute of Clinical Studies Cochrane Users Awards. (Details at: http://www.nicsl.com.au/projects_projects_detail.aspx?view=1&subpage=10&type=Normal)

Winner of a General category award for the 2004 National Institute of Clinical Studies Cochrane Users Awards. Details at: http://www.nicsl.com.au/projects_projects_detail.aspx?view=1&subpage=10&type=Normal)

Chapter 1 INTRODUCTION

The most commonly used definition of evidence based medicine (EBM) is that it is:

... the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice (Sackett et al 1996).

While clinicians, health policy makers and governments have accepted that clinical practice should be evidence based, it is estimated that 30% to 40% of patients in developed countries do not receive best care as shown by current research evidence (Grol & Grimshaw 2003). Measures to reduce the gap between research evidence in clinical practice therefore have the potential to greatly improve health outcomes.

Research evidence is now available to clinicians as original study reports in medical journals, and as reviews of evidence and practice guidelines in journals and databases. Availability of evidence, alone, however, has not always resulted in its adoption. Remaining obstacles to practice changes have been grouped by Grol and Wensing (Grol & Wensing 2004) as problematic features of the innovation itself, or barriers at the level of the individual professional, the patient, the social context, the organisational context or the economic and political context.

Researchers have studied a range of possible strategies to increase the use of evidence in clinical practice (Grimshaw et al 2004). Most of these strategies, for example information campaigns, individual audit and feedback and educational outreach visits, are targeted directly at the clinician. While these methods often improve practice, they are sometimes not cost effective, with improvements modest to moderate and inconsistent from study to study (Grimshaw et al 2004).

Strategies which aim to influence clinicians through the actions of patients, known as patient mediated interventions, have not been well researched. Screening and vaccination reminders delivered to clinicians by patients, and mass media campaigns directed at the general public, have led to increased use of target preventive health services. However, there is little research on patient mediated interventions beyond preventive care (Grimshaw et al 2004) and studies are now needed to test their effectiveness for other types of research-practice gap.

Research on patient mediated interventions is timely, because plain language evidence summaries are becoming increasingly available to support patient participation in medical decision-making (Grol 2000). Patient participation is particularly encouraged for difficult major decisions, where evidence information is supplied in the form of patient decision aids, and in chronic disease management. While there is a small amount of research suggesting that decision aids can influence medical decisions, research is lacking on the implementation effects of providing evidence summaries to chronic disease patients.

1.1 STUDY AIMS

The aim of this study was to show whether providing summaries of evidence to people who have chronic obstructive pulmonary disease (COPD) leads to improved application of that evidence in their medical care. The summaries of evidence were provided in a relatively low-cost manual, developed using current best practice. Application of evidence was measured using three evidence-supported medical interventions for COPD (influenza vaccination, bone density testing and pulmonary rehabilitation).

The primary hypothesis for this study was:

Hypothesis 1

Compared with patients who have been given a conventional pamphlet, patients who have been given the COPD Evidence Manual will have increased:

- a) rate of influenza vaccination within the previous 15 months, by patient self report
- b) rate of bone density testing within the previous 42 months, by patient self-report
- c) enrolment in pulmonary rehabilitation, by patient self report.

In addition, secondary hypotheses proposed that:

Compared with patients who have been given a conventional pamphlet, patients who have been given the COPD Evidence Manual will have:

- **Hypothesis 2** improved mastery of COPD, as measured by the Mastery domain of the Chronic Respiratory Questionnaire (CRQ)
- **Hypothesis 3** improved knowledge of COPD, as measured by a test adapted from Hermiz et al (2002)
- **Hypothesis 4** improved communication with their usual doctor, as measured by the Communication and Comfort and the Rapport subscales of the Medical Interview Satisfaction Scale
- **Hypothesis 5** improved satisfaction with disease related information, as measured by an item adapted from the Medical Interview Satisfaction Scale
- **Hypothesis 6** no increase in anxiety, as measured by the Short-form Spielberger State Anxiety Inventory

The study also aimed to show how the manual was actually used by patients and doctors and to identify barriers and facilitating factors to use of the manual as intended, to support design improvements in future interventions.

1.2 OVERVIEW OF THE THESIS

Following the Introduction, Chapter 2 provides a review of the literature relating to the study for this thesis. A brief overview of EBM is given, and an examination of the literature on implementing EBM, showing the need for research on patient

mediated strategies. The links between patient mediated implementation of evidence and the growing roles of patients in medical decision making is demonstrated, and COPD is identified as suitable condition for a trial of patient mediated implementation. Best practice methods for producing patient summaries of evidence are identified through a comprehensive literature search. Chapter 3 demonstrates how these best practice methods were used to develop a manual of evidence summaries for COPD patients, and describes the resulting manual. Methods for a controlled before-and-after trial of this manual are given in Chapter 4 and methods for process evaluations in Chapter 5. Chapters 6 and 7 report and discuss results of the trial and process evaluations. Finally, Chapter 8 brings together the three elements of the evaluation and draws implications for the design of future interventions which involve patients in the implementation of evidence.

The manual was developed during 2001 and 2002, and the evaluation was carried out in Adelaide, South Australia, from 2002 to 2005.

Chapter 2 LITERATURE REVIEW

This chapter provides the rationale for the study described later in the thesis. It gives an explanation of EBM, and shows that while EBM receives public support from clinicians and policy makers, it is not well implemented. Reviews of existing implementation studies are summarised and the need for further studies of patient mediated interventions is explained. In particular, the value of a trial in a chronic disease such as COPD is outlined. The chapter finishes by showing print to be a practicable medium for a chronic disease patient mediated intervention and reviewing what is known about the effective design of printed patient information materials.

2.1 EVIDENCE BASED MEDICINE

2.1.1 *The growth of evidence based medicine*

An important early impetus towards the use of evidence in clinical practice was a series of lectures given in 1972 by British epidemiologist, Professor Archibald Cochrane (Cochrane 1972). Cochrane pointed out that health care resources should be used to deliver those treatments which had been shown in well designed evaluations to be most effective. The movement grew rapidly during the 1990s as Professor David Sackett and his colleagues in Canada and the UK actively promoted EBM. They challenged the tradition that medical decision making should be based on the expertise and experience of individual doctors, gained from a combination of the teaching from other experts, clinical practice and knowledge of basic disease mechanisms. The EBM movement argued that instead, medical decision making should be based on findings from clinical trials (Haynes 2002). EBM has by now become an accepted part of medical education and clinical practice in the developed world (Sackett et al 1996; Chassin & Galvin 1998; Rubin et al 2000; Haynes 2002).

It has been recognised that an important barrier to EBM is that individual health professionals do not have the time or, often, the skills to find and appraise the evidence relevant to the many clinical questions that they encounter during practice.

In response to this problem, systematic reviews, and evidence-based guidelines based on these systematic reviews, have been created (Cook et al 1997).

Systematic reviews have three key features:

- a strenuous effort to locate all original reports on the topic of interest
- critical appraisal of reports, with examination of differences in findings between reports and, often, pooling of data from like studies
- overall conclusions and practice recommendations are made, with grading of the level of underlying evidence.

Systematic reviews are published as articles in medical journals and are also available online from the Cochrane Collaboration. The Cochrane Collaboration is an international non-profit organisation, named after Professor Cochrane, which coordinates the preparation, maintenance and dissemination of systematic reviews of the effects of health care. Overall, Cochrane reviews have greater methodological rigour, more frequent updating, and provide greater detail, than systematic reviews published in medical journals (Jadad et al 1998). However, systematic reviews can be lengthy documents which are time consuming to read. For example, Cochrane reviews usually take up some forty or more A4 pages. Also, many doctors lack knowledge of the EBM terms and concepts which are used in systematic reviews (Oliveri et al 2004). Evidence-based practice guidelines, incorporating recommendations from systematic reviews, remove the need for individual clinicians to read the systematic reviews (Cook et al 1997). Clinical practice guidelines provide recommendations to health professionals for clinical decisions. As well as guiding clinical practice, they are used for education, quality assurance and improvement, and cost accountability (Berg et al 1997). Guidelines are produced in many formats but high quality guidelines have clear scope and purpose, clear presentation and are practical to implement. They are developed rigorously with clear reference to evidence, stakeholder input, and editorial independence (AGREE Collaboration 2003).

2.1.2 Challenges to evidence based medicine

As it has grown in influence, EBM has dealt with a range of criticisms (Pope 2003). Fears that health administrators would use EBM to usurp the autonomy of clinicians have been countered by use of EBM to demonstrate the effectiveness and scientific basis of medicine (Armstrong 2002). The criticism that EBM relies too heavily on randomised controlled trials which may not have good external validity has been answered with observations about the danger of extrapolating from laboratory studies (Straus & McAlister 2000). Complaints that EBM is time consuming and difficult to practice are answered using examples of successful implementation in busy hospital teams (Sackett et al 1996) and the provision of guidelines and reviews of evidence. Critics have also pointed out that it has not been proven that evidence based practice produces better health outcomes. EBM proponents have responded that a trial of EBM would be practically impossible, and perhaps unethical, but that better outcomes have been demonstrated for patients receiving evidence based treatments (Straus & McAlister 2000). Fears about 'cookbook medicine' which discounts clinical judgement, knowledge and the individual needs of patients was answered by statements from EBM proponents that decisions should be based on clinical expertise and patient preferences as well as research evidence (Haynes 2002).

While criticisms have been answered and most doctors claim a positive attitude to EBM, they also report low use of systematic reviews and guidelines (McCull et al 1998; McAlister et al 1999; Sigouin & Jadad 2002; Toulkidis et al 2005). A gap therefore remains between evidence and practice.

2.2 THE GAP BETWEEN EVIDENCE AND PRACTICE AND THE POTENTIAL OF PATIENT MEDIATED INTERVENTIONS

The gap between research evidence and clinical practice has been noted in many countries, disease conditions and practice settings. Studies in developed countries in hospital and general practice settings have shown at least a third, and sometimes well over half, of patients not receiving care which complies with current evidence (Chassin & Galvin 1998; Schuster et al 1998; Seddon et al 2001; Grol & Grimshaw 2003). A further problem is the provision of treatment that is not needed or is

potentially harmful. A review of USA studies estimated that 20% to 30% of treatments fell into this category (Schuster et al 1998).

2.2.1.1 Reasons for the gap between evidence and practice

A local study in COPD (Smith et al 2003; Smith et al 2004; Smith et al 2005) showed that there are obstacles to the use of evidence even when systematic reviews and high quality clinical practice guidelines are readily available. The study evaluated a new evidence-based 'ACCORD' guideline, designed according to current best practice with extensive multidisciplinary consultation including a patient advocate, and input from international guideline experts (Smith et al 2003). The guideline incorporated many characteristics to facilitate uptake and was actively introduced (Smith et al 2004) but was used to a limited extent in practice. Several barriers were identified including paperwork duplication, lack of time, cultures which did not support guideline use and perceived lack of ownership. Health professionals also saw the guideline as too long, although, paradoxically, the length was a result of multiple inputs which were included in an effort to maximise ownership (Smith et al 2005).

Other studies confirm that while guidelines may overcome problems with accessing and appraising evidence, a range of other barriers to evidence based practice remain. These include perceived conflicts between evidence and patient satisfaction, lack of time, likelihood of non-compliance, disagreement with evidence, organisational systems which support existing practices, and financial costs (Cranney et al 2001; Freeman & Sweeney 2001; Young & Ward 2001; Ford et al 2002; Summerskill & Pope 2002; Flottorp & Oxman 2003; Fitzgerald et al 2003; Powell-Cope et al 2004; Van Der Weijden et al 2004; Toulkidis et al 2005). Barriers apply differently for different health professionals (Fitzgerald et al 2003; O'Donnell 2004), and general practitioners (GPs) appear to see guidelines as more applicable to the disease focus of secondary care, than the whole-patient focus of primary care (Freeman & Sweeney 2001; Fitzgerald et al 2003). While specialists appear to rely on research publications to make prescription decisions, GPs appear to be influenced by pharmaceutical marketing materials (Jones et al 2001)

A group of survey and qualitative studies provide further detail on the perceived incompatibilities between patient satisfaction and EBM. GPs in particular voice beliefs that patients would be dissatisfied with evidence based decisions which conflict with a patient's firm views on the effectiveness of a treatment, or which may overburden the patient with treatments for all their comorbidities and risk factors (Tomlin et al 1999; Scott et al 2001; Freeman & Sweeney 2001; Young & Ward 2001; Summerskill & Pope 2002). Implementation interventions are needed to overcome these patient-related barriers.

2.2.1.2 Interventions which have been trialed and their success in reducing the gap between evidence and practice

Bero and colleagues noted that:

Despite the considerable amount of money spent on clinical research relatively little attention has been paid to ensuring that the findings of research are implemented in routine clinical practice (Bero et al 1998).

However, a field of research is now developing which assesses the effectiveness of interventions in increasing the use of EBM (Grimshaw et al 2002). Trialed interventions have included; educational outreach, reminders, interactional educational meetings, didactic education sessions, audit and feedback, influence of local opinion leaders, local consensus processes, educational materials, and multifaceted interventions. Some work has also been done with patient mediated interventions, where specific information is sought from or given to patients, with the intention of influencing doctors' behaviour (Bero et al 1998).

A group of researchers has authored a series of overviews, collecting together the findings from systematic reviews of implementation studies (Bero et al 1998; Grimshaw et al 2001; Grimshaw et al 2004). Conclusions about the relative usefulness of each type of intervention have been different in each overview, as new systematic reviews have been included and improved methods for synthesising systematic reviews have been used.

When work began on the intervention evaluated in this thesis, the first of the above overviews was available (Bero et al 1998). This overview concluded that educational outreach, reminders, multifaceted interventions and interactive educational meetings appeared most effective. Audit and feedback, local opinion leaders, local consensus processes and patient mediated interventions showed variable effectiveness. Educational materials and didactic educational meetings appeared to have little or no effectiveness. The second overview (Grimshaw et al 2001) also found passive methods ineffective. It found that most other methods could be effective in some circumstances. Educational outreach and reminders were generally effective and multifaceted interventions more likely to be effective than single interventions. The knowledge base did not allow predictions about which interventions would be effective in which circumstances. With more rigorous methods, the most recent overview came to somewhat different conclusions (Grimshaw et al 2004). Most interventions, including passive information delivery, were found to have produced modest to moderate improvements and multifaceted interventions did not appear to be more effective. Again it was noted that the research base did not allow conclusions to be drawn about which methods were most effective in which circumstances. Overview authors recommended that implementation strategies be based on consideration of barriers. They highlighted the need to take the costs of interventions into account, and recommended further evaluation of relatively cheap interventions, such as print (Grimshaw et al 2004).

2.2.1.3 Patient mediated methods for reducing the gap between evidence and practice

The series of overviews summarised above also provide an account of research into patient mediated interventions. In their 1998 overview, Bero and colleagues noted that patient mediated interventions had been trialed in preventive care in North America and appeared to be effective in that situation (Bero et al 1998). The subsequent overview (Grimshaw et al 2001) did not draw separate conclusions about patient mediated interventions. However, their overview included three systematic reviews which dealt with interventions of this type. One of these systematic reviews found that computer generated reminders about preventive health services, sent to

both to patients and doctors, were effective for some types of preventive service (Shea et al 1996). Another found that interactive patient education and patient prompts were effective methods of improving practice (Balas et al 1996). The third found that half of the mass media campaigns which had been trialed had influenced the use of health services (Grilli et al 1998). These findings suggested that patient mediated interventions had not been extensively studied but warranted further attention. In particular, though there were several studies of brief patient mediated reminders about preventive services, there were few studies assessing other types of patient mediated intervention.

The most recent and rigorous overview (Grimshaw et al 2004), published after the development and trial of the manual reported in this thesis, also provides support for broader research on patient mediated interventions. The overview noted the limitations that most trials of patient mediated interventions had been conducted in North America, and that most of them targeted preventive services. However, within these limitations, patient mediated interventions appeared to result in moderate to large improvements in clinical performance.

Research on patient interest in disease related information and patient influence on doctors' decision making is encouraging for patient mediated interventions. While doctors are time-poor and burdened by information overload (Salisbury et al 1998; Coiera 2001; Grimshaw et al 2002) patients, especially those with serious or chronic conditions, want more information relating to their particular condition (Jones et al 1999; Wagner & Hibbard 2001; Nair et al 2002). Studies indicate that, while a small proportion of requests are not voiced, patients do make requests at a medical consultation (Bell et al 2001; Kravitz et al 2002), including requests for treatments which they have read or heard about (Bell et al 1999; Jacobson et al 1999). In addition, doctors beliefs about what patients want can have considerable influence on clinical decision making (Britten & Ukoumune 1997; Krupat et al 1999; Freeman & Sweeney 2001; Kravitz et al 2003). In the USA, direct-to-consumer drug advertising has increased consumer requests and thereby increased prescriptions for the advertised drugs (Gilbody et al 2005).

Overall, there are promising indications that an abridged, practical version of the evidence, read by the patient and then brought by them into the clinical setting might overcome many of the barriers to EBM. Such interventions might influence patient beliefs about treatment effectiveness, overcome clinician perceptions that patients do not want treatments supported by evidence, and enable informed discussion of evidence at a consultation (Birkel et al 2003). They may also overcome time and access barriers by bringing summarised evidence into the consultation at the time it is needed. Research is now required to test this proposal.

2.3 COPD AS A CONDITION FOR STUDIES OF PATIENT MEDIATED INTERVENTIONS IN CHRONIC DISEASE

Discussion below shows why patient mediated interventions should be trialed in chronic diseases such as COPD. Links are demonstrated between patient mediated implementation of evidence and patient education for chronic disease self-care. COPD is shown as a suitable chronic disease for a trial, causing great social and economic burden, with research needed to reduce well-recognised gaps between evidence based practice and actual care delivered.

2.3.1 A possible role for chronic disease patients in promoting the practice of evidence based medicine

Evidence information, in hard copy and on the internet, is now being made accessible for patients as well as clinicians. Reviews of evidence were initially prepared for a clinical audience only (Bero & Jadad 1997). Now, with the movements for patient centred medicine and patient participation (Laine & Davidoff 1996; Charles et al 1999; Bauman et al 2003) developing alongside EBM, consumer summaries of evidence are also seen as essential (Holmes-Rovner et al 2001). However, there are many unanswered questions about practicable and effective ways to provide consumers with evidence summaries (Entwistle et al 1998; Ford et al 2002; Woolf et al 2005) and there is little research on the effects of these consumer summaries on clinical decisions.

Chronic disease patients in particular are commonly given or seek disease related information. Patient education for shared disease management is now an important strategy in limiting the growing burden of chronic disease (Holman & Lorig 2000; Monninkhof et al 2003; Epping-Jordan et al 2004). Even without formal patient education, the ongoing nature of chronic conditions means there is a greater likelihood that patients will seek information at various stages of their disease (Bodenheimer et al 2002). Chronic disease patients and their doctors make multiple treatment decisions over the course of an illness. It follows that information interventions for chronic disease patients ideally should give evidence on the full range of possible treatments. Such interventions are currently lacking (Muhlhauser & Berger 2000).

The frequent contact between doctors, in particular GPs, and people with chronic disease (Britt et al 2005, p.72) provides multiple opportunities for patient mediated implementation. People with poorer health are more likely than are people with better health to talk to their doctor about disease related information that they have encountered (Houston & Allison 2002). In addition, doctors appear to include chronic disease patients in decision making to a greater extent than other patients (Gotler et al 2000) thereby providing an opportunity for patients to influence decision making. However, there has been surprisingly little research to date on the implementation effects of sharing evidence with chronic disease patients.

2.3.2 *The suitability of COPD as a chronic condition for implementation studies*

2.3.2.1 The nature of COPD

COPD is a slowly progressive lung disease, with airflow limitation that is not fully reversible and abnormal inflammatory response of the lungs to particles or gases (Anto et al 2001; Global Initiative for Chronic Obstructive Lung Disease 2001). The most important causal factor is tobacco smoking with 15% to 20% or more of smokers developing COPD. Socioeconomic disadvantage is associated with a higher incidence of COPD, as is past exposure to some environmental and occupational pollutants. People with COPD are usually over 50 years old when their symptoms are

severe enough for them to seek medical help. Coughing, sputum and shortness of breath are the usual symptoms. People with moderate to severe COPD also suffer from exacerbations, acute episodes of worsening breathlessness, which are usually managed in hospital. Reports of one year mortality for people admitted to hospital with an acute exacerbation range from 22% to 43% (Almagro et al 2002; Groenewegen et al 2003).

2.3.2.2 Burden of COPD

COPD is a leading cause of morbidity and mortality worldwide, causing a substantial and increasing social and economic burden. A study by the World Health Organization put COPD as the twelfth ranking cause of disability adjusted life years lost in 1990 world-wide (World Health Organization 1996). It was projected that by 2020 COPD would rank fifth. In Australia, COPD was the third leading cause of disability adjusted life years for men and the sixth leading cause for women in 1996 (Mathers et al 1999, p.65). The cost of COPD to Australia in 2001 was conservatively estimated at between \$818million and \$898 million, excluding costs to carers. These costs are rapidly rising and improved application of proven interventions is required to reduce costs and disease burden (Crockett et al 2002).

2.3.2.3 Current use of evidence in managing COPD

Several national medical associations have produced guidelines for managing COPD (Hackner et al 1999; Pauwels 2000; Ferguson 2000; Smith et al 2003). There are some inconsistencies between these guidelines (Ferguson 2000; Lacasse et al 2001; Iqbal et al 2002; Smith et al 2003) and many give recommendations without showing what kind of supporting evidence or consensus methodology was used to generate them (Lacasse et al 2001; Iqbal et al 2002; Smith et al 2003). Nevertheless, there are serious deviations from well accepted recommendations in all countries where practice has been studied, including Australia, Canada and USA, Denmark, France, UK and Ireland (Roberts et al 2001; Roche et al 2001; Phanareth et al 2002; Cydulka et al 2003; Heron et al 2003; Butler et al 2004; Harvey et al 2005). The studies assessed different aspects of care, but some areas of diagnosis and treatment showed deviations from recommendations in two or more studies. These areas were; use of

spirometry, referral for pulmonary rehabilitation, provision of influenza vaccination, assessment for long term oxygen therapy, provision of smoking cessation advice or pharmacotherapy, blood gas measurement and provision of oxygen in hospital, and use of corticosteroids, antibiotics and bronchodilators. Interventions are now needed to improve the consistency of care for COPD and to close the gap between evidence and practice for this condition.

2.3.2.4 COPD as a model for patient driven implementation

While COPD has unique aspects, people with COPD share many characteristics with those suffering from other important chronic diseases (Australian Institute of Health and Welfare 2002, pp.1-14). Patients have many years of disability during which they play a role in managing the disease, and many live with more than one chronic disease. Prevalence is higher among older people and those with greatest socioeconomic disadvantage (Australian Institute of Health and Welfare 2002, pp.1-14). A trial of COPD patients as drivers of evidence based practice may therefore provide pointers for other chronic conditions among older people.

People with COPD are in frequent contact with their general practitioner. Diagnosed COPD is managed at some 0.8% of all GP-patient encounters in Australia (Britt et al 2005, p.68) and in South Australia an estimated 73% of COPD patients visit their GP eight or more times within a 12 month period (Smith et al 2002). This frequent contact between COPD patients and their GP provides opportunity for patient driven implementation of evidence.

In summary, a trial in COPD might show the way to improve health outcomes in this important but apparently inconsistently managed chronic condition, and provide an indication of the likely success of this kind of intervention with other chronic diseases.

2.4 IDENTIFYING THE ELEMENTS OF EFFECTIVE DESIGN FOR A PATIENT MEDIATED INTERVENTION

The following section aims to identify the best methods for providing evidence information to chronic disease patients. It shows print to be the preferred medium and establishes characteristics of effective patient information materials (PIMs).

2.4.1 *Text as the medium of choice*

A medium used to inform patients about evidence should ideally be low-cost, so that it can be used widely, and must appeal to patients. Print is the most commonly used format for PIMs and is inexpensive when compared to most other formats. Patients appear to prefer print formats (Kenny et al 1998; NHMRC 2000) and learn from print at least as well as they learn from audiovisual formats such as video (Clayton et al 1995; Eaden et al 2002; Gattellari & Ward 2005; Campbell et al 2004). On-line provision via the internet is a less expensive alternative but older chronic disease patients are currently low users of the internet (Morrell et al 2000; Bessell et al 2002).

2.4.2 *Evidence based recommendation on effective design of printed summaries of evidence for chronic disease patients*

Materials which inform patients about evidence should themselves conform to evidence on effective design. This evidence may be found in comprehensive reviews covering studies of collected evidence summaries for chronic disease patients, studies of evidence summaries for other groups of patients, or studies of other types of materials for chronic disease patients. Evidence may also be found in guidelines on the design of patient information materials. The following sections summarise evidence based recommendations on design of PIMs from comprehensive reviews and guidelines.

2.4.2.1 Comprehensive reviews of PIMs on chronic diseases

Systematic reviews of studies in which chronic disease patients were provided with collections of evidence could not be located for the development (in 2002) of the intervention described in this thesis. However, comprehensive reviews of other kinds

of chronic disease PIMs were another possible source of recommendations on effective design. A comprehensive review of PIM effectiveness was located but it covered reports from 1985 to 1992 only, and included no PIMs which dealt with major chronic diseases (Paul & Redman 1997). A new comprehensive literature review is therefore reported below

2.4.2.1.1 *Comprehensive review of studies of PIMs for chronic disease patients*

The aim of this comprehensive review was to identify (i) post 1992 trials of chronic disease PIMs designed to involve patients in disease management and (ii) characteristics of the successful PIMs.

QUALITY CRITERIA FOR STUDIES AND INTERVENTIONS

General trial quality requirements (Altman et al 2001) are applicable to studies of chronic disease PIMs, but there are additional quality requirements for this type of study. As well as outcome measures, trials of health education interventions should include process investigations to show how well they produced the intended links between intervention behaviour and outcomes (WHO European Working Group on Health Promotion Evaluation 1998; Cooper et al 2001; Michie & Abraham 2004). Trial durations should be clinically meaningful for the management of chronic diseases (Cooper et al 2001). In addition, trial reports should also include full descriptions of the intervention, to facilitate uptake and further development by health providers and other researchers (Cooper et al 2001; Michie & Abraham 2004). For this review therefore, trial reports were assessed for the inclusion of process investigation, duration greater than 6 months and full descriptions of interventions.

Trial reports provide a good basis for further research if they give the replicable rationale which underpinned the design of the trialed PIM (Michie & Abraham 2004). This rationale could take the form of extensive consultation with patients (Coulter et al 1999), or progressive development and testing cycles, usually based on educational or psychosocial theories (Tones 1997; Cooper et al 2001; Michie & Abraham 2004). For this review therefore, reports were assessed for evidence of

contributions by patients to intervention development, progressive development of the intervention, or use of psychosocial education/behaviour change theories.

LITERATURE SEARCH

Databases searched were MEDLINE, the Cochrane Central Register of Controlled Trials, EMBASE and CINAHL. Reports published from 1992 onwards were sought and the search was carried out on 31 January 2005. Search terms used in MEDLINE were:

```
(teaching materials/ AND exp patient education/) OR (booklet$ OR
information pack$ OR publication$ OR pamphlet$ or leaflet$).mp OR
patient information/ OR medical information/
AND
chronic disease/ OR exp heart diseases/ OR exp lung diseases,
obstructive/ OR exp cerebrovascular disorders/ OR exp arthritis/
OR exp inflammatory bowel diseases/ OR exp diabetes mellitus/ OR
exp neoplasms/ OR exp prostatic diseases/
AND
(((randomized controlled trial OR controlled clinical trial).pt.
OR (((double blind$ OR placebo OR random$)).ti. OR (random$ adj
(enrol$ OR assign$)).tw. OR randomized controlled trials/) AND
clinical trial.pt.)) NOT (animal/ NOT human/))
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For the Cochrane Central Register of Controlled Trials, the first two sets of terms were used as for Medline, without the third set.

Search terms used in EMBASE were:

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(teaching materials/ AND exp patient education/) OR (booklet$ OR
information pack$ OR publication$ OR pamphlet$ or leaflet$).mp OR
patient information/ OR medical information/ OR consumer health
information/
AND
chronic disease/ OR exp heart disease/ OR exp obstructive airway
disease/ OR chronic obstructive lung disease/ OR exp
cerebrovascular disease/ OR exp arthritis/ OR irritable colon/ OR
exp diabetes mellitus/ OR exp neoplasm/ OR exp prostate disease/
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AND

Random\$.tw OR clinical trial\$.mp. OR exp health care quality NOT
(animal/ NOT human/)

Search terms used in CINAHL were:

(teaching materials/ AND exp patient education/) OR (booklet\$ OR
information pack\$ OR publication\$ OR pamphlet\$ or leaflet\$).mp OR
consumer health information/

AND

chronic disease/ OR exp heart diseases/ OR exp lung diseases,
obstructive/ OR exp cerebrovascular disorders/ OR exp arthritis/
OR exp inflammatory bowel diseases/ OR exp diabetes mellitus/ OR
exp neoplasms/ OR exp prostatic diseases/

AND

Exp clinical trials/ OR clinical trial.pt. OR (clinic\$ adj
trial\$1).tw. OR ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj
(blind\$3 or mask\$3)).tw. OR randomi?ed control\$ trial\$.tw. OR
random assignment/ OR random\$ allocat\$.tw. OR placebo\$.tw. OR
placebos/ OR quantitative studies/ OR allocat\$
random\$.tw.Inclusion criteria

Studies were included if they were controlled trials, had baseline measures, usual care control arms, and health outcomes, quality of life or patient disease management behaviours as measures. Included interventions aimed to increase adult patient participation in management of chronic disease and were print only. Multi-component interventions, which contained text as one of the components, were excluded because of the problems with ascribing effects to particular components.

RESULTS

The search and inclusion criteria yielded seven reports (Maggs et al 1996; Barlow et al 1997; Barlow & Wright 1998; Borgaonkar et al 2002; Kennedy et al 2003a; Simmons et al 2004; Schaffer & Tian 2004). Two reports are of different stages of the same study (Barlow et al 1997; Barlow & Wright 1998). Six studies are therefore assessed below.

Reports are summarised in Table 2.1. and their performance against study and intervention quality criteria in Table 2.2.

No studies were of COPD and none of the PIM interventions were collections of evidence summaries, though part of one PIM summarised evidence for some treatments (Kennedy et al 2003a). Two studies focussed on inflammatory bowel disease (Borgaonkar et al 2002; Kennedy et al 2003a), two on arthritis (Maggs et al 1996; Barlow & Wright 1998), and the others on asthma (Schaffer & Tian 2004) and diabetes (Simmons et al 2004). A variety of outcomes was measured and statistically significant change was found for few. Knowledge improved in three of the five studies which measured it (Maggs et al 1996; Barlow & Wright 1998; Kennedy et al 2003a) but this was an intermediate measure and quality of life outcomes were not changed. In one study (Schaffer & Tian 2004) adherence was increased but disease and quality of life related outcomes were not. In one very brief study quality of life declined in the intervention arm, but this appeared to be due to chance worsening of disease activity in the intervention group (Borgaonkar et al 2002).

In relation to study quality criteria, two studies continued beyond six months (Kennedy et al 2003a; Simmons et al 2004), two provided some process investigation (Barlow & Wright 1998; Kennedy et al 2003a) and only one report provided a full description of the intervention (Kennedy et al 2003a).

Only two studies demonstrated any rigour in intervention design, according to the criteria used. One report stated that topics identified by patients were included and that some behavioural theory contributed to design (Kennedy et al 2003a), and two reports stated that user understanding was checked (Kennedy et al 2003a; Simmons et al 2004).

Table 2.1 Studies of PIMs for chronic disease

First author and year of publication	Target disease	Intervention	Setting	Number of participants	Duration of study in weeks (and preliminary follow up)	Outcome measures	Measures showing significant ³ change and change effect size compared to usual care ⁴
Schaffer 2004	Asthma	Existing booklet produced by (USA) National Heart Lung and Blood Institute	University, health departments and church in a county, USA	25	26 (13)	Medication adherence ¹ (self reported and pharmacy verified) to preventive medication, asthma control ² , asthma QoL ² , asthma self-efficacy ² , knowledge	Adherence: +37%
Simmons 2004	Diabetes, types 1 and 2	Re-draft of previously studied booklet	20 GP practices, New Zealand	398	52 (26)	HbA1c, body weight, knowledge ² , attitude to diabetes (several items), risk factors for tissue damage (several items)	Blood HbA1c: -0.4g/ 100g Body weight: +1kg
Kennedy 2003	Inflammatory bowel disease	Booklet produced for study	6 hospitals, UK	240	39 (4)	Knowledge, anxiety ² , QoL ²	Knowledge score: +1.5 to 2 (depending on imputation) out of 16
Borgaonkar 2002	Inflammatory bowel disease	Existing booklet produced by Crohn's and Colitis Foundation of Canada	Gastroenterology clinic of 1 hospital, Canada	59	2	QoL ^{1,2}	QoL score: -0.45 out of 7
Barlow 1997/8	Rheumatoid arthritis	Existing leaflet produced by (UK) Arthritis & Rheumatism Council	Clinics of 3 hospitals, UK	108/84	26 (13)	Ability in daily activities ² , pain and fatigue ² , anxiety ² , self-efficacy ² , knowledge	Knowledge score: +5.2 out of 80
Maggs 1996	Arthritis	Booklet produced for study	Rheumatology clinic of 1 hospital, UK	100	6	Health status ² , functional disability ² , knowledge	Knowledge score: +4.8 out of 30

1. Primary outcome (if reported). 2. Indicates statement that instrument validity established. 3. With $p < 0.05$. 4. Proportion changed (dichotomous data) or difference in mean change (continuous data) over total duration

Table 2.2 Application of quality criteria to studies of PIMs for chronic disease

First author and year of publication	Study quality criteria – as reported ¹			Intervention quality criteria – as reported ¹			
	Intervention fully described	Duration of study > 26 weeks	Process investigation included	Patients identified topics	User understanding pre-checked	Progressive behaviour based design	Design based on behavioural theories
Schaffer 2004	N	N	N	N	N	N	N
Simmons 2004	P	Y	N	N	Y	N	N
Kennedy 2003	Y ϕ	Y	Y ϕ	Y	Y	P	Y
Borgaonkar 2002	N	N	N	N	N	N	N
Barlow 1997/8	N	N	Y	N	N	N	N
Maggs 1996	N	N	N	N	N	N	N

1. N=no, Y=yes Y ϕ = by reference to a separate report P=partial

TRIALS OF CHRONIC DISEASE PIMs AS A SOURCE OF DESIGN CHARACTERISTICS

These studies do not provide guidance on design of effective PIMs for chronic disease because of the demonstrated shortcomings in most reports for both the studies and the interventions. Outcomes were usually small and process investigations were rarely included. Interventions were poorly described in general and most appear to have been developed with little rigour. It is therefore not possible to establish particular design features which are consistently associated with intermediate or final outcomes across several studies. Other sources of best practice PIM design are needed.

2.4.2.2 Trials of evidence summaries not related to management of chronic disease

A further potential source of PIM design guidance is systematic reviews or trials of evidence information for patients who are facing one-off decisions, rather than dealing with overall management of a chronic disease. Decision aids are patient materials (often printed) designed to provide patients with detailed evidence based

information about options so that they can participate in important single medical decisions. A Cochrane systematic review (O'Connor et al 2003) found that decision aids performed better than usual care. They were associated with greater knowledge, more realistic expectations, lower decisional conflict, increased proportion of people active in decision making and reduced proportion of people who remained undecided. However, reviewers were unable to link these results with particular design features, beyond the observation that more detailed decision aids appeared to be more effective (O'Connor et al 2003). Recent literature raises the need for empirical work to support improved design of decision aids. Patient decision making processes (Bekker et al 2003; Feldman-Stewart & Brundage 2004; Charles et al 2005), and barriers to widespread implementation of decision aids (Graham et al 2003; O'Cathain & Thomas 2004), are being examined as a basis for improved design. This work is in its early stages, and focuses on specific major decisions. It cannot therefore inform the design of PIMs providing large numbers of evidence summaries on chronic disease treatments.

2.4.2.3 Well-founded recommendations from general guidelines on producing patient education materials

Guidelines on the development of PIMs are another potential source of best practice in developing collections of reviews of evidence for chronic disease patients. A search was therefore made for recommendations from guidelines, with some evidence to support them.

Guidelines are of variable quality and should be assessed rather than used uncritically (Shaneyfelt et al 1999). An important quality criterion for guidelines is provision of the evidence which supports recommendations (Shaneyfelt et al 1999). For guidelines on developing PIMs, recommendations might show supporting research measuring patient satisfaction, knowledge, behaviour or health outcomes.

Methods in patient education changed during the 1990s with changes in the roles and expectations of patients and in educational models (Roter 2000; Skelton 2001). For this reason, and to obtain guidelines based on recent evidence, only guidelines published or updated after 1995 were sought.

A search was therefore made for guidelines published after 1995 which gave evidence based recommendations on the development of printed PIMs.

LITERATURE SEARCH

Databases searched were MEDLINE EMBASE and CINAHL. Guidelines published from 1996 onwards were sought and the search was carried out in January 2005.

MESH search terms used in MEDLINE were:

(guidelines/ and pamphlets/) or (guidelines/ and (patient education/ and teaching materials/))

Analogous terms were used in the CINAHL and EMBase databases (though it was apparent that indexing of guidelines and articles about PIMs was very inconsistent in EMBase).

The National Guideline Clearinghouse internet site (National Guideline Clearinghouse 2005) was scanned. As government health departments were thought likely to produce such guidelines, internet sites of national government health organisations of Australia, UK, Canada and the USA were also scanned.

Inclusion criteria

Guidelines were included if they covered the production of printed PIMs, were not limited to specialist types of PIM (eg medicines information leaflets), were published after 1995 and contained any references to other publications (and were therefore potentially evidence-based).

Extraction of recommendations with research support

Included guidelines were scanned for recommendations given with support from research which measured patient satisfaction, knowledge behaviour or health outcomes.

RESULTS

The search and inclusion criteria yielded 2 guidelines; one produced by the Australian NHMRC, National Health and Medical Research Council, (NHMRC 2000) and one published as a journal article (North et al 1996).

Only some of the recommendations in these guidelines were given with supporting references. Furthermore, some of these references were for other collections of recommendations rather than for original research. Those recommendations with clear supporting references to original research are given in Table 2.3 as recommendations (A) to (D).

Table 2.3 Summary of recommendations and supporting research from the guidelines

Guideline	NHMRC		North et al	
	Recommendation	Nature of supporting research	Recommendation	Nature of supporting research
Design characteristics	<p>A) Print may not suit all patients and purposes so other formats should be considered.</p> <p>B) Use a readability formula to match the publication with the skill level of the audience. -</p>	<p>Surveys finding that many people have reading difficulties, and that some want very comprehensive information.</p> <p>A review of trials showing increased understanding and, occasionally, compliance when readability was improved.</p>	Test draft text for readability.	Studies demonstrating literacy difficulties in 12-13% of adults.
Content Characteristics	<p>C) Report risks and benefits in absolute terms eg 'This treatment will reduce your risk of dying within five years from 10% to 7%, that is by 3%'</p> <p>D) Consider different publications for different patient needs.</p>	<p>Studies of patient understanding.</p> <p>Survey findings that some patients want doctors to make decisions, some want to share decisions and others want to make their own decisions.</p>		

FURTHER RESEARCH-SUPPORTED RECOMMENDATIONS

Research support for some other recommendations can be found, even though it was not cited in the guidelines. Recommendations on design characteristics such as size of print, blocks of text and white spaces, typefaces and colour (North et al 1996; NHMRC 2000) are given in guidelines with no research support cited. However, two studies (Paul & Redman 1997; Krass et al 2002) have both reported relationships between commonly recommended design characteristics and patient satisfaction. These characteristics are listed in Figure 2.1 as recommendations (E) to (N). Similarly, the guidelines include unsupported recommendations to obtain patient input and to provide evidence based information (North et al 1996; NHMRC 2000). Taken together, a range of research findings support these recommendations. Studies reporting that health professionals have different priorities and understandings to patients, and often make incorrect assumptions about patient preferences (Mottram & Reed 1997; Montgomery & Fahey 2001), suggest that patient input is necessary if publications are to address patients' needs. Research with medicines information leaflets suggests that understandable materials are achieved only when patient testing and editing are repeated several times (Penman et al 1996; Dickinson et al 2001). Studies of patient and clinician preferences (Coulter et al 1999) also show that readers expect evidence based information. Recommendations on evidence based content, identification of needs by patients and testing with patients are therefore included in Figure 2.1 as recommendations (O) to (Q).

DISCUSSION

Though they represent best available practice, the guideline recommendations in Table 2.3 and Figure 2.1 are supported only by research which has measured patient satisfaction or understanding. There is no evidence that these recommendations lead to patient behaviour change or improved health outcomes. On the other hand, patients are most likely to read information from materials which they like and can understand, and they need to read information so that they can act on it.

- E) Type size 10 point or more
- F) Line spacing 2.2mm or more
- G) Serif typeface for paragraph text
- H) Sharp contrast between ink and background
- I) Margins of blank space around text
- J) Paragraph headings
- K) Use of lists or bullet points
- L) No blocks of upper case
- M) Bolding, boxes or summaries to highlight important points
- N) Relevant illustrations
- O) Evidence based, balanced content which acknowledges uncertainties
- P) Content based on needs identified by patients
- Q) Patient participation in developing and testing PIM

Figure 2.1. Recommendations from guidelines with research support found elsewhere

2.4.2.4 Evidence based design of evidence summaries for chronic disease patients

A number of design recommendations have been identified, supported by research relating to patient preferences or understanding, though not to behaviour change or health outcomes. These constitute the best available evidence to guide the production of a printed patient mediated intervention which provides evidence to COPD patients, and encourages them to discuss this evidence with their doctors.

2.4.2.5 Length of patient education materials

The question of the optimal length for patient education materials has not been thoroughly addressed. Health professionals may believe that patients need only brief information (Nair et al 2002; Dickinson & Raynor 2003). Patient reports of their own needs are variable. Many patients report that they want fuller information than they are given about medicines (Dickinson & Raynor 2003), treatment options (Coulter et al 1999), cancer (Jones et al 1999), and after discharge from hospital (Johansson et al 2003). In trials of information materials, patients have responded better to longer versions of an influenza reminder (Armstrong et al 1999), an educational resource about prostate cancer screening (Gattellari & Ward 2005), and more detailed versions of decision-aids (O'Connor et al 2004). On the other hand, cancer patients may prefer limited information at some stages of their illness (Leydon et al 2000), and fuller information was not associated with benefits for pregnant women in decision-making about screening for Down's syndrome (Michie et al 1997). In the absence of generally applicable rules about the amount of information to provide to patients, it is being recommended that this decision be based on information needs as reported by the target patient group (Coulter et al 1999; NHMRC 2000).

2.5 CONCLUSION

In conclusion, patient mediated interventions have the potential to overcome several important barriers to the use of EBM, especially those which apply in general practice, but these interventions have been little studied. Chronic disease is a suitable focus for new studies on patient mediated interventions and COPD is a chronic disease with demonstrated potential for practice improvement. Print is a practical and popular format, suitable for a patient mediated intervention in COPD. Such interventions should incorporate features associated with effectiveness in PIMs.

Chapter 3 DEVELOPMENT OF A MANUAL CONTAINING EVIDENCE SUMMARIES FOR COPD PATIENTS

The previous chapter showed the need for studies of the effectiveness of patient mediated interventions in reducing the gap between evidence and practice. The suitability of COPD as a focus for this type of study was highlighted, and the characteristics which should be incorporated into printed interventions were identified. This chapter describes how a patient mediated intervention for COPD was developed to incorporate these characteristics, and key features of the resulting COPD Evidence Manual.

3.1 BACKGROUND

In 2001, The Australian Cochrane Airways Group received funding from the Australian Government Department of Health and Ageing for a number of activities across three states. One of these, undertaken in South Australia, was the development of a manual which would inform patients about evidence and thereby promote the use of evidence in disease management. The project to develop and trial a manual for COPD forms the basis of this thesis.

3.2 AIMS AND DEVELOPMENT OF THE COPD EVIDENCE MANUAL

The specific aims for the manual were:

- to inform patients about evidence for treatments used in COPD and
- to encourage patients to initiate conversations with doctors about evidence and
- to thereby prompt doctors to review current treatment of the patient in relation to the evidence.

Design was based on recommendations (A) to (Q) identified in section 2.4.2.3, Table 2.3 and Figure 2.1. Implementation of these recommendations is indicated by bracketed letters in the account below.

The primary source of evidence for the COPD Evidence Manual was Cochrane reviews because these are comprehensive and regularly updated (Jadad et al 1998).

To encourage patients to initiate conversations with doctors about evidence, the COPD Evidence Manual suggested key questions which patients could ask at a consultation. The use of questions rather than overt suggestions is in keeping with patient behaviour in consultations (Beisecker 1990).

Input was obtained from all major stakeholder groups; patients (recommendations A, D, P and Q), specialists, general practitioners, and allied health professionals. Recommendations from these groups were integrated by an editorial team, as shown in Figure 3.1.

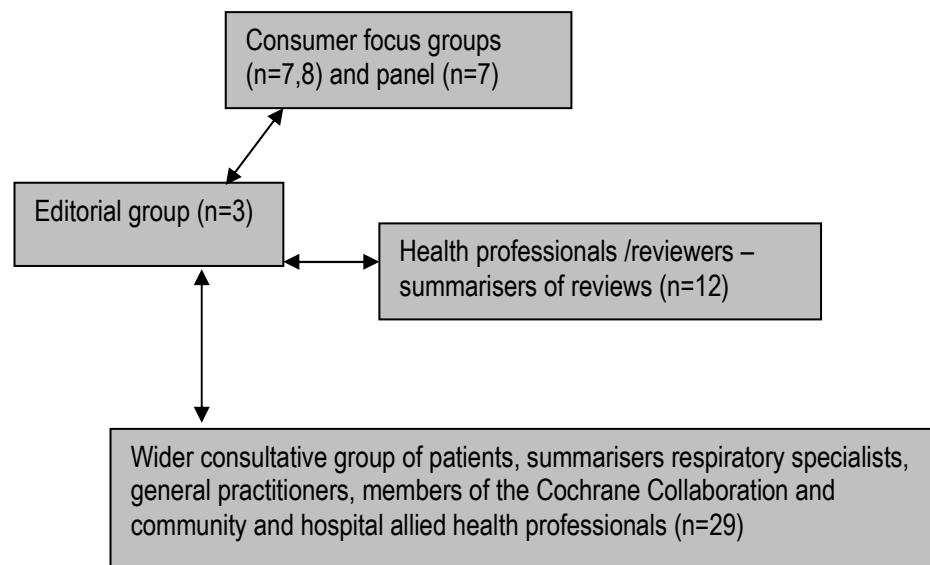


Figure 3.1. Overview of inputs

The editorial group sought patient input by convening two patient and carer focus groups, appointing an advisory patient panel and attending meetings of a community support group, WestAir, for people with COPD and their carers. The focus groups were constructed by purposive sampling (Rice & Ezzy 1999, pp. 42-46) to cover

variation in severity of COPD, gender, carer or patient role, and socio-economic and employment background. Focus groups were recruited via hospital nursing staff at The Queen Elizabeth Hospital and a community support group. Nursing staff approached patients recently discharged from hospital with COPD or who attended outpatient clinics and asked if they would permit contact from a researcher in relation to a focus group. Similarly, office-bearers of the community support group approached members who they know to have COPD. Researchers liaised with nursing staff and office bearers as recruitment progressed so that the focus group comprised people from various backgrounds and ages, carers and sufferers, different durations of COPD diagnosis. Participants were provided with transport to and from the venue, and light refreshments were served prior to the focus group. Of the 7 people in Focus Group 1, four were males and two were carers. Time since diagnosis of COPD ranged from 1 to 40 years, and ages ranged from 50 to 80 years. Of the 8 people in Focus Group 2, five were males and three were carers (with one of these carers also having COPD). Time since diagnosis of COPD ranges from 1 to 20 years, and ages ranged from 56 to 87 years. For both groups, previous or current employment covered a range of service, manual and administrative occupations and unemployment. A professional market research company, Harrison Health Research Pty Ltd, was commissioned to conduct Focus Group 2 as a measure to reduce the chance of bias and therefore increase reliability. The advisory patient panel (n=7) was constructed similarly with individuals who were willing to participate more intensively and over a period of months. The community support group met monthly with attendances ranging from 14 to over 30.

Health professional input was obtained in two main ways. Firstly, twelve health professionals familiar with both COPD and systematic review methods agreed to work on individual summaries. These individuals are acknowledged in Appendix 1. Secondly a varied group of health professionals (n=29), along with the patient panel, made up a consultative group that was consulted at critical points in the development of the resource. These and other, one-off, consultations are summarised as a table in Appendix 2.

The COPD Evidence Manual was developed in three phases as described below.

3.2.1 Phase 1. Initial input for content decisions

3.2.1.1 Methods

The focus groups and the community support group were asked about patient interest in reviews of research evidence, and which other topics should be included in the manual.

Participants in Focus group 1 were specifically asked about interest in provision of evidence to patients and were asked to propose other topics. The focus group was conducted by MH and another researcher (AH) using a theme list, shown in Appendix 3, developed by MH, AH and BS (supervisor). Analysis was performed by MH with discussion by all.

At a meeting of the community support group, 14 people worked in pairs to prioritise and add to these topics, then whole group discussion produced an overall list.

Focus Group 2 reviewed and added to this list. A professional market research company, Harrison Health Research Pty Ltd was commissioned to conduct Focus Group 2 as a strategy to improve validity by reducing possible researcher bias. The brief for Focus Group 2 is shown in Appendix 4.

The editorial team included as many of the suggested topics as could be included in the aims for the project.

3.2.1.2 Results

Patients in focus groups and support group meetings endorsed the production of patient summaries of reviews of evidence and responded positively when asked if their practice was to take new information on COPD to their GP. There were no dissenting voices to these statements. Patients wanted side effects of medications to be included with the summaries.

Additional topics requested by patients were:

Usual progress of COPD

Depression and COPD

How lungs work and what's wrong in COPD

COPD as a condition to be managed rather than cured

(Feedback from the patient panel later led to the removal of the section on usual progress of COPD. Several panellists commented that this information was confronting and many readers would not want it conspicuously presented. The COPD Evidence Manual instead listed sources where interested readers could obtain this information.)

Other topics which had some patient support were: getting a referral to a specialist, correct use of inhaler devices, benefits of support groups and dealing with family and sexuality issues arising from COPD. The editorial team felt that referrals could not be addressed as a separate topic, but that referrals would result from patients and doctors discussing other topics in the manual. Teaching on correct use of inhaler devices was not included because demonstration and feedback have been shown to be more effective than print instructions for inhaler technique (Skaer et al 1996; Savage & Goodyer 2003). Research evidence on support groups in COPD could not be found. The editorial team decided instead to provide information on finding a support group. Finally, dealing with family and sexuality issues was omitted because it was given very low priority when all potential topics were assessed by Focus Group 2.

A transcript of Focus Group 1 is shown in Appendix 5 and the executive summary of the report of Focus Group 2 in Appendix 6.

3.2.2 Phase 2a. Decisions on style and terminology

3.2.2.1 Methods

A multi-step process was used prior to drafting to find which of several credible writing styles patients preferred. While initial examples were based on relevant design recommendations (recommendations B, C, and E to M), patient input was the main driver for writing style and illness-related terminology (recommendation Q).

STEP 1. STYLE OPTIONS

Three writing styles were generated. Style I was based on currently available patient summaries of evidence (now found at Health Education and Research Foundation 2005). Style II was based on the experience of contributing health professionals in writing for patients. Style III was based on descriptions of preferred writing from Focus Group 1 and a support group meeting, and was similar to published advice about writing for patients (NHMRC 2000). Styles are illustrated in Figure 3.2, applied to a review of evidence on home care nursing for COPD.

STEP 2. INITIAL STYLE ASSESSMENT

The patient panel rated and commented on two examples of each of the three styles (in different order for each person) for readability, learning, and as a prompt to talk to a doctor about the topic. Record sheets containing spaces for comments on the styles and three or four point descriptive scales were used (shown in Appendix 7). Though statistical analyses cannot be used with this kind of descriptive scale (Macnaughton 1996) or with purposive samples, the scales made patient judgements explicit and facilitated the preparation of a summary.

STYLE I:

Home care by nurses may be of some help to people with less severe COPD (emphysema or chronic bronchitis), but does not improve outcomes when COPD is severe.

Home visits for people with chronic lung disease (COPD – emphysema or chronic bronchitis) aim to help people maintain their health and need fewer hospital stays. The nurses aim to help people use their treatments well, provide education about coping strategies, and monitor the lung disease. However, the review found that trials have shown that this is an expensive form of care, that has not been shown to improve lung function. There may be some benefits for people with less severe disease, but more research is needed to demonstrate this.

STYLE II:

Home care by nurses

Some hospitals have tried outreach nurses to visit patients in their own homes to provide support, education, monitor the patient's well being and provide liaison with the patient's general practitioner and hospital physicians. Improvement in quality of life was found in patients with moderate chronic obstructive airways disease, although not in another study of patients with more severe disease. In spite of attempts to optimise therapies through the outreach nurse there was no demonstrable improvement in lung function or exercise performance in the studies that have looked at this. Also, there was no evidence that hospital admissions were reduced or that there were any cost savings to the health system.

STYLE III:

Home care by nurses

What is home care by nurses?

This is a home service for people with COPD. Nurses come once a month or so to your home to help, answer questions and check how well you are. They can also talk to your doctors for you. This service has been tried by some hospitals but is not available to most people with COPD.

What does the research show?

The research shows that the benefits are small for the cost of the service.

Overall, how useful is this service?

People who get this service might feel a little better but research hasn't shown enough benefits for home nurse service to be provided to everyone.

STYLE IV:

Home care by nurses

What is home care by nurses?

This is a home service for people with COPD. Nurses come once a month or so to your home to help, answer questions and check how well you are. They can also talk to your doctors for you. This service has been tried by some hospitals but is not available to most people with COPD.

What does the research show?

The research shows that the benefits are small for the cost of the service.

Two research studies measured people's quality of life. In one study, people with moderate COPD got the service and their quality of life improved. In another study, people with more severe COPD got the service and their quality of life didn't improve.

Figure 3.2. Extracts illustrating Styles I to IV

STEP 3. DETAILED STYLE ASSESSMENT

In a further patient rating round, the least preferred style (Style I) was omitted and a more detailed variant (Style IV) of the highest scoring style (Style III) was added. Style IV is illustrated in Figure 3.2. In response to health professionals' concerns that some styles might be too simplistic and patronising, questions were included to ask about this.

In a final step, the resulting preferred style was appraised by Focus Group 2.

DETERMINING TERMINOLOGY PREFERENCES

To obtain patient preferences relating to disease terminology, patients at all stages of consultation were asked to identify poorly understood terms. In addition, editors pro-actively asked panellists and community support group members about their understanding of particular medical terms. Substitute lay terms were identified through consultation and testing with panellists and support group members.

3.2.2.2 Results

STYLE PREFERENCES

Comments and scoring showed a clear preference for Styles III and IV over Styles I and II for most criteria. Participants generally did not understand material written in Styles I and II well enough to give detailed feedback. In contrast, comments on Styles III and IV illustrated that the content was understood. For example the comments *"Doesn't seem very long"* (Panellist 5) and *"Why were they lost? Did they stop doing it?"* (Panellist 1) were made in response to the clause, "These benefits [of pulmonary rehabilitation] were lost as time went on, and had disappeared by four years". Panel evaluations are summarised in Table 3.1.

Table 3.1. Summary of panel assessments of styles

Style	Evaluation for:			Illustrative comments from panellists
	Readability	Learning	Incentive to talk to doctor	
I	**	*	**	<i>[I] needed to read this several times [trying to understand it]. (Panellist 4)</i> <i>Gobbledegook. I did not understand this one at all. (Panellist 1)</i>
II	***	**	***	<i>[I] don't understand the written words. (Panellist 2)</i> <i>[I] don't understand this. (Panellist3)</i>
III	****	***	***	<i>Not as informative on all aspects as the first copy [Style IV]. (Panellist 5)</i> <i>This is good. I would like to see the results of the research we are still waiting for. (Panellist1)</i>
IV	***	***	****	<i>I like this one. This explains it pretty well. (Panellist 2)</i> <i>[There are] some interesting paragraphs here. (Panellist3)</i>

No style was judged too simplistic or to deliver too much detail. Only Style II was judged by some patients to be too complex.

Of the two styles most liked by patients and carers, health professionals preferred Style IV over Style III as it allowed fuller explanation of evidence. Style IV was unanimously and strongly supported, spontaneously and through probing when assessed by Focus Group 2. Typical comments were:

I can't fault it

It puts it all out in detail. It's well put out.

TERMINOLOGY PREFERENCES

Patients did not understand some terms frequently used by health professionals.

[S]ome people don't understand none of these things even if you do have the information. Because its in too technical terms. (Focus Group 1)

[We want it] In plain English" (Focus Group 2)

Because names are too hard to remember, [you] need to be more simple, as most people that have COPD are older and have trouble remembering. (Panellist 1)

Patients stated that they were deterred by medical terms, even if explanations were provided, and preferred lay terms. The exception was the term COPD which patients accepted as one they should learn. Table 3.2 shows lay terms which were understood by these Australian patients and therefore used in the COPD Evidence Manual.

Table 3.2. Examples of terms preferred by patients

Medical term	Term preferred by patients
Alveolus	Air sac
Adverse effects	Side effects
Bronchus, bronchiole	Breathing tube
Bronchodilators	Relievers (understood by some), puffers
Exacerbation	Being very sick with COPD
Mortality	Death, risk of dying
Osteoporosis	Thinning of the bones
Pulmonary rehabilitation	Courses for people with COPD
Smoking cessation	Giving up smoking, quitting

3.2.3 Phase 2b. Drafting summaries of evidence using the preferred style and terminology

Health professionals who had volunteered to summarise reviews worked individually with editors to create initial drafts from Cochrane reviews. Where a Cochrane review had not been done, another evidence-based source such as GOLD (Global Initiative for Chronic Obstructive Lung Disease 2001) was used. Drafts included a related tip or suggested question that the patient could ask their doctor to promote consideration of the evidence. These questions were created by health professionals, many of them doctors, to be acceptable as questions patients might ask their doctors in consultations. Editors worked with the health professionals and patient panellists to re-draft to Style IV and to the terminology wanted by patients, and to optimise accuracy and understandability. Additional topics were developed from standard medical texts by a similar process.

Two rounds of editing based on comment from panellists and the consultative group completed consultation on content and style. A professional editor completed print formatting and advised on photographs (recommendation N) to accompany the text. Members of the support group were models for these photographs.

3.2.4 Phase 3. Presentation format

3.2.4.1 Methods

Patients were consulted in several different ways about general and then particular presentation preferences. Participants at focus groups were asked whether a printed or electronic form would be more used by this target audience. Building on a clear preference for a printed manual, particular preferences were explored by creating examples for evaluation. Health professionals, a health education professional and a text editing professional identified eight presentation options for the printed information. These were ring binders, stapled books, grip binders and pocket folders, all in A4 and A5 sizes. Patient panellists examined mock-ups of these presentation options. Panellists were asked for their views on each format and were then asked to assess each for reading and storage convenience and the likelihood that they would

take it along to a medical consultation. The recording form used by the interviewer is shown in Appendix 8. The same mock-ups were displayed and discussed at a meeting of the community support group and comments and preferences were recorded.

An important aspect of format was print size, and this was evaluated in some detail. Following advice from support group members, and published guidance, (NHMRC 2000) all mock-ups for the above consultations were presented in 14-point type. However, a text-editing professional advocated smaller text with more space between lines. Therefore a further five people with COPD rated two sets of three documents for reading ease. Each set showed the same text in same serif font with different sizing; 14 point type and single spacing, 11 point type and 19 point spacing and 12 point type with 18 point spacing.

3.2.4.2 Results

Patients consistently disliked the packet folder format, commenting that sheets were likely to be lost from it or get out of order. Comments on A4 size mock-ups included *“too big”*, *“too clumsy”*, and *“cumbersome”*. An A5 size was preferred, as a stapled book or, if updates were available, as a ring binder. Patients commented that they would be more likely to read an A5 item and to take an A5 item with them to a medical consultation. Patients preferred 14-point type that was single-spaced to slightly smaller text with bigger line spacing.

3.3 PATIENT PREFERENCES INCORPORATED INTO THE COPD EVIDENCE MANUAL

The consultation process used in this project identified patient preferences for content, style and presentation format, many of which were not predicted by health and editorial professionals. Plain language summaries of research evidence which could be discussed with a doctor were welcomed. Patients and carers wanted additional topics including adverse effects of treatments, psychological depression and COPD, aetiology, and the need to manage COPD. Patients and carers preferred

very plain language, lay terminology, and a printed book or file with small page size and large print.

Sections from the COPD Evidence Manual are reproduced in Appendix 9.

3.4 IN-USE CONSULTATION AND PILOT

A brief consultative pilot with two doctors and five patients was conducted to give an indication of how the COPD Evidence Manual would be received and used in practice, and whether any instructions or additional elements were needed.

A meeting was held with a respiratory specialist and a general practitioner/medical educator and their views on possible problems or barriers to use of the COPD Evidence Manual in practice were noted. Concerns raised were;

- the size of the manual could deter some patients from reading
- some patients might bring overly long lists of suggestions to a consultation
- if patients asked questions without showing the manual, doctors might not be exposed to the summary of evidence.

While these health professionals felt that patients might be deterred by the length of the manual, direct consultation with patients themselves had not shown length to be a concern. Patients had indicated in focus groups that they wanted full information. Community group and editorial panel members had not raised concerns about the length of the manual when consulted during its development and had not suggested that any sections be removed. Designers of patient information materials are advised to base the content of materials on this kind of consultation rather than rely on health professionals' predictions of patient needs (NHMRC 2000). The manual was not therefore modified as a result of the comments from health professionals.

Five people with COPD who attended The Queen Elizabeth Hospital and who had not been involved in the development of the COPD Evidence Manual were

approached by their hospital doctor and agreed to take a COPD Evidence Manual and to give their views to researchers. These participants differed demographically, as shown in Table 3.3. Participants were contacted by visit or phone between one and five times over the subsequent 5 weeks. Participants 1, 2, 4 and 5 all reported that they read most of the manual within one week and found it helpful. In addition, Participant 1 said she intended to ask her doctor about a treatment covered in the manual. Participant 2 said he now had a better understanding of his condition and why his doctor had prescribed particular treatments. Participant 4 loaned the manual to a family member with COPD. Participant 3 was preoccupied with home issues, and withdrew after 2 weeks without having read the manual.

Table 3.3. Demographic variables for pilot participants

Patient	Gender	Yr 12 school completed	Lives with carer	On oxygen therapy	English speaking background	Age years
		Yes/No	Yes/No	Yes/No	Yes/No	
1	F	Y	N	N	Y	64
2	M	N	Y	N	Y	82
3	M	N	Y	Y	N	78
4	M	N	N	N	Y	69
5	F	Y	Y	N	Y	85

As a result of this consultation and brief pilot, a short list of tips was prepared for distribution with the COPD Evidence Manual. It encouraged gradual reading, sharing reading with carers, prioritising of questions for doctors, and taking the COPD Evidence Manual to consultations. This list is shown in Appendix 10. In addition, an application form was included with the manual enabling the patient's doctor to send for their own copy (Appendix 11).

3.5 CONCLUSION

The COPD Evidence Manual produced collaboratively using current best practice appeared to be effective in informing patients and in encouraging them to initiate conversations with doctors. However, a formal trial was required to properly evaluate its effectiveness.

Chapter 4 TRIAL OF THE COPD EVIDENCE

MANUAL: HYPOTHESES AND METHODS

The previous chapter described the development of the COPD Evidence Manual for patients. This chapter gives the methods for a controlled trial to test the success of the manual in increasing the implementation of evidence by the patients' doctors.

4.1 INTRODUCTION

The evaluation of the COPD Evidence Manual included a trial of outcomes and a process evaluation to elucidate how those outcomes were achieved. This chapter gives methods for the trial, with methods for the process evaluation given in the next chapter.

The principal element of the evaluation of the COPD Evidence Manual was a controlled trial of its effectiveness in changing medical practice. Trial participants were people with moderate to severe COPD living in and around Adelaide, South Australia. Intervention participants received the manual and control participants received an existing conventional pamphlet on COPD available from The Australian Lung Foundation online (The Australian Lung Foundation 2002a) or in print (The Australian Lung Foundation 2002b). The primary hypothesis was that the manual would be associated with improved application of evidence, as measured by a three-component indicator measure of evidence based management of COPD. The three components of this indicator measure were current influenza vaccination, recent bone density testing and enrolment in pulmonary rehabilitation. . Three hospitals in metropolitan Adelaide in South Australia were the recruitment sites for this study. Participants' primary care was provided by GPs in the areas covered by the Adelaide Western and Southern Divisions of General Practice. A trial duration of 12 months was selected because interventions such as the manual take time to have an effect (Cooper et al 2001). However, early effects and their duration are of interest as well, therefore outcome measures were also taken at 3 months. Hypotheses and methods are detailed below.

4.2 HYPOTHESES

The primary hypothesis to be tested was:

Hypothesis 1

Compared with patients who have been given a conventional pamphlet, patients who have been given the COPD Evidence Manual will have increased:

- d) rate of influenza vaccination within the previous 15 months, by patient self report
- e) rate of bone density testing within the previous 42 months, by patient self-report
- f) enrolment in pulmonary rehabilitation, by patient self report.

The following secondary hypotheses were also tested:

Compared with patients who have been given a conventional pamphlet, patients who have been given the COPD Evidence Manual will have:

- **Hypothesis 2** improved mastery of COPD, as measured by the Mastery domain of the Chronic Respiratory Questionnaire (CRQ)
- **Hypothesis 3** improved knowledge of COPD, as measured by a test adapted from Hermiz et al (2002)
- **Hypothesis 4** improved communication with their usual doctor, as measured by the Communication and Comfort and the Rapport subscales of the Medical Interview Satisfaction Scale
- **Hypothesis 5** improved satisfaction with disease related information, as measured by an item adapted from the Medical Interview Satisfaction Scale
- **Hypothesis 6** no increase in anxiety, as measured by the Short-form Spielberger State Anxiety Inventory

4.3 METHODS

4.3.1 Recruitment

Patients with moderate to severe COPD were sought, as they were likely to be receiving multiple medications and therefore present a relatively high potential for evidence based treatment change. Patients were excluded if they also had a diagnosis of lung cancer (which would be the focus of attention) or dementia (where reading and comprehension skills were likely to be compromised).

Patients of The Queen Elizabeth Hospital, the Flinders Medical Centre and the Repatriation General Hospital were identified at or near to discharge or when they attended clinic at these hospitals for care of their COPD. Four methods of patient identification were used, which were compatible with hospital administrative systems. Firstly, patients discharged with COPD from The Queen Elizabeth Hospital and Flinders Medical Centre were identified by data collection staff who extracted monthly lists of patients discharged after exacerbations of COPD who did not also suffer from cancer. After experience that many of these patients suffered from dementia, this condition was also specified as an exclusion. The International Statistical Classification of Diseases and Related Health Problems, 10th Revision, codes specified for this data extraction are shown in Figure 4.1. Secondly, researchers asked doctors conducting ward rounds whether patients who might meet the criteria were near to discharge. Thirdly, COPD patients attending outpatient clinics at these hospitals were identified by manual scanning of case notes prior to clinics. Fourthly, in-patients and outpatients of the Repatriation General Hospital were identified by manual scanning of notes as patients attended the lung function testing laboratory.

Invitations addressed to patients identified as above were provided to the patient's doctor. Doctors were asked to sign the invitation if the following criteria were met:

- COPD is moderate or severe (Global Initiative for Chronic Obstructive Lung Disease 2001)
- the doctor considers the patient is well enough be invited to participate in an interview-based study and able to give informed consent

- patient or agreed carer reads English at basic level
- patient is not currently a participant in another trial.

.....Only patients with ICD-10 codes as follows:

Either

Primary discharge code one of -

J41.1
 J41.8
 J42
 J43 codes - J43.0, J43.1, J43.2, J43.8, J43.9
 J44 codes - J44.0, J44.1, J44.8, J44.9

Or

Any of above as secondary discharge code **with** primary discharge code one of -

J06 codes - J06.0, J06.8, J06.9
 J10 codes - J10.0, J10.1, J10.8
 J11 codes - J11.0, J11.1, J11.8
 J12 codes - J12.0, J12.1, J12.2, J12.8, J12.9
 J13
 J14
 J15 codes - J15.0, J15.1, J15.2, J15.3, J15.4, J15.5, J15.6, J15.7, J15.8, J15.9
 J16 codes - J16.0, J16.8
 J18 codes - J18.0, J18.1, J18.2, J18.8, J18.9
 J21 codes - J21.0, J21.8, J21.9
 J22
 J81
 J96 codes - J96.0, J96.1, J96.9

But excluding:

patients with malignant neoplasms of respiratory organs anywhere among the coding - all C30 to C34 codes
 patients with dementia anywhere among the coding - all F00 to F03 codes

Figure 4.1. ICD-10 coding specification for patient identification

In summary, each inclusion/exclusion criterion was assessed as follows:

- | | |
|--|--|
| 1. COPD as major health problem | For patients discharged from hospital, automated extraction from hospital data files of patients with primary discharge ICD code indicating COPD, or secondary code indicating COPD with primary code for a problem commonly associated with COPD (See Figure 4.1). For patients attending clinic, manual scanning of notes. |
| 2. Not lung cancer or dementia | For patients discharged from hospital, automatic extraction excluded patients with discharge codes indicating these conditions. For patients attending clinic, manual scanning included a check for these conditions. |
| 3. COPD moderate to severe | Criteria 3 to 6 assessed by the patient's doctor |
| 4. Patient is well enough to participate and give informed consent | issuing the invitation |
| 5. Patient or carer reads English at a basic level | |
| 6. Patient is not currently in another trial | |

Invitations included a letter informing patients about the study and inviting them to join or request further information, a form to indicate acceptance or refusal, and a prepaid envelope for return of the completed form. Invitation and form are shown in Appendix 12. For patients discharged from hospital, researchers mailed signed invitations to the patients' homes. For patients about to be discharged, researchers handed invitations to patients. For patients attending clinic, doctors handed over

invitations at the end of consultations. A reminder was mailed to patients invited after discharge if no response was received after 3 weeks.

Research interviewers contacted patients who indicated interest in the study and, with the patient's agreement, made an appointment convenient for the patient (eg. at their home or the hospital). At the meeting, the interviewer explained the study requirements and, if the patient wanted to join, asked for signed consent. If the patient preferred, or if they lived more than an hour's drive from metropolitan Adelaide, phone and mail were used for discussion and consent.

Recruitment continued progressively from 04/03/2003 to 05/03/2005 until the sample size was reached.

CHARACTERISTICS OF PARTICIPANTS IN RELATION TO SAMPLING FRAME

During recruitment, the following data was collected so that the generalisability of study results to the total COPD population could later be assessed.

Patients who were not given invitations: Doctors at four clinic sessions were asked to fill out survey forms (Appendix 13) giving reasons for not issuing invitations. In addition, when doctors volunteered reasons for not inviting patients these were recorded.

Patients who refused invitations: Patients were given space on invitation reply forms to give reasons for refusing the invitation to participate, and several people gave reasons if they made a refusal by telephone. These reasons were recorded and categorised.

Patients who did not reply to invitations: Demographic data was retained for participants who did not respond to invitations.

Patients who withdrew from the study: Reasons volunteered by participants for withdrawal during the trial were recorded.

4.3.2 Allocation and blinding

Randomised and non-randomised study designs were considered for the evaluation of the effectiveness of the manual in changing clinical practice. Potentially suitable designs were randomised trials with randomisation at the patient, general practitioner, general practice group or hospital level, and a controlled before-and-after trial (Morgan et al 2000; Eccles et al 2003). There are advantages and

disadvantages for each of these designs in relation to the planned evaluation. A randomised design provides the best evidence that an intervention is responsible for any effects found. It does this by providing a high likelihood that known and unknown confounders are distributed evenly between intervention and control groups. Randomisation works well for pharmaceutical interventions but has practical disadvantages for behavioural interventions where contamination and clustering effects are likely. Cluster randomisation can overcome these disadvantages but clustering inflates sample sizes and therefore study costs, especially if the cluster size must be large. Furthermore, if contamination is possible at a fairly high level, and few clusters are available, the design is less strong and baseline differences between intervention and control groups must be identified and adjusted for, as with a non-randomised controlled before-and-after trial. Randomised allocation may not therefore always be advisable when a behavioural intervention can contaminate the control group (Black 1996; McKee et al 1999). Controlled before-and-after trials are useful where there are practical difficulties with randomisation. With this design, researchers must attempt to identify a control population with similar baseline characteristics to the study population. Differences between post-intervention performance or change scores are attributed to the intervention, but plausible rival hypotheses are more likely than in randomised designs (Morgan et al 2000; Eccles et al 2003). However, rival hypotheses can be reduced, though not eliminated, by identifying possible confounding or effect modifying factors (Normand et al 2005) and adjusting, using techniques such as propensity scoring (D'Agostino 1998; Lunceford & Davidian 2004) and stratification (McKee et al 1999; Normand et al 2005). These research designs were considered in relation to the way the study manual would be used. It was likely that patients would discuss topics from the manual with several general practitioners and hospital and clinic doctors, as well as family, friends and fellow sufferers, during a 12 month period. Contamination of the control group was therefore highly likely if control and intervention participants were geographically close.

Extensive sharing of the COPD Evidence Manual with other patients was observed during development and piloting, indicating high potential for patient to patient contamination for this study, both directly and via a GP. Contamination

could not be restricted by asking participants not to share their manuals. This was a pragmatic trial, evaluating the impact of an intervention in actual clinical and community practice. People with COPD manage and make decisions about their condition in cooperation with family and friends and by accessing wider community support as well as health services. The manual was designed to be shared with others who helped the person with COPD. Limitations on sharing, if effective, would have limited its use. Confusion about who could and could not read the manual would also have been likely, causing worry for participants.

Within metropolitan Adelaide two regions were identified containing demographically similar groups of patients who received care from distinct primary and secondary health care providers. A decision was therefore made to adopt a controlled before and after design, comparing two geographically separate but otherwise similar groups of patients.

Patients living in north west areas of Adelaide were allocated to the control group and patients living in southern areas were allocated to the intervention group. Baseline differences between these two groups were not expected. Control and intervention regions both included a range of demographic characteristics and a mixture of high and low socioeconomic disadvantage (Hetzl et al 2004). A map showing disadvantage levels for areas included in the two regions is shown in Appendix 14. Both regions had major hospitals providing outpatient respiratory services and programmes which provided at least the essential elements of pulmonary rehabilitation as defined in the Cochrane review (Lacasse et al 2002). There was some exchange of medical staff between hospitals of the two regions and no notable practice differences.

Contamination was likely to be confined within the intervention area. The possibility of contamination via a hospital doctor who had transferred from the intervention to the control area was small as exchanges of medical staff were not frequent.

Because of the nature of the intervention and allocation, interviewers could not be blinded. Interviewers were, however, trained to administer questionnaires, record

answers, and hand out the resources in a consistent way. Participants were blind to their intervention/control status because all study documentation and explanation stated that different forms of information were being tested and that each participant would receive one of them in the first instance, and the other at the end of the study.

4.3.3 Data collection

Data was collected by interviewer administration to minimise burden on participants. At the meeting between interviewer and participant, following written consent, (or by phone, following receipt of mailed consent) baseline measures were obtained using interviewer administered questionnaire (shown in Appendix 15). The participant was then given the pamphlet or COPD Evidence Manual and an appointment made for an interview to collect follow up data 3 months later.

4.3.4 Outcome measures

4.3.4.1 Primary outcome: Indicator of evidence based COPD management

For the primary outcome, an indicator of the degree of correspondence between actual and evidence based treatment was required. The following criteria were applied in selecting components of this indicator:

- topic included in COPD Evidence Manual
- applicable to a large proportion of people with COPD
- initial implementation low enough for statistically significant improvement with reasonable sample size
- readily measurable by non-clinical research workers, eg by participant self-report.

Components selected as meeting these criteria were influenza vaccination within the previous fifteen months, bone density testing within the previous forty two months, and enrolment (ever) in pulmonary rehabilitation. Selection rationale is shown in Table 4.1. A three month buffer period was added to the one year interval for

influenza vaccination to allow for vaccination appointment and vaccine availability delays. The 42 month interval was used for bone density testing, because repeat screening within one to four years is advised for patients on therapy (Sturtridge et al 1996), and because of continuing risk for people with moderate to severe COPD.

Also shown in Table 4.1 are estimates of initial rates and target rates for each component. A target increase for influenza vaccination from 80% to 95% was judged as achievable in the light of 10-16% increases obtained with other text-based patient educational interventions (Moran et al 1996; Armstrong et al 1999). A target increase from 10% to 30% was judged as achievable for bone density testing in line with the upper range of effectiveness for screening reminders (Shea et al 1996). In the absence of studies on uptake rates, the target increase from 25% to 45% for pulmonary rehabilitation enrolment was based on judgement and experience that patients were frequently unaware of pulmonary rehabilitation but interested in enrolling when made aware. All components of the indicator were expected to show these target increases.

Table 4.1. Components of primary outcome measure

Component	General applicability in COPD	Indication of initial rate in area where trial was planned	Estimated initial rate/ target rate (%)
a) Influenza vaccination current	Recommended treatment for all stages of COPD (Global Initiative for Chronic Obstructive Lung Disease 2001)	Eighty percent of South Australian people 65 years and over received influenza vaccination in 2002 and previous 2 years (SA Immunisation Coordination Unit 2002)	80/95
b) Bone density monitored	COPD is an important risk factor for osteoporosis (Smith et al 1999; Sin et al 2003)	Eight percent of people with symptoms or risk factors tested (Nguyen et al 2004)	10/30
c) Participation in pulmonary rehabilitation	Recommended treatment for moderate and severe COPD (Global Initiative for Chronic Obstructive Lung Disease 2001)	Rate for Australia has been estimated at 27% (Gibson 2001).	25/45

The primary outcome was measured by asking participants:

- a) As far as you can remember, what was the date of your last influenza vaccination?
- b) As far as you can remember, what was the date of your last bone density test? *
- c) Have you been to a programme of classes or sessions, for people with your lung condition, that included arm or leg exercises and that you attended for 4 weeks or more? *If no* Are you booked for a programme like this?

The wording of (c) reflected the definition of rehabilitation used in the Cochrane review (Lacasse et al 2002) and was piloted with 6 patients who showed varied demographic and disease stage characteristics. There were concerns that question (c) itself would prompt patient inquiries about pulmonary rehabilitation, so the question was asked retrospectively at 12 months. This component of the primary outcome measure was therefore unavailable for participants who were lost to the study before 12 months.

4.3.4.2 Secondary outcome: Improved disease mastery

Quality of life is an important health outcome in progressive conditions like COPD (Jones 2001), has been improved by face to face educational interventions (Hui & Hewitt 2003) and may also be improved by less intensive interventions (Hermiz et al 2002). The disease mastery component of quality of life, in particular, is expected to

* When asked this question, the participant was shown a photograph of a patient undergoing dual energy X-ray absorptiometry densitometry

improve when patients have information about treatment options for a variety of situations which they may encounter.

The mastery aspect of quality of life was measured using the CRQ (Guyatt et al 1987). This instrument is a widely used interviewer administered measure of COPD patient quality of life change (Jones 2001). It has good reliability, validity and sensitivity, with a minimum clinically important difference of 0.5 on a scale from 1 to 7 (Redelmeier et al 1996).

4.3.4.3 Secondary outcome: Increased knowledge

Increased patient knowledge is commonly seen as a benefit in itself in chronic disease and an important prerequisite for patient action. Knowledge has been improved by other chronic disease PIMs (Maggs et al 1996; Barlow & Wright 1998; Kennedy et al 2003a).

A knowledge test which was relevant and had been validated could not be found. A validated knowledge test is available for pulmonary rehabilitation (Hopp et al 1989) but there was little overlap between questions in this test and the content of the COPD Evidence Manual. A non-validated knowledge test developed by Hermiz and colleagues (Hermiz et al 2002) overlapped with the content of the COPD Evidence Manual. It had demonstrated statistically significant differences between intervention and control participants in a trial of home visits (n=177) (Hermiz et al 2002) and was therefore adapted for this study by consultation with three respiratory specialists and piloting with seven patients who showed varied demographic and disease stage characteristics. The adapted questions are shown in Table 4.2 and the complete test in the questionnaire (Appendix 15). A maximum score of 16 was possible for the knowledge test.

Table 4.2. Changes to knowledge test of Hermiz et al (2002)

Original question	New question	Reason for change
Which immunisations/vaccines do you think might help you reduce the risk of getting a bad attack of your chest condition?	Sometimes people with your chest condition get very sick for a time. Which immunisations or vaccines might help reduce the risk of getting very sick?	Improved patient understanding
Which of the following may help delay your chest condition from deteriorating? - stop smoking, become familiar with your medication, maintain vaccination, exercise heavily, drink plenty of fluids, consume sugar rich diet.	Which of the following can help you manage your chest condition? - stopping smoking, reliever medications, vaccinations, exercise, sugar rich diet, drinking very large amounts of water.	Improved patient/specialist understanding and match with content of manual.
The following symptoms are indications that you need to seek help. True or false? Increasing body temperature, increasing shortness of breath, changing the colour of the sputum, prolonged cough.	Which of the following symptoms show that you might be starting to get very sick with your chest condition? Breathlessness gets worse, coughing up more phlegm, phlegm changes in colour, appetite for food increases.	Improved patient understanding, match with content of manual, and suggestion that an including and incorrect statement would prevent respondents from assuming all statements were correct.
	Is there any benefit in stopping smoking if you already have COPD?	Question added because of evidence (covered in the manual) that stopping smoking is the only change which slows the progress of COPD.
	When should you take relievers such as Ventolin, Bricanyl, Airomir or Asmol?	Specialist experience that though there was no evidence for it, many patients feared reduced effect from frequent use of bronchodilators.
	What is wrong with the lungs in diseases such as COPD, emphysema and chronic bronchitis	Covered in manual (at the request of patients).

4.3.4.4 Secondary outcome: Improved communication with doctor

The COPD Evidence Manual could also be expected to improve patients' communication with their doctor by providing patients with information and offering discussion-opening questions.

The Communication and Comfort and Rapport subscales of the Medical Interview Satisfaction Scale (Wolf et al 1978; Meakin & Weinman 2002) were used. This scale has extremely limited evidence of reliability and validity (Wilkin et al 1992, pp230-260; Meakin & Weinman 2002) and no evidence for sensitivity (Wilkin et al 1992, pp230-260). However, it was adopted because of the lack of other scales which measure satisfaction with a provider or consultation (Wilkin et al 1992, pp230-260;

Meakin & Weinman 2002). USA (Wilkin et al 1992, pp230-260) and UK (Meakin & Weinman 2002) versions were assessed by three research workers of the Clinical Epidemiology Unit of The Queen Elizabeth Hospital, a community nurse, a patient and a carer who was Chair of a community support group for people with lung diseases and their families. All judged that the UK version was more comprehensible to Australian patients.

4.3.4.5 Secondary outcome: Improved satisfaction with information

It was reasonable to predict also that the COPD Evidence Manual would improve patient satisfaction with information, as the COPD Evidence Manual provided information which patient groups had identified as of interest to them.

Published validated scales were not found for patient satisfaction with information. Instead, other researchers had used study specific survey items (Papagiannis et al 1995; Courtney 1997; Jones et al 1999; Molenaar et al 2001). For this study an item was adapted for use with the seven-option Likert scale of the Medical Interview Satisfaction Scale, ranging from “Very strongly disagree” to “Very strongly agree”;

I have enough information about my lung condition.

4.3.4.6 Secondary outcome: No increase in anxiety

Some health professionals are concerned that disease related information makes patients anxious (McGrath 1999; Garrud et al 2001; Kennedy et al 2003a; White et al 2004). However, manual contributors had used techniques to minimise anxiety, and other forms of patient information about evidence have not increased anxiety (O'Connor et al 2003; Kennedy et al 2003a). As a final secondary outcome, the COPD Evidence Manual was therefore expected to cause no increase in anxiety.

The short form of the Spielberger State Anxiety Inventory (Marteau & Bekker 1992) was used to assess participant anxiety at baseline and after viewing the information source that they received in the trial. This inventory has been assessed for validity and reliability and used in other trials where evidence was presented to

patients (Michie et al 1997; Murray et al 2001). Increases of about 10 on the scale from 20 to 80 are found after adverse results in screening (Marteau & Bekker 1992).

4.3.5 Sample size

Though a non-randomised design was judged necessary for this study, baseline differences between groups were not expected and therefore standard sample size calculations were used. Minimum sample size requirements for changes in proportion for components of the primary outcome measure with alpha set at 0.05 and power 80% are shown in Table 4.3.

Table 4.3. Sample size calculations

Change expected	Sample size required to demonstrate the expected change in proportion, power 80% and alpha 0.05 (with continuity correction)
Influenza vaccination current rate increased from 80% to 95%	88 per arm
Bone density test in previous 3 years increased from 10% to 30%	71 per arm
Pulmonary rehabilitation enrolment ever rate 25% to 45%	98 per arm

The calculated minimum was 98 participants per arm but to allow for some loss of patients and other possible factors (eg. adjustment for any group differences) it was planned to recruit 120 people into each arm of the study.

A sample size of 98 per arm provided high levels of power for those secondary hypotheses which had historical measurement data available to use in calculations. Setting alpha at 0.05, power was 99% to detect a 0.5 unit difference in the Mastery domain of the CRQ (for SD 0.80 as in Puhan et al 2004). Power was 94% and 98% to detect 0.5 unit differences on the Communication and Comfort and the Rapport sub-scale of the MISS (for SDs 0.98 and 0.85 as in Meakin & Weinman 2002). Power was 83% to detect a 5 unit difference on the Short-form Spielberger State Anxiety Inventory (for SD 12 as in Marteau & Bekker 1992). A limitation of the adapted knowledge scale and the question used to assess satisfaction with information was the lack of historical standard deviation and target effect size data that would be

required to calculate sample size. Power calculations were therefore not possible for these two variables.

4.3.6 Baseline comparisons

Intervention and control groups were first compared to assess the potential for confounding and effect modification (Lilienfeld & Stolley 1994; Mamdani et al 2005). Confounding factors are variables which are associated with the dependent variable. Unequal distribution of these variables may lead to the false conclusion that there is an association between the intervention and the dependent variable. Effect modifiers interact with the intervention, so that the strength of the intervention effect is different for different levels of the modifier (Lilienfeld & Stolley 1994). For this study, groups were compared at baseline measurements for outcome variables and additional demographic and social variables which were potential confounders or effect modifiers. Tests could then be made for confounding or effect modification, by running analyses of outcome variables using median split of any variables found to be unequally distributed at baseline.

Baseline comparison between groups was made using the outcome measures and the following additional demographic and disease related variables potentially associated with patient use of the COPD Evidence Manual:

- i. Gender
- ii. Use of oxygen therapy (as indicator of stage of COPD)
- iii. Smoking status
- iv. Age
- v. Years of formal education
- vi. Index of Relative Socio-Economic Disadvantage for postcode (Australian Bureau of Statistics 2004)
- vii. Whether or not the participant lived alone
- viii. Overall score for the Medical Interview Satisfaction Scale (Meakin & Weinman 2002)
- ix. Dyspnea, Fatigue and Emotional Function domains of the CRQ (Guyatt et al 1987).

Variables (v) and (vi) related to socioeconomic status and were included because health behaviours, health status and mortality are all associated with socioeconomic status (Pill et al 1995; Lynch et al 1997; Turrell & Mathers 2000; Turrell & Mathers 2001). Indicators of socioeconomic status which have been used for older adults include occupationally defined social class, income, educational qualifications, years of completed schooling, housing tenure and household resources, and deprivation indicators (Grundy & Holt 2001; Daly et al 2002). Years of formal education and Index of Relative Socio-Economic Disadvantage for postcode (Australian Bureau of Statistics 2004) were used in this study because these are commonly used and easily collected indicators, applicable to people from various educational systems who are no longer in employment. In addition to providing for baseline comparison, these measures make it possible to check associations between socioeconomic status and any positive outcomes. This is important because health interventions should not disproportionately benefit the socioeconomically advantaged, and thereby increase health inequalities (Grundy & Holt 2001).

Variable (vii) was included in baseline comparisons because living alone has been related to health outcomes in the elderly (Mahoney et al 2000), and the involvement of carers in COPD disease management was noted during development of the COPD Evidence Manual. A question about living alone was identified as security-related and potentially threatening to the participant's confidence in the study, if asked when the interviewer was a first-time visitor to the patient's home. This information was therefore collected retrospectively at the final interview and was unavailable for participants who were lost to the study before 12 months.

For variable (viii), two modifications were made to the Medical Interview Satisfaction Scale (Meakin & Weinman 2002). The following item was omitted as inapplicable for a progressive condition like COPD, and likely to cause distress.

After talking with the doctor, I have a good idea of how long it will be before I am well again

Pro-rating was planned to adjust for the missing item in one subscale. For similar reasons, the following item was removed.

The doctor has relieved my worries about my illness

It was replaced with the following.

The doctor has helped me deal with my worries about my illness.

4.3.7 Analysis and imputation

Baseline demographic and clinical comparisons were made using the chi-square test for dichotomous variables, or Fisher's exact test if numbers in any cells were less than 5, and Student's t test for continuous variables. For all outcomes except enrolment in pulmonary rehabilitation, change scores to 3 months were analysed using analysis-of-covariance, with adjustment for baseline score, to remove the effect of regression to the mean. Poisson modelling was used to compare proportions attending pulmonary rehabilitation. The conventional 0.05 probability level for statistical significance was used throughout. Missing interviews were excluded from analysis. Missing data elements (needed only for the Medical Interview Satisfaction Scale which contained 5.1% missing data) were imputed by expectation-minimisation imputation and used SPSS 12 For Windows software. Data were otherwise analysed using Stata 8.2 software.

In the event of any baseline differences which also appeared to be effect modifiers, stratified analyses were planned. If several modifiers were found, the inclusion of propensity scores (D'Agostino 1998) in analysis-of-covariance models was planned.

4.4 ETHICS COMMITTEE APPROVALS

Ethical approval for all components of this evaluation was obtained from the committees of The Queen Elizabeth Hospital and Health Service, the Flinders Medical Centre, the Repatriation General Hospital and the Commonwealth

Department of Veterans Affairs. General practitioner organisations for the areas covered by these hospitals also approved the study.

Chapter 5 PROCESS EVALUATION OF THE COPD

EVIDENCE MANUAL: AIMS AND METHODS

The previous chapter gave methods for a controlled trial to test the effectiveness of the COPD Evidence Manual. This chapter gives methods for two components of a process evaluation which aimed to augment the results of the trial by elucidating how the manual was used in practice.

5.1 INTRODUCTION

The aim of the COPD Evidence Manual was to change doctors' behaviour through prompts from patients who had learned something new about COPD treatments by reading the manual. The manual is therefore an educational and behavioural intervention.

Evaluation of an educational or behavioural intervention requires a trial of outcomes but should also include a process investigation (WHO European Working Group on Health Promotion Evaluation 1998; Cooper et al 2001). Process investigations reveal the mechanisms by which interventions succeed or fail to produce desired outcomes, and provide the basis for improvements which build on successful elements and discard unsuccessful ones (Hulscher et al 2003). The inclusion of qualitative methods in evaluations can reveal processes not previously considered by researchers (Campbell et al 2000; Borkan 2004). Survey and qualitative methods used for a process evaluation of the COPD Evidence Manual are described below.

5.2 SURVEY OF PROCESSES

5.2.1 Background and aims for survey

The hypothesised link between provision of the manual and improved COPD management implies a series of causal steps:

- i. Reading: The patient reads at least some parts of the manual (using tagged sections to access summaries relevant to a situation they are encountering)
- ii. Question-asking: The patient raises a treatment topic with their doctor using the boxed question offered in the manual
- iii. Doctor understanding: The doctor understands this as a request to review treatment in the light of evidence
- iv. Treatment change: The doctor and/or patient decide to change the treatment where relevant

The aim for this survey was to assess how well each step had been achieved in practice, and to identify whether any particular steps were obstacles to the success of the intervention.

5.2.2 Methods for survey

At the 3 month and 12 month trial data collection interviews, participants were asked a series of closed survey questions about their use of the manual or pamphlet that they had received at baseline. Table 5.1 shows how survey questions assessed the execution of steps (i) to (iv).

Table 5.1. Survey questions for behavioural steps

Behavioural step	Survey questions assessing this step
i	Do you remember receiving the information? Did you or your carer read any of the information? - <i>If read:</i> Did you/they read part or all of it? - <i>If read:</i> Did you or your carer learn anything from the information? - <i>If read:</i> How often did you or your carer refer back to any of the information after you had read it for the first time?
ii	- <i>If read:</i> Did you talk about any of the information with your doctor?
iii/iv	- <i>If yes:</i> Did your treatment change at all because of what you talked about?
i	- <i>If read:</i> Overall, how helpful was the information to you or your carer: - very helpful, quite helpful, not helpful

The survey also included questions to ascertain whether the intervention motivated participants to continue to read, by giving helpful explanations about COPD and its treatments, and whether it helped participants to talk to their doctors. Participants were asked:

If read: Overall, how helpful was the information to you or your carer?: very helpful () quite helpful () not helpful ()

If yes: Do any of the following describe why you found the information useful?

- I understand more about my lung condition
- I understand more about my treatments
- I felt more able to ask questions when I visit the doctor

The chi-square test (or Fisher's exact test if numbers were small) was used to analyse process survey data.

5.3 QUALITATIVE STUDY OF PROCESSES

5.3.1 Background and aims for qualitative study

This component of the study aimed to provide explanations for the trial findings by identifying the barriers and facilitating factors to use of the COPD Evidence Manual as intended. Qualitative methods would reveal participants' points of view, and were therefore most suitable (Green & Britten 1998; Patton 2002, pp.159-162; Pope et al 2002). As this qualitative study aimed to complement, rather than challenge, the knowledge base of medical science (Armstrong 2000), the theoretical standpoint was positivist and reality-oriented (Patton 2002, pp.91-96).

The outcomes measured in the controlled trial required completion of all the five steps shown in section 5.2.1. The qualitative study focussed on the first two of these steps: reading the manual (step i) and patient question-asking based on the manual (step ii). These early steps are an essential starting point for the success of this intervention, and pertinent to patient mediated interventions more generally.

5.3.2 Methods for qualitative study

5.3.2.1 Sampling

Intervention participants from the clinical trial were asked if they wished to be available for a further study which involved talking in more detail to interviewers. Fifty-one of the 125 agreed and formed the sampling pool for the qualitative study. Compared to all participants in the intervention group of the clinical trial, those in the sampling pool for this study were younger (average age on joining 64.5 years compared to 73.6 years for all intervention participants). They were also from postcodes of slightly lower socioeconomic status (average Index of Relative Socio-Economic Disadvantage (Australian Bureau of Statistics 2004) of 995.5 compared to

1002.4) and slightly different in gender balance (51.9% were males compared to 55.2%).

Rather than reflect the intervention group or wider population numerically however, the aim for this component was to explore the range of behaviours, barriers and facilitating factors. Maximum variation purposive sampling (Rice & Ezzy 1999, p.44) was therefore applied to this sampling pool, for variation in reading and use of the manual, as indicated by the trial questionnaire at 3 months, and for gender, socioeconomic status, severity of COPD and presence/absence of carer. Participants were selected by listing available participants in random order and tabulating major demographic, social, and disease-related characteristics and survey responses at 3 months. Patients were contacted for interviews in groups of four, using the table to identify a group with varying characteristics and responses. Where a patient was uncontactable or unwell, a person with similar characteristics and responses was selected instead. Sampling was continued until analysis revealed no new information.

5.3.2.2 Data collection and analysis

The data needed were detailed accounts of participants' behaviour, and explanations of the thoughts and feelings that led to that behaviour. Possible methods included observation, patient diaries, interviews and combinations of these (Creswell 2003, pp.185-188). Diary keeping was rejected as incompatible with the priorities and preferences of people in the study. Observation was rejected because of the difficulties of predicting and arranging observations of medical consultations where the manual would be discussed. In-depth interviews were selected as a method acceptable to participants which would provide historical accounts, opinions and explanations of reading and question-asking from the patient's viewpoint (Rice & Ezzy 1999, pp.51-70). Audio-tapes of interviews were transcribed by an external word processing agency, and interviewers recorded brief field notes of background information and unrecorded conversation after each interview.

Photographic vignettes (Mansell et al 2000; Salomon et al 2004) were shown to participants during interviews. Before being asked about reading the manual, participants were shown a photograph of someone of the same gender reading a

manual in a home setting. Before being asked about question-asking based on the manual, participants were shown a photograph of someone of the same gender in a consulting room setting, holding a manual and in discussion with a doctor of the same gender as the participant's general practitioner. When showing these vignettes, interviewers asked participants to try to remember their own thoughts and feelings when they were in the depicted situation. Sample vignettes are shown in Appendix 16.

Interview transcripts and field notes were analysed, using QSR NUD.IST 4 software, concurrently with collection (Rice & Ezzy 1999, pp.190-214) in three phases as outlined below.

PHASE 1

An open interview structure and inductive data analysis were used to reflect participants' points of view about using the manual as part of living with COPD (Rice & Ezzy 1999, pp10-12; Patton 2002, pp343-344). The theme guide for this phase is shown in Appendix 17.

PHASE 2:

The pragmatic 'framework' method (Ritchie & Spencer 1994), which has been extensively used in applied health-related research, was employed to examine in more detail the barriers and facilitating factors to the actions of reading and question-asking. Opening questions in standardised open-ended interviews (Patton 2002, pp344-347) were adapted from behavioural determinants consistently given in theoretical models from behavioural psychology and health promotion (Tones & Tilford 1994, pp83-103; Fishbein et al 2001; Bandura 2004). These questions (shown in the theme list in Appendix 18) explored:

- a) Outcome expectations: perceived outcome to the actions and value placed on those outcomes (perceived advantages and disadvantages)
- b) Social pressures: Social pressures felt by the participant to perform or not perform the actions

- c) Capability: participant perceptions of their own capability to perform the action
- d) External factors: participant perception of environmental factors helping or hindering them from performing the action

Data were analysed using descriptions of the actions and the above factors as the framework (Ritchie & Spencer 1994).

PHASE 3

Analysis from Phase 1 was integrated into the framework used for Phase 2. A summary was sent to 15 participants (one participant having withdrawn due to extreme ill health). Participants were asked if their views were reflected and if any additions should be made. Thirteen replied and a check was made that the one suggested addition was included in the final analysis.

LATER ANALYSES

Participant accounts were later examined for:

- common features of cases where use of the manual was similar to that envisaged in the design of the manual
- doctors' responses when participants raised evidence-related questions at consultations.

5.3.2.2.1 Multiple viewpoints for analytical rigour

To ensure rigour in data collection and analysis, MH obtained input from others for all stages of the qualitative study. DW (a research officer who had not been involved with development of the manual or the quantitative trial) assisted with theme list development, data collection and analysis. AV and BS (supervisors) and BJ (academic experienced in qualitative research) contributed to study planning and theme list development. MH and DW made individual preliminary analyses of a small number of transcripts then jointly agreed on concept definitions, which they then used for all

transcripts. Concepts arising during analysis were defined jointly. Analytical rigour was also appraised in periodic discussions with AV.

5.4 ETHICS COMMITTEE APPROVALS

Ethical approval for all components of this evaluation was obtained from the committees of The Queen Elizabeth Hospital and Health Service, the Flinders Medical Centre, the Repatriation General Hospital and the Commonwealth Department of Veterans Affairs. General practitioner organisations for the areas covered by these hospitals also approved the study.

Chapter 6 TRIAL: RESULTS AND DISCUSSION

Previous chapters gave methods for a trial and process evaluation of the COPD Evidence Manual for patients. This chapter reports and discusses results of the trial which measured the effect of the manual on implementation of evidence, and on patient mastery and knowledge of COPD, communication with doctors, satisfaction with information, and anxiety.

6.1 RESULTS

6.1.1 *Characteristics of participants in relation to sampling frame*

Approximately 1,400 patients were identified as potential candidates for the study, and doctors signed invitations for 711 of these. An unknown number of potential candidates were not assessed by doctors, for example when invitations were overlooked during clinics. Numbers of participants at each stage of the study are shown in Figure 6.1. Of the 249 participants, 124 were recruited from The Queen Elizabeth Hospital, 108 from the Flinders Medical Centre and the remainder from the Repatriation General Hospital.

Doctors sometimes volunteered their reasons for not inviting patients who were identified as potential candidates and these are summarised in Table 6.1.

Four surveys of doctors were carried out during recruitment to collect in a more systematic way their reasons for not inviting patients, but response was low. Of the 18 patients attending the three surveyed clinics at The Queen Elizabeth Hospital clinics with a diagnosis of COPD recorded in case notes, eight were given the invitations which researchers prepared. Three patients did not attend, four did not have moderate to severe COPD, and two had language and comorbidity exclusions. Data was not provided on the other two patients. No response was obtained for the surveyed clinic at Flinders Medical Centre, where research staff were unable to make contact with doctors to brief them and request cooperation.

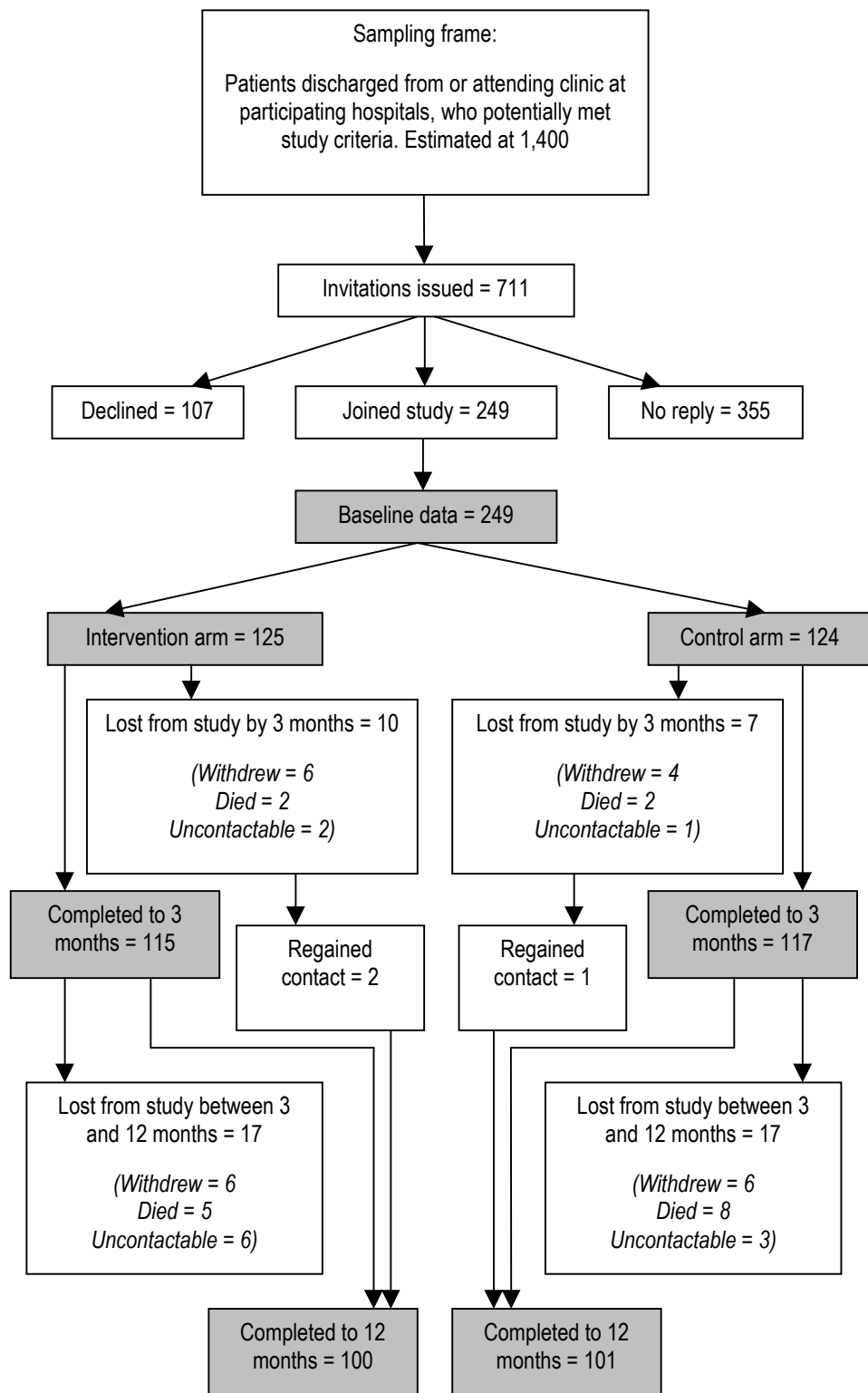


Figure 6.1. Participant flow

Table 6.1. Reasons volunteered by doctors for not inviting patients into study

Reasons volunteered by doctors for not inviting a patient	Frequency*
Not well enough/severe comorbidities/ severe social issues	21
English skills limited	19
COPD is mild	9
Cognition problems/dementia	5
In another trial	5
Vision problems	4
Large component of asthma	4
Diagnosis incomplete	4

**Some patients had multiple exclusions*

PATIENTS WHO REFUSED INVITATIONS

Fifty-five of the patients who declined invitations volunteered reasons for declining, and these are given in Table 6.2. Patients who declined invitations (n=107) were not significantly different in gender breakdown and socioeconomic disadvantage but were older than those who joined the study with mean ages 76.5 and 73.4 years respectively (p=0.02). (See Table 6.3.)

PATIENTS WHO DID NOT REPLY TO INVITATIONS

Patients who did not reply to invitations (n=355) were not significantly different in age, gender breakdown and socioeconomic disadvantage to those who joined the study (n=249). (See Table 6.3.)

Table 6.2. Reasons given by the 55 (of 107) patients who volunteered reasons for refusing invitations

Reason volunteered	Frequency*
Not well enough	24
COPD is not important concern	11
English/reading skills limited	8
Too busy	8
Cognition problems (reported by carers)	7
Feels information would not be helpful	6
Deliberately avoiding information on COPD	3

*Some patients gave multiple reasons so frequencies add up to more than 55

Table 6.3. Demographic comparison of patients who joined the study with patients who did not reply to invitations and patients who refused

	Mean age, years	Percent male	Mean index of socio-economic disadvantage
Patients who joined study	73.4	54	970.76
Patients who did not reply to invitations	72.5	55	965.32
Patients who refused	76.5*	53	971.23

Using data available to researchers at time of invitation

* $p=0.02$ for comparison with patient who joined the study, otherwise all $p>0.05$

PATIENTS WHO WITHDREW FROM STUDY

Ten participants withdrew before 3 months and a further 12 afterwards. Reasons given were feeling very unwell, or serious worsening of vision, hearing or cognition.

6.1.2 Baseline comparisons

For variables found at this stage to be unequally distributed at baseline, tests were made for confounding or effect modification by running analyses of outcome variables using median split of this test variable. Where effects were similar within

high and low levels of the test variable, regardless of intervention or control status, this would indicate confounding. Where effects were different for high and low levels of the test variable and also for intervention or control status, this would indicate effect modification.

Table 6.4 shows baseline demographic and clinical comparisons, using data available at baseline. The groups were similar at baseline for all but one measure. They were significantly different for the Australian Bureau of Statistics Index of Relative Socio-Economic Disadvantage (Australian Bureau of Statistics 2004) and this variable also appeared to be an effect modifier. For this reason, outcome analyses at 3 months are shown below by median split of this variable.

At 12 months, participants were asked for retrospective data on pulmonary rehabilitation enrolment and whether they lived alone. Results are shown in Table 6.5. These measures showed further baseline differences between groups, though, individually, these did not appear to be effect modifiers. Because a number of baseline differences were now demonstrated, a propensity score was created for each participant by including all baseline measures in a logistic regression with the grouping variable as the dependent variable. This score was included in analysis-of-covariance models for outcomes at 12 months to adjust for baseline differences (D'Agostino 1998). Propensity score distributions are shown in Table 6.6.

The need to introduce a stratifying variable was unforeseen and had a detrimental effect on study power. At protocol stage when *a priori* sample size was calculated, intervention and control areas were thought to be broadly similar and a large difference between groups for socio-economic status was not expected. The need to use SES as a stratifying variable at the analysis stage was not therefore foreseen. Original sample size calculations were based on 80% power but stratifying had the effect of lowering power. Using the same assumptions as for original power calculations and using stratified sample numbers at 12 months, power calculations for the group with high socioeconomic disadvantage showed 18% for influenza vaccination, 50% for bone density testing and 33% for pulmonary rehabilitation rates. Power calculations for the group with lowest socioeconomic disadvantage, showed 51% for influenza vaccination, 45% for bone density testing and 37% for

pulmonary rehabilitation rates. Both the reduced number in each stratum compared with the sample size as a whole, and uneven group sizes within strata, contributed to this lowering of power.

Table 6.4. Baseline comparisons between intervention and control groups

Characteristic	Intervention group n=125	Control group n=124	Significance	Test
<u>Demographics:</u>				
i. % Male	55	52	0.66	χ^2
ii. % On oxygen at baseline	34	25	0.12	χ^2
iii. % Smoker at baseline	18	23	0.38	χ^2
iv. Mean age	73.6	73.1	0.64	t
v. Mean years of formal education	10	10	0.18	t
vi. Mean index of socioeconomic disadvantage for postcode	1002.41	938.85	<0.001	t
<u>Additional clinical baseline comparisons:</u>				
viii. Mean MISS score (possible range 1 to 7)	5.0	5.2	0.07	t
ix a. Mean CRQ dyspnea (possible range 1 to 7)	3.2	3.1	0.50	t
ix b. Mean CRQ fatigue (possible range 1 to 7)	3.5	3.6	0.70	t
ix c. Mean CRQ emotional function (possible range 1 to 7)	4.8	4.8	0.83	t
<u>Outcome measures:</u>				
1a. % Current flu vaccination	88	87	0.83	χ^2
1b. % Bone density test in last 3 1/2 yrs	31	32	0.97	χ^2
2. Mean CRQ mastery (possible range 1 to 7)	4.9	5.0	0.91	t
3. Mean knowledge (possible range 0 to 16)	12	11	0.10	t
4a. Mean MISS communication and comfort (possible range 1 to 7)	5.0	5.2	0.19	t
4b. Mean MISS rapport (possible range 1 to 7)	5.3	5.5	0.20	t
5. Mean "Enough information" score (possible range 1 to 7)	4	4	0.72	t
6. Mean state anxiety score (possible range 20 to 80)	32.2	32.1	0.97	t

Table 6.5. Additional baseline comparisons

Characteristic	Intervention group n=125	Control group n=124	Significance	Test
1 c. % Ever attended pulmonary rehabilitation	19	3	<0.001	Fisher's exact
viii. % Living alone	23	45	0.001	χ^2

Table 6.6. Propensity scores for intervention and control arms

	Intervention group n=125	Control group n=124
Mean	0.754	0.236
Standard deviation	0.246	0.252
Range	0.002 – 0.972	0.068 – 0.999

6.1.3 Main Results

6.1.3.1 Outcomes at 3 months

There were two statistically significant findings at 3 months, each applying to one of the two SES strata. In the socioeconomically disadvantaged stratum, intervention participants showed a significant increase in bone density testing when compared with control participants ($p=0.04$). In the socioeconomically advantaged stratum, intervention participants showed improved anxiety levels when compared with control participants ($p=0.001$). There was no significant change attributable to the intervention for other outcome comparisons, though virtually all trends favoured the intervention group. Analyses for all outcomes are shown in Table 6.7.

No adverse effects were reported.

Table 6.7. Outcome change scores at 3 months by socioeconomic disadvantage median split

Group:	Intervention		Control		Significance level for comparison of interventions and control groups*	
	Socioeconomic disadvantage level:		Socioeconomic disadvantage level:		Socioeconomic disadvantage level:	
	Higher n=25	Lower n=90	Higher n=84	Lower n=33	Higher	Lower
1 a. Flu vaccination rate (%)	+4	+2	0	0	0.13	0.44
1 b. Bone density test within 3 yrs, rate (%)	+12	+4	+1	0	0.04	0.36
2. CRQ mastery (mean)	+0.2	0	+0.1	-0.2	0.94	0.47
3. Knowledge (mean)	0	+1	0	+1	0.14	0.08
4. Enough information (mean)	+1	+1	0	+1	0.36	0.69
5. MISS rapport (mean)	0	0	-0.2	-0.1	0.52	0.44
6. MISS Communication & comfort (mean)	-0.2	0	-0.1	-0.2	0.77	0.53
7. Anxiety (mean)	+1.8	-2.2	+2.9	+5.9	0.86	0.001

*Using Analysis-of-covariance on change score, adjusted for baseline

6.1.3.2 Outcomes at 12 months

At 12 months outcome measures showed a statistically significant difference between intervention and control groups for enrolments in pulmonary rehabilitation for the most socioeconomically disadvantaged stratum. There was a non-significant trend in the same direction for pulmonary rehabilitation in the most socioeconomically advantaged stratum. There were no other significant differences and few trends in favour of either group. Outcomes at 12 months are shown in Table 6.8.

Table 6.8. Outcome change scores at 12 months by socioeconomic disadvantage median split

Group:	Intervention		Control		Significance level for comparison of interventions and control groups*	
	Socioeconomic disadvantage level:		Socioeconomic disadvantage level:		Socioeconomic disadvantage level:	
	Higher n=22	Lower n=78	Higher n=72	Lower n=29	Higher	Lower
1 a. Flu vaccination rate (%)	+7	+7	-1	+5	0.83	0.98
1 b. Bone density test within 3 yrs, rate (%)	+6	+16	+7	+17	0.62	0.39
1 c. Pulmonary rehabilitation rate (%)	+18	+12	0	+7	0.05	0.29
8. CRQ mastery (mean)	-0.1	0	0	0	0.70	0.50
9. Knowledge (mean)	0	+1	+1	+2	0.82	0.75
10. Enough information (mean)	+1	+1	+1	+1	0.64	0.92
11. MISS rapport (mean)	-0.1	-0.1	-0.5	-0.1	0.72	0.26
12. MISS Communication & comfort (mean)	-0.2	0	-0.4	0	0.45	0.71
13. Anxiety (mean)	+2.0	+2.2	+2.0	+2.6	0.96	0.93

*Using Analysis-of-covariance on change score, controlled for baseline measure and propensity score, except for pulmonary rehabilitation rate (1c) which was analysed using Poisson modelling with robust errors, adjusted for baseline rate.

6.1.4 Post hoc analyses

6.1.4.1 Inclusion of propensity score adjustment in analyses of outcomes at 3 months

A new analysis of outcomes at 3 months was performed with the inclusion of propensity scores (restricting analysis to participants who continued to 12 months and therefore had full baseline data available for calculation of propensity). This analysis showed no new significant results. The anxiety benefit for less disadvantaged intervention participants was statistically significant ($p=0.03$), as it had been in the

original analysis. The bone density testing benefit for more disadvantaged intervention participants was not statistically significant in this analysis ($p=0.08$), though it had been in the original analysis.

6.1.4.2 Comparison of hospital admissions for intervention and control groups

Reduced hospital admissions was not an aim of this study. More intensive interventions than the COPD Evidence Manual have failed to reduce admissions for COPD (Smith et al 2002; Monninkhof et al 2003). Furthermore, admissions can be a feature of good disease management (for example when a short early hospital stay reduces the severity of an exacerbation) as well as poor disease management (for example when an exacerbation results from delayed treatment of infection). However, because most studies in COPD include the number of COPD-related hospital admissions as an outcome measure, a decision was made to report admissions for this study also.

With approval from ethics committees of all participating hospitals, participants were asked whether they would permit access to admissions data for both the 12 months that they were part of the study, and the 12 months before they joined the study. One hundred and seventy five participants provided signed approval. Data departments of participating hospitals provided COPD related admissions for each participant for the two 12 month periods. This method provided admissions to the participant's usual hospital but not admissions to other hospitals, raising the possibility of bias if the proportion of admissions to other hospitals varied by region.

Table 6.9 shows change in admissions during the 12 months participants were in the study, compared with the previous 12 months, for intervention and control participants, stratified by socioeconomic disadvantage. Results indicate that the intervention was associated with neither greater nor lesser hospitalisation.

Table 6.9. Admissions to hospital for COPD-related problems: change in admissions for 12 months in study compared to 12 months before study, by socioeconomic disadvantage median split

Group:	Intervention		Control		Significance level for comparison of intervention and control groups*	
	Disadvantage level:		Disadvantage level:		Disadvantage level:	
	Higher	Lower	Higher	Lower	Higher	Lower
Hospital admissions change (mean)	- 0.4	- 0.4	- 0.5	- 0.2	0.28	0.99

**Using Analysis-of-covariance on change score, controlled for baseline measure and propensity score*

6.2 DISCUSSION

In the following sections, findings are summarised for each hypothesis and discussed in relation to other studies. Limitations of the trial and remaining questions are then discussed.

6.2.1 Summary of findings and comparisons with other studies for Hypotheses 1 to 6

6.2.1.1 Hypothesis 1

Hypothesis 1 was that, compared with patients who have been given a conventional pamphlet, disease management in patients who have been given the COPD Evidence Manual will more closely correspond with research evidence. Findings were different for the three components of the measure of best practice management, as described below. However after adjustment for baseline differences, the study was under-powered to show differences between groups for component of the primary hypothesis.

1a) Increased rate of influenza vaccination within the previous 15 months, by patient self report, from 80% to 95%

There was a rise in the number of patients who received influenza vaccination in the intervention group, but because the initial prevalence of vaccination was higher than anticipated and because vaccination also increased in the control group, there was no statistically significant difference between groups at 3 or 12 months.

Other studies have increased influenza vaccination rates using educational reminders (Armstrong et al 1999). These studies used interventions which were different to the COPD Evidence Manual, in that they focussed on influenza vaccination only, and initial vaccination rates were low in study populations (Moran et al 1996; Clayton et al 1999).

1b) Increased rate of bone density testing within the previous 42 months, by patient self-report, from 10% to 30%.

Bone density testing was greater in the intervention group at 3 months, showing statistical significance only among those with greatest socioeconomic disadvantage (though this was not seen when propensity score was included in the model, suggesting that factors other than the intervention were influential). By 12 months, rates were higher throughout, with no differences between groups. Again, initial rates were much higher than expected at baseline.

1c) Increased enrolment in pulmonary rehabilitation, by patient self report, from 25% to 45%.

New pulmonary rehabilitation enrolments were greater at 12 months among intervention participants compared to controls for the stratum with greatest socioeconomic disadvantage. This difference should be interpreted with some caution because the controlled before-and-after design does leave open the possibility that some other change operating only in the intervention region caused the increase (Eccles et al 2003).

Overall, by 12 months Hypothesis 1 was not supported with respect to two of the indicator components, but was supported for the third component for the

socioeconomically disadvantaged stratum only. This contrasts with findings that reminders (Grimshaw et al 2004) and decision aids (Evans et al 2005; O'Connor et al 2004) can influence medical practice. However, patient-mediated reminders focus on one (preventive) treatment only and decision aids summarise evidence for major and immediate one-off decisions. Differences between the purpose or design of these interventions and the COPD Evidence Manual, or between the study populations, may be the cause of these differences in results. Unfortunately, key differences cannot be identified because of multiple differences between studies (Grimshaw et al 2004) and because intervention design is usually poorly explained (O'Connor et al 2003; Grimshaw et al 2004). It should also be highlighted that the introduction of stratification and propensity score adjustment effectively reduced the power of the trial of the COPD Evidence Manual to detect the hypothesised changes.

6.2.1.2 Hypothesis 2

Hypothesis 2 was that the manual would improve mastery of COPD. At 3 months there was a non-significant trend favouring the intervention group for mastery of COPD, with mean improvement less than the 0.5 units which correspond to clinically significant change. By 12 months this trend had disappeared with no benefit evident for intervention group. Again, lack of power may have meant that differences which did exist were not demonstrated.

Though quality of life domains like mastery are important outcomes, positive results in COPD have been obtained only with more intensive face to face education (Hermiz et al 2002; Hui & Hewitt 2003). Similarly, studies of PIMs for other chronic conditions have failed to produce the expected quality of life improvements (Maggs et al 1996; Barlow & Wright 1998; Kennedy et al 2003a; Jorm et al 2003; Schaffer & Tian 2004).

6.2.1.3 Hypothesis 3

Hypothesis 3 was that the manual would improve knowledge about COPD. Knowledge scores had not improved in intervention or control groups by 3 months,

and at 12 months, there was some non-significant trend of improved knowledge among control participants.

The COPD Evidence Manual contained much detail about treatments as well as brief background information about COPD. Particular points of background information relevant to the knowledge test may not have been noted. Alternatively, patients may have read and noted the information provided without changing their own personal understandings. For example, interviewers noted that when responding to knowledge test questions about the advisability of stopping smoking, many participants commented that though others said smoking was very damaging, they themselves felt that it was not. Similarly in answer to another question, many participants said that exacerbations were not associated with increased phlegm, commenting that this knowledge was based on their own experience and that they had little interest in symptoms of patients more generally.

Studies of printed materials in other diseases have shown variable results for knowledge. Short leaflets about rheumatoid arthritis (Maggs et al 1996; Barlow & Wright 1998), a guidebook about ulcerative colitis (Kennedy et al 2003a) and a booklet (Little et al 2001) and leaflet (Roberts et al 2002) about back pain have increased patient knowledge test scores. On the other hand, patient/carer information packs about stroke (Mant et al 1998) and an educational “passport” about diabetes (Simmons et al 2004) did not. Target groups for these studies vary greatly and interventions are poorly described, so it is not possible to draw inferences about the characteristics associated with knowledge increase (Harris et al 2005).

6.2.1.4 Hypothesis 4

Hypothesis 4 was that the manual would improve patient communication with usual doctor. At 3 months there were some non-significant trends favouring intervention participants for measures of communication with their usual doctor but at 12 months no effect was evident, though lack of power must again be taken into account. It may be that participants did not take up the prompts in the COPD Evidence Manual to raise questions with their doctor, or that raising questions had both positive and negative effects on patient/doctor communication. Alternatively, there may have

been a change which was not detected by the MISS. The MISS did appear to have shortcomings. The lack of validation of the MISS was noted in Chapter 4, and missing data supported anecdotal interviewer reports that participants had difficulty in understanding items in this instrument.

6.2.1.5 Hypothesis 5

Hypothesis 5 was that the manual would increase satisfaction with COPD-related information. Although at 3 months there was a non-significant trend towards feeling more satisfied with the amount of available disease related information among intervention participants in the most socioeconomically disadvantaged stratum, by 12 months no effect was apparent. A possible explanation is that information provided in the COPD Evidence Manual (additional to that provided in the control pamphlet) did help some participants in the short term but then led them to want further information. Alternatively it may be that the additional information in the COPD Evidence Manual was not the information that was wanted by participants.

6.2.1.6 Hypothesis 6

Hypothesis 6 was that the manual would not be associated with increased anxiety. At the 3-month interview, intervention participants showed less anxiety than control participants for the more socioeconomically advantaged stratum and this difference was at statistical but not clinically significant levels. At 12 months, there was a slight increase in anxiety (not clinically significant) for both intervention and control groups but no effect associated with the intervention. The hypothesis that giving comprehensive evidence information to patients would not increase their anxiety was supported, but as the study was not well powered to detect anxiety differences between groups.

6.2.1.7 Hospital admissions

Post hoc analysis showed no effect on hospital admissions for the COPD Evidence Manual.

6.2.1.8 All comparisons

In summary, at 3 months the intervention was associated with a statistically significant increase in bone density testing for the most socioeconomically disadvantaged stratum of participants but other comparisons showed no differences. There was lower anxiety at 3 months among intervention participants for the least socioeconomically disadvantaged stratum, and, as hypothesised, no increase in anxiety associated with the intervention. At 12 months the intervention was associated with a statistically significant increase in pulmonary rehabilitation enrolments for the most socioeconomically disadvantaged stratum. Other comparisons showed no difference between intervention and control participants. The hypothesised lack of increase in anxiety was supported. No effect on hospital admissions was found. However, the lack of power resulting from adjustment for baseline differences meant that there may have been differences between groups which were not demonstrated by this study.

6.2.2 *Limitations of the trial*

Some trial design limitations may have compromised the generalisability of findings to the wider COPD population and missed positive effects.

The sampling frame excluded some people with COPD, for example those with dementia or from non-English speaking background who did not read English, limiting generalisability. Many reasons given by doctors for excluding patients are likely to occur frequently in the COPD population more generally. These reasons include burdensome comorbidities and social issues, and culturally or cognitively based difficulties with reading English. Even among those regarded by their doctor as suitable to invite, the acceptance rate was only 35%. Demographically, those who declined were similar to those included, except that they were some three years older on average. Most patients did not provide reasons for declining to participate, but feeling too unwell was the most common reason among those who did give reasons. The exclusion of people who could not read English was recognised in advance, but study participants were also likely to be less physically and cognitively compromised than the general population of people with moderate to severe COPD. It is also

likely that those with strongest interest in their health participated. Similar interventions, even if they were successful, may be applicable to only a proportion of people with moderate to severe COPD.

Many outcomes failed to show significant change but design limitations may have meant that effects were missed. These include the choice of primary measure, lack of power and possible contamination of the control group.

The indicator of best practice management was made up of three readily measurable treatments recommended for most people with COPD. However, other, unmeasured, treatment changes may have been prompted by the manual.

Components of the best practice indicator proved to be unexpectedly high at baseline, providing little room for improvement and weakening the power of the study. Though expected baseline rates were based on published data, this group of patients discharged from public teaching hospitals may have been receiving care that was more evidence based than is care received by people with COPD more generally. People with COPD who had never been admitted to hospital may have shown poorer care at baseline and greater benefit from the manual.

The quasi-experimental trial design, used to reduce contamination, is not as strong as a randomised design (Eccles et al 2003). A small number of baseline differences were found, and measures had to be introduced during analysis in an attempt to adjust for any bias caused by these differences, with consequent loss of power. While the groups were similar at baseline for many variables, the intervention group proved to have significantly lower socioeconomic disadvantage, a higher baseline rate of pulmonary rehabilitation and a lower proportion of people living alone. It was possible that these factors would be associated with greater receptivity to educational interventions. Because any outcomes might be attributable to baseline differences and not to the intervention, propensity score adjustment (D'Agostino 1998; Pasta 2000; Lunceford & Davidian 2004) and stratification (Normand et al 2005) were used in analysis. While propensity scores adjusted for measured baseline differences between groups they could not deal with any unmeasured variables as effectively as would randomisation (Altman & Bland 1999). When propensity scores

differ between groups, as in this trial, statistical significance of treatment effects is weakened (Pasta 2000). One of the baseline differences in this trial, socioeconomic disadvantage, appeared to be an effect modifier and analyses were therefore also stratified by this variable. Stratification has the disadvantage of not totally removing the effect of the difference between groups. Stratification also effectively reduced the available sample sizes (Normand et al 2005). Overall, statistical techniques required to deal with the effects of unexpected group differences at baseline did not completely remove the possibility of systematic differences between groups and, by weakening power, made the originally calculated sample size inadequate.

The possibility remains that some contamination contributed to negative results through sharing of information from the manual from patient to patient or *via* doctors. In addition, doctors of intervention patients might have treated subsequent patients differently because of the influence of the manual. If these subsequent patients were then recruited to the study, their baseline measures may have been affected. Alternatively, if these subsequent patients were already in the study, their treatment may have been affected even if these patients did not themselves raise issues from the manual. These effects would have operated in different directions: the first to reduce apparent effectiveness and the second to increase it. In practice, 125 intervention patients named 103 different general practitioners as their usual doctor therefore this type contamination would probably be quite limited. Any contamination via the doctor was more likely to be related to GP visits than hospital visits, due to the relative frequency of visits to the GP (Britt et al 2005).

A randomised design might have been feasible. Options were patient level randomisation with sample size increase to allow for control group contamination, or cluster randomisation by GP practice with sample size increase to allow for intracluster correlation (Slymen & Hovell 1997; Moerbeek 2005). Investigation of expected levels of control group contamination, both directly from participant to participant and via the GP, would have shown whether cluster or patient level randomisation was preferable and would have enabled calculation of a sample size taking clustering and contamination into account (Slymen & Hovell 1997; Moerbeek 2005). Sample size increases would, however, have increased costs.

The control pamphlet could have weakened the apparent effectiveness of the manual. This pamphlet contained some advice on dealing with exacerbations, stopping smoking, influenza vaccination, pulmonary rehabilitation, and home oxygen, and may have influenced treatments used by some control participants. It was expected that the content of this pamphlet would be familiar to most participants at baseline because it is displayed and freely available in outpatient clinic and specialist ward areas of hospitals from which participants were recruited. When control patients at the first few interviews remarked that they had not seen this pamphlet, interviewers began to record this information. Of 100 control participants who were asked, 83 reported that they had not seen this pamphlet before. The control condition did not therefore reflect usual practice.

Data collection questions (for example about influenza vaccination and bone density testing) may have influenced behaviour. When asked about this possibility, interviewers commented that participants did not appear to note or remember particular questions among the many in the questionnaire. Any influence of questions would apply to both groups, though it could be argued that intervention participants had greater access to information to follow up on any interest created.

Non-blinded interviewers could have influenced the results in spite of standardising of methods. Greater blinding of interviewers could have been attempted by such measures as wrapping intervention and control materials, but, in practice, participant comments during interviews revealed their intervention or control status and the geographic pattern of allocation would have soon become apparent to interviewers visiting participants' homes.

The duration of the trial may have been insufficient to demonstrate change because only a few of the evidence summaries would be relevant to any one participant over a 12 month period. For example, until a patient was experiencing an exacerbation, they might not consult the part of the manual which covered treatments for exacerbations. In addition, the effects of improved treatments, for example, reduced exacerbations from influenza vaccination, may have been seen after the study finished.

6.2.3 Conclusion

This chapter showed that the COPD evidence Manual did not produce the hypothesised practice change or other benefits, though reported interventions with some similarities have sometimes been successful. Possible reasons for these differences and their implications for the design future interventions will be discussed in the last chapter. Knowledge of the processes by which patient mediated interventions produce, or fail to produce, the desired outcomes can also indicate reasons for success or failure and contribute to the design of future interventions. The next chapter will give results for the process evaluations which accompanied the trial of the COPD Evidence Manual.

Chapter 7 PROCESS EVALUATION: FINDINGS AND DISCUSSION

The previous chapter reported outcomes of the trial of the COPD Evidence Manual for patients. This chapter reports and discusses findings from the process evaluation which accompanied the trial. The two components of this process evaluation were a survey of behavioural processes, and a qualitative study to elucidate any factors which blocked or assisted participants from using the manual as intended.

7.1 SURVEY OF PROCESSES

7.1.1 Results

Tables 7.1 and 7.2 compare survey responses at 3 and 12 months for intervention and control groups. At both time intervals, the material given was remembered, read, learned from, referred back to and found helpful by a larger proportion of intervention than control participants. Even with stratification, involving loss of power, differences between intervention and control groups were statistically significant for many comparisons. At 3 months, differences between intervention and control groups reached statistical significance in participants with greatest socio-economic disadvantage for remembering, learning referring, and finding the material helpful. In participants with least socioeconomic disadvantage, differences reached significance for remembering, reading part or all, and finding the material helpful. By 12 months, differences reached statistical significance in the participants with greatest socio-economic disadvantage for all comparisons except treatment change. In participants with least socioeconomic disadvantage, differences reached significance for remembering, reading and finding the material helpful.

Table 7.1. Process survey results – 3 months

Group:	Intervention		Control		Significance level for comparison of interventions and control groups*	
	Number (Percentage)		Number (Percentage)		Socioeconomic disadvantage level:	
Measure:	Socioeconomic disadvantage level:		Socioeconomic disadvantage level:		Socioeconomic disadvantage level:	
	Higher	Lower	Higher	Lower	Higher	Lower
Remember receiving	24 (96)	88 (98)	64 (76)	25 (76)	0.03*	<0.001*
Read part or all	23 (92)	83 (92)	62 (74)	23 (70)	0.05*	0.001*
Read all	16 (64)	54 (60)	44 (52)	15 (45)	0.31*	0.15*
Learned something	15 (60)	47 (52)	22 (26)	13 (39)	0.002*	0.21*
Referred back	11 (44)	53 (59)	17 (20)	14 (42)	0.02*	0.10*
Very or quite helpful	20 (80)	73 (81)	45 (54)	15 (45)	0.02*	<0.001*
Talked to doctor	12 (48)	29 (32)	16 (19)	6 (18)	0.004*	0.13*
Treatment changed	3 (12)	3 (3)	2 (2)	0 (0)	0.08§	0.56§

* Chi square or § Fisher's exact test

Table 7.2. Process survey results – 12 months

Group:	Intervention		Control		Significance level for comparison of interventions and control groups*	
	Number (Percentage)		Number (Percentage)		Socioeconomic disadvantage level:	
Measure:	Socioeconomic disadvantage level:		Socioeconomic disadvantage level:		Socioeconomic disadvantage level:	
	Higher	Lower	Higher	Lower	Higher	Lower
Remember receiving	22(100)	71(91)	53(74)	22(76)	0.005§	0.04*
Read part or all	20(91)	71(91)	46(64)	21(72)	0.02§	0.01*
Read all	18(82)	51(65)	38(53)	16(55)	0.02§	0.33*
Learned something	15(68)	42(54)	27(37)	11(38)	0.01*	0.14*
Referred back	13(59)	38(49)	14(19)	12(41)	<0.001*	0.50*
Very or quite helpful	19(86)	62(79)	34(47)	16(55)	0.001§	0.01*
Talked to doctor	8(36)	34(44)	11(15)	7(24)	0.03*	0.07*
Treatment changed	2(9)	8(10)	2(3)	2(7)	0.23§	0.72§

* Chi square or § Fisher's exact test

Table 7.3 shows survey results for the intervention group as a whole at 3 and 12 months indicating little or no increase in conversations with doctors, or in treatment change, over the 9 month period.

There were quite high levels of failure at some of the causal steps between receipt of the manual by the patient and treatment change (shown in section 5.2.1). Although at 12 months over 90% of participants who received the manual reported reading at least some of it, less than a half (46%) of those who read the manual reported talking to their doctor about a topic from the manual and less than a quarter (24%) of those who talked to their doctor, reported that this led to treatment changes.

Table 7.3. Process survey results for all intervention participants 3 and 12months

Measure	3 months	12 months
	Number (Percentage)	Number (Percentage)
	N=115	N=100
Remember receiving	112 (97)	93(93)
Read part or all	106 (92)	91(91)
Read all	70 (61)	69(69)
Learned something	62 (54)	57(57)
Referred back	64 (56)	51(51)
Very or quite helpful	93 (81)	81(81)
Talked to doctor	41 (36)	42(42)
Treatment changed	6 (5)	10(10)

Table 7.4 reports responses of intervention participants at 3 and 12 months to the survey questions on reasons for finding the manual helpful. Fewer than half of manual recipients agreed that the manual helped them to talk to their doctor.

Table 7.4. Responses for reasons for finding the manual helpful, 3 and 12 months*

Reason	I understand more about my lung condition Number (Percentage)	I understand more about my treatments Number (Percentage)	I felt more able to ask questions when I visit the doctor Number (Percentage)
3 months n=115	69 (60)	61 (53)	54 (47)
12 months n=100	59 (59)	55 (55)	41 (41)

Some participants agreed for more than one reason

SEARCH FOR COMMON FEATURES OF PARTICIPANTS WHO REPORTED TALKING TO THEIR DOCTOR OR TREATMENT CHANGE

Post-hoc, demographic variables were assessed for relationship with talking to a doctor about a topic from the manual and with treatment change. Those reporting treatment change were in the lower three age quintiles (76 years and younger) ($p=0.04$). No other relationships were found.

7.1.2 Discussion

7.1.2.1 Summary of findings

According to participant reports, the COPD Evidence Manual was read more than a conventional pamphlet and was seen as providing more new information.

Survey findings indicated that the manual was read more than the control pamphlet, demonstrating that the length of the manual was not a deterrent.

While almost all recipients reported reading the manual, a much smaller proportion reported asking questions at consultations with a doctor, and it appears that this rarely resulted in treatment change.

7.1.2.2 Limitations

Some of the limitations of the trial are applicable also to the survey of processes. Many patients were excluded from the trial because of burden of COPD and

comorbidities, and people who's COPD was managed solely through primary care were not included in the sampling frame. Survey responses given by this group may therefore not be typical of people with moderate to severe COPD more generally. As for the trial, stratification may not have completely removed bias in survey results which may have been due to socioeconomic differences rather than the intervention. Finally, though interview procedures were standardised, the possibility of interviewer bias cannot be completely discounted.

As well as being evidence based, the COPD Evidence Manual differed from the control pamphlet in other ways. For example, the manual was much longer and was developed using best practice methods. In addition to behaviours prompted by receiving evidence summaries, these other features of the manual may also have influenced participants' behaviours.

Some other limitations apply particularly to the survey. Recall bias may have been a problem with some questions. For example, participants may have forgotten that they had referred back to the information they were given, or talked to their doctor about a topic from the information. Social desirability bias may have influenced participants' answers about reading or learning from the information that they had been given, or its helpfulness. These limitations would apply to both groups, however.

7.1.2.3 Comparison with results from other studies

There do not appear to be other studies comparing patient use of evidence based information with use of conventional patient information. In a large Canadian study, most participants reported that evidence based leaflets on sore throat, 'heartburn' and osteoporosis were easy to understand and helpful in decision-making (McCormack et al 2003). However the study could not demonstrate a preference for information that was evidence based because there was no comparison with conventional leaflets, and patients find any kind of disease related information better than none at all (Coulter et al 1999).

Process surveys are occasionally reported for other trials of PIMs and these show results similar to those for the COPD Evidence Manual. A one-year controlled study of an information booklet people with hypertension reported both outcome and survey results (Watkins et al 1987). The booklet led to improved knowledge but not decreased blood pressure. It was remembered by 86% of recipients. It had been read only once by 48% of recipients and was referred to more often by 20%. The booklet contained pages for patient or doctor to record blood pressure readings, but only 25% had any entries (Watkins et al 1987). In another study, which demonstrated that a leaflet on rheumatoid arthritis increased patient knowledge, all intervention participants reported reading the leaflet and most reported reading it twice (Barlow 1997). However, the study did not measure any patient actions beyond reading and therefore few comparisons can be made with the trial of the COPD Evidence Manual. Another process study was conducted as part of the trial of a guidebook which had been designed to promote sharing of disease management in ulcerative colitis (Kennedy 2002). The guidebook contained sections devoted to disease related information, and a section where test results could be entered at a consultation. The guidebook was liked better than other PIMs by 88% of respondents. On the other hand, while 84% of patients wanted test results recorded, only 20% of intervention patients took guidebooks to consultations and only three of 67 intervention patients had any test results entered (Kennedy 2002). These process evaluations support the suggestion from the evaluation of the COPD Evidence Manual, that it may be easier to design an intervention which will be read by most recipients than to design one which will cause readers to take a recommended action.

7.1.2.4 Interpretation

Though high rates of reading were reported for the COPD Evidence Manual, this reading may have been fairly superficial in many cases. Only about half of intervention participants reported learning from the manual even though it contained research findings on a large range of possible treatments; information which is unlikely to have been available to patients from any other source. Also, higher rates of referring back would be expected if reading had been in-depth. Superficial reading implies low interest in the content of the manual. These findings are at odds with

predictions by patients involved in the development of the manual that summaries of research relating to COPD would be of interest to other patients.

Rates of talking to a doctor about a topic from the manual were rather low. This again contrasts with consistent statements from patient groups involved in the development of the manual that they often discussed new information about treatments with their doctors. Though questions for doctors were suggested in the manual, participants did not find that the manual helped them to talk to their doctor.

When participants did talk to their doctor about a topic from the manual, treatment change rarely resulted from this conversation. Several explanations are possible. The patient may have spoken about a topic without wanting or suggesting a treatment change, or the doctor may not have recognised the patient's spoken words as a request for a treatment change. Even if a participant clearly requested a treatment change, the doctor may not have accessed the evidence, or may have disagreed with the recommendation of the evidence review. Alternatively, the patient's current treatment may have already been consistent with available evidence.

7.2 QUALITATIVE STUDY OF BARRIERS AND FACILITATING FACTORS

7.2.1 Findings

7.2.1.1 Sample Characteristics

Eight participants sampled as described in section 5.3.2.1 were interviewed for phase 1 and a further eight for phase 2. Of the total 16 participants, eight were male and eight female, ages ranged from 45 to 90 years, four reported that they currently smoked and three used oxygen therapy. Participant postcode ratings on the Index of Relative Socio-Economic Disadvantage (Australian Bureau of Statistics 2004) ranged from second highest to second lowest of five index divisions. Duration of formal education ranged from 7 to 13 years.

7.2.1.2 Behaviours, barriers and facilitating factors

Participants' descriptions of reading the manual and question-asking from the manual are given below. Barriers and facilitating factors are then reported for: outcome expectations, social pressures, capability, and external factors. Finally, findings are reported for:

- common features of cases where use of the manual was similar to that envisaged in the design of the manual
- doctors' responses when participants raised evidence-related questions at consultations

Sections of interview transcripts are used below to illustrate findings, with alphanumeric participant codes and transcript line number ranges given in brackets. Where speech of both participant and interviewer is given, contributions are denoted by the use of 'P' and 'I' respectively. A complete sample transcript is shown in Appendix 19.

DESCRIPTIONS OF READING

Participants had read the book with varying levels of interest.

... I didn't put it down until I'd finished. (M5: 618)

When I first got it I used it a great deal but I was in a lot of strife at that stage and I used it very much as a referral. I have a bit of a glance at it now and again but I just about know the salient points by heart. (D2: 3-5)

Yeah, I went through it and then I have gone back and thought what was that about and gone back and read a bit more. (M1: 320-322)

I. ... So did you read this booklet [manual] when you were first interviewed?

P. Well I did but it was ages ago. (D6: 67-73)

I've read through it yes. (D3: 42)

No, I read it once, it is a bit boring. (M2: 170)

I. So you read through this booklet [manual]. Did you find anything in it to be of use?

P. I can't remember now it's been such a long time. I was thinking about it today and I thought I don't know what I did with that book. (D4: 32-36)

DESCRIPTIONS OF QUESTION-ASKING

No participant said that they asked, or wanted to ask, the particular questions offered in the COPD Evidence Manual.

It [manual] tells you what to ask your doctor, but me being me, I don't do things. (M7: 131-132)

No, it [manual] does things to - questions you can ask. Which I never ask questions because I just don't know what to ask. (D1: 197-198)

No, I didn't think I needed to talk to him [the doctor] about them all [the questions from the manual]. (M1: 671)

No, I don't suppose. They [the questions I asked] may have been in there, but I just ask him, just ordinary, just how I feel. (M6 213-214)

Some participants raised issues covered in the COPD Evidence Manual using questions that they formulated themselves, but accounts did not include any reference to evidence.

*I. Did you yourself ask any of those [questions] in the little boxes?
P. Not really. There was one about a drug that was in there that I think I asked the specialist about.*

I. Which one was that?

P. I can't remember. In there [manual]. I asked the specialist about it. I couldn't have it for some reason. It obviously didn't go with something I had, or he didn't want to change my medication. (M5: 326-336)

Oh he just discussed with me what he thought. ... He said, well, Ventolin. And after a while we discussed it again and he said we will try this. That is all the discussion we have had. (M8: 168-173)

BARRIERS AND FACILITATING FACTORS TO READING AND QUESTION-ASKING

Barriers and facilitating factors identified from participant accounts are shown in Table 7.5 for reading the manual and Table 7.6 for question-asking at a consultation. For each behaviour, barriers and facilitating factors are grouped according to whether they relate most closely to outcome expectations, social pressures, capability or external factors.

Table 7.5. Barriers and facilitating factors for reading the manual

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
Outcome expectations as barriers	<p>Information in general not seen as providing advantages</p> <p>Some absent outcome expectations were linked to participants' feelings that their current level of knowledge was sufficient for their purposes.</p>	<p><i>I. And you found some useful information in [manual]?</i> <i>P. No. No only because I suppose I'm inclined to ask questions and I know what's going on. I've got a doctor who explains everything and he always explains things at the hospital so in that sense no. (D3: 44-47)</i></p> <p><i>... I don't take notice, I can be a funny person I suppose, but I sort of take my life as it rolls along. (M6: 70-71)</i></p> <p><i>The book just covers the medical side of it, the physical changes happening to your body and the medical things you can do for it but it doesn't explain to you how to cope with the day to day living, as a person.(M4: 617-620)</i></p>
	<p>Particular information in manual not seen as providing beneficial outcomes, or information wanted by participant was not provided in manual</p>	<p><i>The book just covers the medical side of it, the physical changes happening to your body and the medical things you can do for it but it doesn't explain to you how to cope with the day to day living, as a person.(M4: 617-620)</i></p> <p><i>I don't see any point in it. It doesn't, well, I suppose it doesn't answer the questions that I've asked about this business. (D3: 212-215)</i></p>
	<p>Possible negative outcome that information may cause worry</p> <p>Thought the manual was commonly seen as not confronting, some participants who were coping by avoiding particular kinds of information about COPD experienced some worry when reading parts of the manual.</p>	<p><i>I. ... what was going through your head while you were [reading the manual]?</i> <i>P. Well I was a little bit worried actually, because when you read about something that you've got well it is only natural that, you know, is that me? (M3: 265-268)</i></p>

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
Outcome expectations as facilitating factors	<p>Information advantageous in itself</p> <p>Information was valued by some if specific to participants current concerns, or in general, especially for participants who self-identified as information seekers.</p>	<p><i>...at certain points it jumps out at you and you think oh my God I was wondering about that... (D5: 269)</i></p> <p><i>... I mean you can pick it, you know if there's something not right. I mean I could go and pick the book up and probably find it in there because it is related to the chest. (M5: 123 -125)</i></p> <p><i>I think the booklet, for someone who wasn't informed, it was very good. (D8: 31-32)</i></p> <p><i>Yes, yes, we [participant and wife] are big readers and right oh if I'm in the library and some funny little thing has come up I will look it up in their books. Mind you I've got fair references myself but by the same token I will go and look these things up and read about them. I feel that information is what you need all the time, it really is. (D2: 201-206)</i></p> <p><i>... if I get something like that and I've got diabetes, I usually go and research into it myself anyway and then find out what my body needs and what I should do and all that. But you know there are things in there [manual] too that were a bit different that helped. (D7: 63-67)</i></p>
	<p>Information as potentially helpful for self management of COPD</p> <p>Positive outcome expectations were occasionally expressed towards information which might help in self-management of COPD but these positive outcome expectations were not clearly linked to the experimental manual.</p>	<p><i>Oh its good to find out like if you've got anything and what you do about it and you know if you need to sort of – like I go to the respiratory doctor regularly at the hospital ... but this is what I mean you know – reading – that it sort of tells me that you've got to look after yourself. (D7: 71)</i></p>
	<p>Information in manual did not cause distress.</p> <p>Many participatns were not worried by the content of the manual.</p>	<p><i>I don't see any disadvantages at all. If someone is someone who wants to ignore the information available to them about their illness then that is their business, but personally myself I think you need to have more information available, I think people should know what they are dealing with. (D8 81-84)</i></p>

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
Social norms as barriers	<p>Not reading because reading can encourage hypochondria</p> <p>Reading some kinds of medical information was thought to encourage lay self-diagnosis. However, it appears that this outcome expectation did not apply to the experimental manual.</p>	<p><i>I'm not one of those who goes into reading. You know when you get a book and you read everything. I think no I don't want to know about that. You get everything that's in the book. (D4: 179-180)</i></p> <p><i>Well I would say the only disadvantage is the same as reading any medical conditions that people have a tendency to think that they have got them symptoms. (M8: 134-136)</i></p>
Social norms as facilitating factors	<p>Supportive or neutral norms set by family and close contacts</p>	<p><i>I showed it to my sister because she's got emphysema - she's younger than me - and she had a quick read... (M5: 169-170)</i></p> <p><i>... you can show your friends, family and loved ones what you are having to deal with, which I have done with this book so yeah I think a hard copy is quite useful. (D8:57-60)</i></p>
	<p>Supportive norms set by doctor</p> <p>The social acceptability of the manual was demonstrated by the many participants who informed their GP and/or specialist about it.</p>	<p><i>... I took it to my doctor like a while ago, just after I'd got it and he said oh, that's good and he'd heard about it ... yes. (D7: 148-149)</i></p> <p><i>And I told him I'd got this book and he said that's interesting and he said did you read it and I said 'course I read it (M5: 354:360)</i></p>
Capability barriers	<p>Perceptions of low reading ability</p> <p>One participant saw the manual as containing much medical terminology and some did not read books of any sort.</p>	<p><i>Well right through I had to refer a couple of times to the dictionary and everything... Plus I have got a daughter that is connected with medical position, so she helped me a few times. (M8: 110-113)</i></p> <p><i>... but as to pick a book up and read it no ways, I can't. I've only ever read one book in my life. (M1: 334-335)</i></p>

<p>Capability - facilitating factors</p>	<p>Facilitating factor: Perceptions of ability in reading</p> <p>Most participants said they found the manual easy to read and understand</p>	<p><i>Oh aye good, and I'm not the most educated person but yes it was very easy to understand. (D5: 305-306)</i></p> <p><i>Yeah I didn't find it [reading and understanding the manual] a problem, I think it was easy to reference, it was easy text, the information was pretty straightforward, the headings were pretty straightforward. (D8: 86-91)</i></p>
<p>External factors as barriers or facilitating factors</p>	<p>No external factors identified as barriers or facilitating factors for reading</p>	

Table 7.6. Barriers and facilitating factors for question-asking from the manual

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
Outcome expectations as barriers	<p>No outcomes from asking questions in manual apparent to participants</p> <p>Even when probed, participants had very little to say about any possible outcomes of asking the particular questions from the manual.</p>	<p><i>No, I didn't think I needed to talk to him [the doctor] about them all [the questions from the booklet]. (M1: 671)</i></p> <p><i>I. Did you take the booklet to your doctor - your GP or your specialist?</i> <i>P. No I didn't actually because, no. I don't know why I didn't. My GP is an - actually an asthma specialist and is actually very, really up in this sort of stuff. I don't actually know why I didn't take it to him. (D8: 125-130)</i></p> <p><i>I. Is there anything that you wanted to ask your doctor out of this booklet?</i> <i>P. No I don't think so.</i></p> <p><i>I. Can you see any advantages in asking your doctor any of the questions that are in this book...</i> <i>P. No. I think that if I was more advanced than what I am and got a little bit, well. I could easily do that. (M6: 237-242)</i></p>
	<p>No beneficial outcomes apparent from asking questions in general</p> <p>Though participants had not taken note of the questions suggested in the manual, they spoke about their own questions. A common remark was that the participant's questions had already been asked earlier in the course of their COPD.</p>	<p><i>P. But I feel such an old stager at this, I think to myself, well what else is there you know what I mean about my condition. And that's what we're talking about, not everything else.</i> <i>I. So was there anything that you thought you needed to do in relation to it.</i> <i>P. No, not at all.... I don't mean to sound blasé but I mean that you have a condition and you just live with it. (D6: 137-151)</i></p> <p><i>No, I was pretty well informed about the drugs ... I was pretty well informed by my GP and also by myself, because I have got a very good GP. He is very straightforward and very informative cause he does specialise in COPD and asthma and stuff like that. (D8: 138-141)</i></p>
	<p>No beneficial outcomes apparent from application of evidence</p> <p>Even for participants who recognised that questions were to promote evidence, this evidence was not seen as providing advantages.</p>	<p><i>P. Yes, yes, you can see that that's only research. You are looking for clues to try to get something to help people. But you are not there yet.</i> <i>I. No, what do you think about people ... getting that information when it is in that stage?</i> <i>P. Unless something is found it doesn't help a lot. ... No, I read it once, it is bit boring. (M2: 160-170)</i></p>

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
	<p>Disadvantageous outcome is that doctor's answer to a question may cause worry</p> <p>There was sometimes a reluctance to ask questions to avoid answers which may cause worry. Participants spoke about worry in terms of their own questions, so this barrier may not be applicable to the questions given in the manual.</p>	<p><i>I. Do you ever ask the doctor any questions...?</i> <i>P. No, I was given a book with what to ask your doctor but I suppose it's a sort of denial thing. If he thinks I'm bad, he'll tell me. Otherwise, I don't want to know, you know? (M4: 267-271)</i></p> <p><i>Or a couple of times you want to ask something but you don't really want to know the answer. It is a vicious circle, in one way you want to know but if it is not going to be good you don't want to know. It is hard. (D1: 199-201)</i></p>
Social norms as barriers	<p>A norm that doctors, rather than patients, make decisions about treatments</p> <p>Treatment selection and initiating change seemed to be seen as solely or mainly the doctor's concern. Participants did not see themselves suggesting treatment reviews. When participants spoke about making suggestions about treatments, this was limited to asking about adjusting timing or delivery of medications.</p>	<p><i>Well you see he is basically a professional. You're supposed to trust him. He is the doctor, not you, although you know your body. And if he advises you against a particular medicine like the one on page 31, who are you to dispute that, thinking that, OK, well maybe the reason is because it might counteract something else. And that's why, you know, you basically don't question him. Especially if you trust your doctor, which you are supposed to trust him. (M2 carer: 554-560)</i></p> <p><i>I. Did you feel that you needed to do anything in relation to your lung condition after you had read the book?</i> <i>P. No, only under my doctors supervision. (M: 52-55)</i></p> <p><i>I. Would [the doctor] be open to [changing the dose of a medication]?</i> <i>P. I don't know. I am going to ask when I go. (D1: 173-187)</i></p>

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
	<p>The patient's role is as recipient of medical instruction</p> <p>Though participants reported asking questions when visiting the doctor, these questions were invariably described in terms of requests for information from someone with greater knowledge. Participants never spoke of using questions as a way of making suggestions.</p>	<p><i>My doctor would give me an answer, you know, depending if I wanted to know, and he would be only too happy to put me right. (M6: 246-247)</i></p> <p><i>Here is ... [vignette of patient with manual consulting doctor]. Can you remember any of the things that you did ask your doctor?</i> <i>P. Well, just general things like why am I so short of breath, and what is the COPD doing to me, and what should I be doing about it. (M7: 62-65)</i></p>
	<p>The patients focus is on non-medical issues</p> <p>Though not asked about them, participants often spoke about life issues which were affected by their COPD. They appeared to see these, not treatment issues, as those the patient should manage.</p>	<p><i>I am looking for a unit. I thought I would try and find something a little bit newer that doesn't need a lot of work and perhaps a strata title, just a small block. And that will give me a few dollars for a trip to England and that will give me a big boost.(D1: 70-78)</i></p> <p><i>Oh, I hate a desolate place I am very pleased to be able to keep going. It is a delight to grow our own bits and pieces and I have a pride in it and when someone stops and says Wow! [laughter](D2: 366-369)</i></p> <p><i>The campervan yes, that's a project we got that last year and we were going away you know, up the Riverland. Oh, I am all right driving that's terrific if I take my time . (D5: 81-83)</i></p>
Capability barriers	<p>Perceived inability to ask questions of some doctors.</p> <p>Difficulties with asking or persisting with questions were sometimes experienced only with particular doctors.</p>	<p><i>I. ... Did you try and talk to the GP?</i> <i>P. Yes I tried to but he didn't seem to, he seemed to think that I knew what it was all about, you know. And didn't enlighten me much ... (M3: 105-111)</i></p> <p><i>I. And what about in the hospital, did you find them pretty easy to talk to - the doctors there?</i> <i>P. No, very hard. Perhaps because they are busy, with so many patients and they are always looking to squeeze something in, so I thought it was a bit hard.</i> <i>I. And have you ever had a GP like that?</i> <i>P. Well, not really. No, because with the GP you, you keep them, like. (M8: 210-217)</i></p>

Type of barrier or facilitating factor	Barriers and Facilitating factors	Illustrative comments
	<p>Perceived inability to ask questions due to perception of relative ignorance</p>	<p><i>I don't really understand much. I'm not a very good educated person so you know so I thought oh well they're going to tell me if something's really bad I suppose. (M3: 217-219)</i></p>
	<p>Perceived inability to ask questions due to memory problems</p>	<p><i>I must write down all those things I've got to remember - I usually forget something. (D4: 400)</i></p>
<p>Capability - facilitating factors</p>	<p>Participant ability to ask questions</p> <p>Most participants were not conscious of any personal skill deficiencies to asking questions of their GP, in particular, though they appeared to see this in terms of requesting information rather than making suggestions. They sometimes ascribed this ability to the skills of the doctor rather than the patient.</p>	<p><i>No, it doesn't worry me, I just ask anything. (D7 194)</i></p> <p><i>Quite easy [to talk] as far as I am concerned because as I say, if you can't talk to your doctor [GP] you are wasting your time to go and see the doctor. (M8: 302-304)</i></p> <p><i>It is just the sort of person I am. I've got an inquiring mind. If I had anything to ask, I'd ask it. (D5: 224-5)</i></p> <p><i>I just thought, ask the doctor. Because I have got a really good doctor, Dr [M]. and he is a very understanding man and I just have a talk to him about things and he gives me a truthful answer to what I want. (M6: 207-211)</i></p>
<p>External factors as barriers</p>	<p>Awareness of doctors' lack of time</p> <p>Several participants spoke about doctors' time limitations. However, most saw this as a surmountable barrier when they had an important question to ask.</p>	<p><i>... some people get some doctors and they are feeling that they can't wait to get to the next game of golf (D5: 310-312)</i></p> <p><i>I. Would the busyness ever make you think you would ask the question another day, or would you ask it anyway? P. Six of one and half a dozen of the other. If it was an important question yes I would ask him but if it was just something I wanted to know I would leave it till next time. (M7: 139-145)</i></p>

COMMON FEATURES OF CASES WHERE QUESTION-ASKING WAS SIMILAR TO THAT INTENDED

While participants did not use the questions offered in the COPD Evidence Manual, some asked their doctors questions of their own as a result of reading the manual. There did not appear to be demographic variables associated with this type of question-asking, but question-askers were participants who described themselves as people who usually sought out information relevant to their current concerns. The one self-identified information seeker who did not question his doctor said that he had been diagnosed for several years and was now less active in learning about COPD.

DOCTOR RESPONSES TO EVIDENCE-RELATED PARTICIPANT QUESTIONS

As reported in section 7.2.1.2, most questions asked by participants at consultations with doctors were requests for information rather than suggestions to use the evidence summarised in the COPD Evidence Manual. It was therefore difficult to make inferences about whether doctors would understand and comply with patient requests for consideration of evidence. The qualitative study included accounts from only two participants who asked their doctors questions clearly related to the COPD Evidence Manual. One doctor supported treatment change and the other did not but neither doctor appeared to consult evidence.

Well I had read in the book [manual] about the [pulmonary rehabilitation] courses and I said to [GP] that I wanted to do something that I felt was more positive and if he thought it was a good idea and he said yes, he did. (M4: 386-388)

I So can you tell me what happened for you when you went to the Doctor and

P Well, I told him about that book, he agreed to send the letter to get one. And I asked him about some medicine on page 31 and he said that he didn't think it was any good for me.

I So did you discuss it any further or did you just accept that?

P No, No I believe him so, you have got to believe something. (M2 117-129)

These were only two accounts but theoretical sampling (Rice & Ezzy 1999, pp.47-48) could not be continued because few participants had asked questions related the COPD Evidence Manual. No conclusions could therefore be made about factors associated with doctor compliance with patient requests.

7.2.2 Discussion

7.2.2.1 Summary of findings

The process evaluation suggested that variation in reading behaviour was linked to varying interest and need for the kind of information given in the manual. Some participants read and re-read with great interest while others showed low interest in the summaries and may not have understood them fully. It was not obvious to many participants that the manual was about research evidence and that in this way it was different to other disease-related information. Occasionally, reluctance to read was associated with coping mechanisms or to difficulties with print

For some participants low interest in the information in the manual was also a reason for not using the information to ask questions of the doctor. Where reading did lead to questioning a doctor, this was invariably a tentative or general query to obtain the doctor's own opinion about the suitability of a treatment for the particular patient. There were no instances of suggestions by patients that doctors consult the research evidence. Advantages of raising issues from the manual did not seem very apparent to participants. Participants appeared to hold strongly to the social norm that doctors and not patients were the ones to initiate reviews of medical treatments. Participants also explained that doctors were highly trained in the kind of material included in the manual and were therefore able to understand and use this kind of information far better than a patient.

Overall, patients' ability to read plain English materials, an interest for some in the kind of material presented in the manual and a willingness to ask questions, if not the kind suggested in the manual, were facilitating factors to this kind of intervention. On the other hand, many participants had limited interest in the material presented in the manual and did not appear to see that it was possible or acceptable for a patient

to master research evidence or raise it with doctors. These were barriers to the effectiveness of the intervention.

7.2.2.2 Study limitations

Some limitations are inherent to the methodology used for this element of the evaluation. Although sampling was to saturation, further barriers and facilitating factors may have been identified with continued sampling. While multiple analysts were used to lessen any effect of any individual researcher preconceptions, they may have had some influence, as with any qualitative study (Patton 2002, pp.49-54). Further data about patient understanding and intentions could have been obtained by use of think aloud or similar techniques which capture user reactions to an information resource (Crain-Thoreson et al 1997). Further data on consultation behaviour could have been obtained by the use of observational methods (Patton 2002, pp.259-332) and examination of consultation records, though there were logistical difficulties with these methods.

Some limitations relate to the timing of interviews. Little evaluation of consultation behaviour was possible. Patients' memories about what happened at a consultation in relation to topics from the manual were unclear and partial. It was not possible, however, to predict when a particular participant would raise a topic from the manual so that an interview could be held immediately after the consultation.

A further limitation is the absence of accounts from doctors. For example focus group discussions with doctors who had ordered the manual would have added another point of view on barriers and facilitating factors.

7.2.2.3 Findings in relation to other studies

PATIENT INTEREST IN READING ABOUT EVIDENCE

The finding that the COPD Evidence Manual did not cater for the primary interests of many participants is contrary to responses from patients involved in development of the manual, who responded positively when asked if they would be interested in

research evidence. There are mixed findings also from other studies of patients' interest in evidence about treatment options. Some patients appear to want this information (NHMRC 2000); but it may be that only some groups of patients are interested in disease-related information (Coulter et al 1998, pp22-23) and not chronic disease patients generally. Research about treatments is not listed among the self-identified concerns of people with COPD (Nicolson & Anderson 2003). Rather, people with COPD and other chronic illnesses patients appear to be primarily focused on life issues (Barry et al 2001; Hunt & Arar 2001; Nicolson & Anderson 2003), with disease treatments taking second place (Cooper et al 2003; Jerant et al 2005; Noel et al 2005). An interest in materials seen as relevant to current life role concerns, as perceived by the patient, is consistent with models of adult learning (Merriam & Caffarella 1999, pp.271-287; Tusting & Barton 2003). If patients read most attentively when materials are developed primarily to answer patient identified topics (NHMRC 2000, Kennedy 2003b), designers of patient mediated interventions will have to carefully integrate evidence information, and patient prompts for clinicians, into these topics.

A few participants reported being reluctant to read some disease-related material to shield themselves from possible worry. Those patients using information avoidance and denial as way of coping with serious illness (Buetow et al 2001; Davey et al 2003; Hesselink et al 2004), may continue to avoid even sensitively designed PIMs (Ness & Ende 1994).

PATIENTS RAISING TREATMENT ISSUES

Suggesting treatment reviews did not accord with the norms of participants in this study. These findings are supported by recent findings that even patients who want information do not necessarily want to participate in medical decision making (Beisecker 1990; Broadstock M. & Borland R. 1998; Leydon et al 2000; Kennelly & Bowling 2001; Ford et al 2003). Older patients and those with greater socioeconomic disadvantage and disease severity are least likely to participate in consultations (Arora & McHorney 2000; Robinson & Thomson 2001) and these were characteristics of many people who received the COPD manual, and of people with COPD more generally (van Manen et al 2001; Anto et al 2001).

Even when patients have self-identified issues they do not always raise them (Barry et al 2000; Bell et al 2001) therefore it may be more difficult to encourage patients to raise issues suggested in printed materials. Furthermore, in studies aiming to encourage patient participation overall in consultations, printed training materials have had low success in encouraging patients to raise issues during consultations (Harrington et al 2004).

Participant accounts indicated that when the COPD Evidence Manual prompted patient question-asking, these questions were devised by patients themselves and did not focus on evidence. The formulation of individualised questions by participants is consistent with the constructivist basis of most major theories of adult learning. These see the learner as actively constructing their own individual knowledge and understandings (Sutherland 1998; Merriam & Caffarella 1999, pp.249-266; Marsick & Watkins 2001) with lay people developing different constructs of scientific and health knowledge to those of experts (Short 1998; Sutherland 1998; Kessels 2003; Lee & Garvin 2003). Patient understandings remain different from those of health professionals, even for people with long-term chronic disease (Wagner 2003). Verbal suggestions to doctors, from patients who have been given digests of evidence summaries, may therefore rarely be replications of the recommendations of the original evidence summary.

While participants did not appear to suggest treatment reviews explicitly, some asked their doctor's opinion about a treatment covered in the COPD Evidence Manual. This accords with the findings of a study of patients who took information from the internet to their doctor. Rather than wanting the doctor to take a particular action, patients usually wanted the doctor's opinion on the information (Murray et al 2003). Patients see evaluating treatments and working according to good practice as fundamental parts of the GP role (Grol et al 1999) and may not see a need for doctors to be given prompts to consider evidence.

For both question-asking and reading, qualitative findings are at odds with predictions of patients involved in development of the manual. Other reports also show differences between self-reported and observed behaviours for both patients and health professionals (Barry 2002; Stevenson et al 2004).

REMAINING STEPS: DOCTOR UNDERSTANDING AND TREATMENT CHANGE

Though these stages were not investigated in the qualitative study, the survey indicated substantial failure at one or both of these steps. New reports also suggest that these stages may contain barriers. Patient requests may sometimes be disliked by doctors (Kravitz et al 2002; Kravitz et al 2003; Murray et al 2003; Toiviainen et al 2005). In recent studies of PIMs, maternity care clients and people with diabetes and ulcerative colitis were provided with information so that they could play a major role in medical decisions. However, where clinicians had not been prepared for greater patient participation, their actions excluded patients from decision-making (Kennedy & Rogers 2002; Stapleton et al 2002; Kennedy et al 2003a; Cooper et al 2003). Additional organisational constraints may present further to be overcome for patient mediated change (Kennedy et al 2003c; Cooper et al 2003).

7.3 CONCLUSION

The process evaluation showed that trial participants did not use the COPD Evidence Manual exactly as expected. It has also provided some possible reasons for differences between expected and actual use. Findings from the trial and process evaluation can now be combined, and implications drawn for future interventions.

Chapter 8 Discussion

This chapter summarises and links findings from the outcome and process evaluations of the COPD Evidence Manual. It assesses the generalisability of these findings to other conditions and draws implications for the design of patient mediated interventions. The process used to develop the manual is also reassessed in the light of recent recommendations on the design and evaluation of complex interventions.

8.1 INTEGRATION OF EVALUATION RESULTS

A comprehensive picture of the effectiveness of the COPD Evidence Manual at each of the causal steps given in section 5.2.1 can be obtained by combining findings from the trial and process evaluations, as shown in Table 8.1.

Most participants reported reading the COPD Evidence Manual and this appeared to reduce anxiety for a time for a number of them. The qualitative study showed the match between the style of the manual and the reading skills and preferences of participants to be a facilitating factor. However, trial and qualitative findings suggested that some reading may have been superficial rather than attentive. Where pre-existing patient interests were not covered in the manual, this appeared to be a barrier to in-depth reading. A further barrier was the use of information avoidance as a coping strategy.

While survey responses indicated that over 40% of participants questioned their doctor about a topic from the manual, qualitative findings suggest that most patients asked questions which were quite different to those suggested in the manual. Patient questions appeared to be consistent with norms where patients expected, and deferred to, medical expertise held by doctors. The qualitative study suggested also that many patients did not readily see the need for, or benefits of, reminding doctors about the research summarised in the manual.

Table 8.1 Success of the manual at each step required for effectiveness

Causal step	Information provided by trial	Information provided by survey	Information provided by qualitative study
i. Reading	<p>Study lacked power but showed no change in COPD mastery, knowledge score, or satisfaction with information, suggesting that participants did not learn from the manual.</p> <p>At 3 months the manual appeared to reduce anxiety for people with least socioeconomic disadvantage suggesting benefit from information provided, though this effect had disappeared by 12 months.</p>	<p>Over 90% of intervention participants reported reading at least part, and over 60% reported reading all by 12 months.</p> <p>About half reported learning something from the manual.</p>	<p>Participants were able to read the manual and generally not worried by the content.</p> <p>There were few barriers to reading. Reasons for not reading – or for not reading attentively – were feelings that new knowledge would not be useful, absence of content that was wanted by participant, and avoiding potentially worrying prognostic information.</p> <p>These findings suggest that reading may have been less frequent and less in-depth than suggested by the survey.</p>
ii. Question-asking	<p>There was no change in rapport/communication comfort with usual doctor. This finding does not support change in communication between patient and doctor, caused by manual, but could result from under-powering.</p>	<p>By 12 months 42% of intervention participants (and 46% of those who reported reading) reported discussing topics with their doctor.</p>	<p>Any participant questions were requests for doctors' opinions about topics from manual, not the offered questions. There were several barriers to question asking. Benefits not seen in discussing issues from manual with doctors. Considering and choosing treatments seen as the role of doctors. Participants deferred to doctors in consultations and were conscious of consultation time limitations.</p>
iii Doctor understanding			<p>When participants raised issues with doctors, they did not appear to suggest consulting evidence, and they may not have spoken about the manual. Doctors may not have recognised issue-raising as an opportunity to look at the evidence.</p> <p>On the other hand, many doctors had their own copy of the manual and could easily use it to consult evidence relating to an issue raised by a patient.</p>
iii Treatment change	<p>Study lacked power but at 3 months the manual may have increased uptake of bone density testing for people with greatest socioeconomic disadvantage and at 12 months it was associated with increased pulmonary rehabilitation for people with greatest socioeconomic disadvantage.</p>	<p>Five percent (at 3 months) and 10% (at 12 months) of intervention participants reported treatment changes resulting from discussion. At 12 months 24% of those who reported talking to their doctor also reported that treatment was changed.</p>	<p>Treatment changes prompted by patient question-asking did not appear to include reference to evidence by patient or doctor.</p>

Indicator measures of treatment change showed a small number of outcome improvements for sections of the intervention group at 3 and 12 months, but no large-scale treatment change. The selective measures used in the trial may have failed to detect all treatment change, and under-powering may have meant that changes occurred but were not detected, but survey responses and qualitative interviews support the finding that by 12 months the manual had not produced changes in clinical practice.

The following section assesses whether barriers to the success of this intervention would be applicable beyond the context of COPD. Subsequent sections suggest how future interventions might be designed to overcome barriers.

8.2 COMMENTS ON GENERALISABILITY OF FINDINGS TO OTHER CHRONIC DISEASES

While several features of COPD make it a good choice for a study of methods to improve uptake of evidence, other features may limit generalisability to other chronic conditions. Patient mediated interventions in COPD may face special hurdles related to the very high burden on patients, patient cognition and health professionals' perceptions about the condition. COPD is an extremely burdensome condition (The Australian Lung Foundation 2001) and the rate of comorbidities is high (van Manen et al 2001). This burden may leave many patients with little capacity to learn about and contribute to treatment selection. In addition, the COPD manual relied for its effectiveness on patients pro-actively selecting treatment issues and raising them with their doctors. However, the cognitive abilities required for this activity may be somewhat compromised among some older people with COPD. Population-wide cognitive declines which occur at the age when COPD is usually diagnosed (Boulton-Lewis 1998; Australian Institute of Health and Welfare 2004) may be even more marked in COPD (Liesker et al 2004). A further factor which might compromise the effectiveness of practice improvement in COPD is a belief held by some health professionals that little can be done to improve outcomes in this condition (Global Initiative for Chronic Obstructive Lung Disease 2001). In short, some features of

COPD could have reduced the effectiveness of the manual. Research on similar manuals for other chronic conditions may show greater practice improvement.

8.3 IMPLICATIONS FOR FUTURE PATIENT MEDIATED INTERVENTIONS

The COPD Evidence Manual was a carefully designed intervention with optimal chance of success, based on available research:

- It targeted a range of barriers cited by GPs (perceptions that some evidence based treatments could lead to patient dissatisfaction, lack of time to consult evidence resources)
- It dealt with a condition with demonstrated gaps between evidence and practice
- It made use of the patient's influence on prescribing
- Methods were employed to match the style and presentation of the manual with the reading skills and preferences of patients
- Encouragement for patients to progress from reading to questioning their doctors about applying evidence in their case was provided in the form of "Questions to ask your doctor"
- Suggested "Questions to ask your doctor" were created by health professionals, usually doctors to be consistent with questions they might be asked in practice
- In several consultative forums, patients agreed that they were interested in the research on treatments used in COPD, and that it was their usual practice to take new information they found on COPD to their doctors
- In brief piloting, people with COPD reported reading the manual with interest and intending to talk to their doctor.

However, the formal evaluation did not show the hypothesised change in management of COPD.

Study limitations may have contributed to the observed lack of patient-driven treatment change. An important limitation was the better than expected care at baseline for the study population. Study participants were receiving care from both GPs and teaching hospitals and may have felt less need to take an active role in management of their condition than would people who saw a GP only.

In addition, several barriers and facilitating factors were identified as influencing the effectiveness of the COPD Evidence Manual. Changes, to overcome these barriers, might improve the effectiveness of future interventions. Suggestions for overcoming barriers are discussed below. Possible improvements to the design process as a whole are then discussed.

POSSIBLE IMPROVEMENTS TO THE MANUAL

Readability was a facilitating factor to patient use of the COPD Evidence Manual therefore the same strategies to meet reading skills and preferences of the target group should be employed for other interventions.

Interventions like the COPD manual will be successful in engaging patient interest only if the patient can see personal benefits. A perception that the COPD Evidence Manual contained mainly medically oriented material seemed to limit its appeal for some participants. This perception was not overcome by the use of plain language, non-medical photographic illustrations and plain-language tips and suggested questions. Instead of merely collecting and summarising reviews of evidence, researchers may need to structure interventions according to common patient concerns, with evidence summaries integrated into this structure. This may be particularly necessary for chronic disease interventions where summaries of evidence for the many potential treatment decisions form lengthy documents.

One reason for participants failing to discuss evidence with doctors was a belief that doctors were already taking evidence into account in treatment decisions. Interventions which clearly explained that doctors may not be completely up to date with the practice implications of current evidence, for all the conditions they may encounter, could overcome this barrier. Such explanations would need to be developed collaboratively with doctors to be consistent with good patient/doctor relationships.

Other barriers centred on norms of the doctor patient relationship. Providing questions in the manual for patients to ask their doctor did not overcome this barrier. Explicit demonstration of the desired behaviour is suggested by social learning

theory (Bandura 2004) therefore photographs or cartoons, showing patients asking these questions, may better facilitate question-asking (Delp & Jones 1996). It may also be possible to provide alternative ways for patients to suggest treatments to doctors. The success of direct-to-consumer advertising of brand name prescription drugs, and brief vaccination reminder information cards for patients, suggests that these interventions are more compatible with consultation norms. In contrast to the COPD Evidence Manual, these interventions do not require patients to select from multiple possible topics or to master the treatment related information before speaking to their doctor.

Though participants did not ask the suggested questions, they did take action by asking questions of their own. Interventions such as those suggested above in which the patient hands over a card, or dual interventions which provide information to doctors as well as patients, may ensure that messages about evidence are transmitted along with patient self-identified concerns.

It remains to investigate barriers to doctors acting on patient suggestions and ways of preparing doctors to respond to patient mediated interventions.

8.4 THE DESIGN PROCESS FOR PATIENT MEDIATED INTERVENTIONS

The development and evaluation of the COPD manual coincided with the beginning of a body of publications advising on ways to design and test interventions to improve medical practice (Campbell et al 2000; van Bokhoven et al 2003; Grol & Wensing 2005; Hardeman et al 2005). While some of these publications include consideration of intervention development procedures advocated for health promotion (Kok et al 2004), most build on the framework for the development and evaluation of complex interventions published by the Medical Research Council in the UK (2000). This framework includes phased development, incorporating features which are indicated by existing research and behavioural and educational theories, and successive empirical tests.

While the COPD Evidence Manual was consultatively designed and well founded on available research evidence, a more effective intervention may have resulted from

a development process more closely following the four-stage Medical Research Council model. For example, an investigation of the particular reasons for evidence-practice gaps in COPD would have been conducted in stage 1. An intervention would then be purpose-designed, and a patient mediated intervention would be indicated only if reasons for gaps were demonstrably related to patient inaction or patient opposition to evidence-based treatment. In addition, design of the COPD Evidence Manual was based on patients' predictions that they would read about research and that they talked with their doctors about new information on COPD. In the event, actual patient behaviour was somewhat different. Testing for optimal design in stage 2 would have shown these discrepancies between predicted and actual behaviour before the formal trial. Overall, the development procedures advised by the Medical Research Council may leave fewer barriers to be discovered during a trial and may therefore produce more effective interventions.

8.5 IMPLICATIONS FOR EVIDENCE SUMMARIES TO SUPPORT

DECISION SHARING

As noted in Chapter 1, while the aim for the COPD Evidence Manual was to improve implementation of evidence through patient participation, for most plain English evidence summaries the aim is to facilitate decision-sharing as an end-point in itself. However, whether summaries are designed to increase implementation of evidence or to facilitate decision sharing, they must be understandable and accurate and must help patients to discuss possible treatments with their clinicians. The same barriers may need to be overcome for both types of summaries, though they may apply to different extents for different patient groups. Similarly, the same facilitating factors may apply. Whether the aim is to influence practice or to facilitate decision-sharing, patient summaries of evidence can build on patients' willingness to read information provided by health professionals, patients' interest in managing life with a medical condition, and patients' preparedness to raise issues with doctors in ways consistent with consultation norms.

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APPENDICES

Appendix 1 Health professionals and Cochrane reviewers who contributed to development of the manual

DRAFTING AND REVIEWING

Bob Adams
Sarah Appleton
Huw Davies
Peter Frith
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Terry Jones
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Anne-Marie Southcott
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REVIEWING

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Tom Clarke
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Kathy Fennel
Peter Gibson
Rob Green
Lydia Kotal
Louis Pilotto
Helena Williams

Note: Patients and carers who participated in this research project were assured of confidentiality. For this reason, focus group participants, panellists and members of the WestAir community support group are thanked but cannot be named individually.

Appendix 2 Table of consultations for development of the COPD Evidence Manual

Time Period	Individual consumers	Focus groups	WestAir	Reader panel	Expert Authors	Other health workers	Other
Nov - Dec 2001	Exploratory interviews with 2 carer/ patient couples and one patient at their homes.		Meeting: Informal discussion about booklet idea.			Exploratory interview with respiratory nurses (LK, KF) about patient/family information needs. Exploratory interview with psychologist (PC) organiser of pulmonary rehabilitation training.	Discussion with health education practitioner/ academic (AJ) about current approaches in patient education information Editorial team decisions about list of reviews to summarise.
Dec 2001 - Jun 2002					Drafting and redrafting by contributors/editorial team.		
Feb - Jun 2002	Individual queries (WestAir Committee, panelists) to find terms used/understood by patients and to consult about sensitive terms/ concepts eg death.			Individual readers reviewing drafts-as needed.	Review group suggested further topics.		
Feb - Apr 2002		Focus groups 1 and 2.	Meeting: Identifying and prioritising topics.	Style test 1 Style test 2 Consultation on consumer need for ratings on strength of evidence.			Visit to health education materials production manager (DS) for advice on options/costs for booklet production.
Jul - Dec 2002	Hospital patients scored font/spacing sizes.		Meeting: Presentations test Feedback on style issues.	Presentations test Panellists reviewed whole draft, marked problem parts and interviewed by MH to discover any further problems.		Review of close to final draft. Consultation on photographs: PS, LK, RG.	Professional editor: review of wording, advice on font, spacing, lay-out, photographs, diagrams.

Appendix 3 Focus Group 1 theme list and guide

Theme list

What books or other information about COPD do you have already?

What are the good points and weaknesses about the books and leaflets you already have?

What topics would be most helpful for COPD patients and carers?

IF NEEDED TO GET ABOVE INFORMATION

- What are the most important questions or decision or problems facing you at the moment with your COPD? What do you wish you knew?
- What important questions, decisions, or problems you have had since the diagnosis? What did you need to know about?
- Should there be a description of how COPD normally progresses?
- Should there be diagrams and information about what is wrong in the lungs?

How honest should we be with negative information or "bad news" about the disease?

How honest should we be about research that shows some medicines don't work very well or have side effects?

How easy is it to talk about COPD with your doctors?

If the booklet gave you some new information about a COPD medication would you discuss it with your doctor?

What would you do if the booklet said something wasn't useful but your doctor wanted to give it to you?

IF NEEDED

Were you more inclined to try almost anything, in hope that it would work, when you were first diagnosed?

Finally, do you have any tips for us on the style of the booklet?

IF NEEDED

What about print size, use of medical jargon, would a folder - with sheets that you could add to - be better than a booklet?

Guide for focus group

- Thank you for helping with this project.
- Introductions.

BACKGROUND

- We have a government grant to produce a booklet for COPD patients.
- The grant specifies that we include the best research information about medicines and treatments.
- We want to include other material that people with COPD need.
- We also want to know how and whether you and your doctors work together.
- You are the experts so we need your views.

LIMITS

- I know there are lots of subjects that we could talk about but for this research we are talking about what patients and carers need to know to help them with their disease.

GROUND RULES

- Asking you to be as honest and open as you can.
- Asking people not to repeat what they have heard once we are outside the room – keep other people's thoughts and feelings confidential.
- We want to hear everyone's views and get a range of opinions. There is no right and wrong and everyone's experience is different.

WE PROMISE

- We will record the conversation to type up but no names will be recorded in any reports or attached to any comments. We would like some brief details so we know what kind of people we have talked to today, but won't report your names.
- We are researchers and not connected with your medical care so what happens today won't affect that.

WHAT'S GOING TO HAPPEN

- We will ask some questions to get some discussion going. Please just talk to each other and give your views. We need to take turns so that we can record everything.

Appendix 4 Brief for Focus Group 2

What information do people with COPD want about their disease?

How honest should we be with negative information?

Will patients in fact discuss information about treatments with their GPs and participate in decisions?

If possible, what are patients views on formats and writing styles.

Appendix 5 Transcript of Focus Group 1

Researcher A: Can I just get an idea from people um, what books and information you have already about COPD? Where are you getting your information from? If at all?

FA: I've just been told I've got it and asked no questions about it, so I don't know anything about it.

Researcher A: You don't know anything it all?

FA: No.

Researcher A: No information at all?

FA: No information.

Researcher A: OK.

FB: I think the main time when I had any information is when I joined WestAir. (inaudible) had an introductory what do you call it? Folder, bag, whatever and in there it had been explained in there about you should have exercise, you should do this will and oh, there's so much information in that handout.

MA: We suggest that we take it from lots of different sources (FB agrees in b/g) to prepare it.

FB: But I got nothing from the hospital, when I came over here, or my doctors

MB: I had no information whatsoever. My doctor, diagnosed me to start with, once they ask you questions like were you been smoking and obviously say 'yes' they lose interest in you and they want to get onto the next subject like I don't want to know you, you are waste of time so to speak. And that for what it is how it is and not for 40 years I've been in the building trade
lots and lots of dangerous chemicals have been handled and other things, dust, metal and dust, quite a health, health hazard. If anyone wants to smoke, you are on the outer like they don't want to know you.

Researcher A: And no information at all? What about other people?

MC: I'll second that no information, I'm not a sufferer but the point is that um, my wife was in that way for about 10 years um she did get a few books and things about it, but um, they weren't clearly available, to a, to a sufferer.

Researcher A: Do you remember what sort of books and things you had?

MC: Yes, there were exercises, diets, er, you know breathing exercise, wasn't useful, absolutely bloody hopeless, there no lungs to breathe with. The bloody thing that kept her going was the ah, gas or oxygen, whatever you called it to um, last for about seven years.

Researcher A: So these breathing exercises, where did they come from?

MC: Er....from here I believe.

Researcher A: From a physio? Or a...

MC: Um...from...whats 4B, I got it from up there, from Lydia from there, yeah.

Researcher A: And R, for you it was the same?

FA: Yeah I was the same too, I came back in six months. The first doctor said to me that I had emphysema, that's it, that's the end. Never heard anything, never heard about puffers or anything. When, when I moved to Henley Beach it was the same group of doctors and he got puffers and showed me how to use them and that that's all I knew. I found out when I ended up in hospital I wasn't using the puffers right and I ended up with three puffers and a few directions on a bit of exercise which I knew a lot because I do yoga. But I mean, it was surprising that the simple breathing things the relief it brought me, making an attempt to keep the chest clear of phlegm. Because she just, conk, conk, conk, and it dissipated, you don't bother to bring it up. The importance of it was brought to me in hospital only this year, after really. And it wasn't just smoking from the age of 14 I was in places where I got shocking dust to breathe in, including in factories breathing in smoke again, er, you know, hours a day, and I worked in making uniforms from fabric, for the gunners, khaki. It was full of you know, there was a rats, a rats nest inside apart from all the blooming flats. And goodness knows the fact they had a perfect excuse down Petticoat Lane and all the Jewish places, that have been made over into factories to make the uniforms etc. to not do any repairs or had any help so I had them in the thing.

Researcher A: So, this is the first common thing for some people that about

FA: Right, from the age of fourteen, people my age we worked from 14, 13...oh sorry. I'm going too far.

MD: Er, started off by my daughter led me to the doctor or in the chest centre in North Terrace, and I get this doctor, he's number one. He actually kept me alive, because I used to be a chain smoker, after my wife died and all this and he told I had three months, to live

Researcher A: Any information? When you got...

MD: First he just told me to stop smoking.

Researcher A: Right...

MD: And he gave me one of these blowers, you know, how much you can blow...

Researcher A: Yeah.

MD: It was very low, then he said that you have to do something to save yourself, walking. And I done it and I increased to 330 you know, on this, blower. Its very good for me because I started with 200, I couldn't walk one stair case up, and they were to...and now I have to have this, because...

Researcher A: Twenty years ago and he gave you three months to live...twenty years ago, well that's been a bit success story hasn't it?

MD: It depends on the people themselves too.

Researcher A: It depends on the kind of doctor you get to then, but then some people are starting to sound a bit like this information thing is that when you get diagnosed with COPD it's a bit of a death sentence and there's no information.

FB: You go on working hard, and you do work hard and its not academic type people, you have to use your physical strength, and you just go on working hard. You don't breathe properly, that's another thing, I don't think I've breathed properly since I got Scarlet Fever when I was six years old.

Researcher A: So, just can I go onto....yeah, G?

MD: See, another thing you have to keep in mind, when I come here I have a property, so I'm the head of the property, if I kick the bucket, who'll look after them? So the will power has to be there, my thing is will power, do you want to live? And I'm right three times from now. First time the Queen Elizabeth, they ring me up, second time here, and third time in Ashford. Still here.

Researcher A: Yeah, good on you.

ME: We, we got a chap that's a sponsor now and he fixes up all these machines and er, like you know what do you call them?

Researcher A: Nebulisers.

ME: Nebulisers and all that kind and he came down and he's been there twice to give us a lecture. I'll tell you what, it was amazing that the people that were there weren't their things right, absolutely amazing what the uh, you know, what we announced. And when asked, they told they never been taught, shown. They were never shown.

Researcher A: It's a common thread sometimes isn't it? So with the WestAir information, what sort of information is provided with WestAir when you come in?

MF: Mostly what we've provided and starting off with the little bag of goodies that we give to people who are potential members of...

FB: Did I get that?

MF: ...I'm sure you must, uh, we have information that's supplied by the Lung Foundation. We have sheets that we've actually put together ourselves or in consultation with the LungNet group itself, more so in terms of the value of being a member of a support group, because essentially that's what it is, its support. And the other parts have come from where we've had a...we call it an education day. There's only been one of those held per year, which is a meeting of all of the LungNet support groups in Adelaide, and we've had physiotherapists and we were talking about the breathing and so forth, and the number of people from the um, the medical ranks who prepared papers. And we have copies of those that we've also included in with the material we have given to potential members. So we've sourced out information from a number of different spots.

Researcher A: OK. What sort of those materials have people found useful? Can we get some ideas on what sort of things have been the most helpful?. We're talking about printed information here too, basically, can you just....

MF: Breathing exercises, we've have the physical exercises that you can do just sitting in a chair, so you can keep some upper-body strength and its not associated with the actual breathing its just keeping the muscle, some reasonable muscle tone. As well as the other side of the information which has come from LungNet which really tells you about the various different lung diseases that are around the place. It just raises one question if I can ask, and it's probably out of turn doing it, but bronchiectasis, I've noticed its been exclusively deleted from this last questionnaire that people were talking about before, which came from the Lung Foundation. And yet I think in your um, prior to us you included bronchiectasis in with the COPD.

Researcher B: Do you want to talk about that later J?

MF: Yeah, sure, yes. I'd like some clarification on that...

Researcher B: We'll do that later J.

MF: Great, thanks.

Researcher B: We might get back to some of the bits of information that people have had.

Researcher A: Yes, so what did other people found useful out of the WestAir information?

MA: With the WestAir, you walk into a health centre say, or say to see your doctor or say see your GP because he's not a specialist. And there's absolutely from the bottom of the floor to the top of the wall is all this information about every disease you can think of. And we can't find something, I must reckon with this chest thing, this serious and insidious disease that should be given to the patient by the doctor. Because if its given to them by the doctor, they know its good or supposed to be good, whereas if you rely on the person to pull it out of the what-say, they're never gonna read it.

Researcher A: Do you find anything on COPD on those doctors' stands?

MA: No.

Researcher A: Anyone else find anything?

FB: No.

Researcher A: So there's just, nothing available. They cover every other condition or most of the conditions.

MB: Well, what one of the biggest things is I mean even in the medical profession you know, there is some confusion there. There's so many things, now comes down to everything is listed now as COPD, you had CO-AD, you had [?], and half a dozen other things now its all listed under one name, you got one and I got COPD, I'm better off than you because I haven't got the other one, CO-AD or something. Then you find out it's the same thing, then you go down to another [?]. So I mean, the information or lack of information from the medical profession will have to be addressed there because they're confused.

Researcher A: OK, can we just move on a bit then, we've got very much in the same area. For the information you would like see provided, what are the important topics? What are the key areas that would like to see information about?

FB: That its not a death sentence. Or its not a sentence when you're given this and people sort of oh, you know, they don't explain. Nobody explains that it can be not, you can't get better, but that should in black and white, but if you exercise, if you do the breathing, if you have, power over yourself, to do the right thing er, its not a sentence like that. And there was nothing there, there was nothing it was sort of, oh I know, I went to the nursing home, and I saw all these poor darlings, in the nursing home, and that's what I'm, that's what's facing me, I got no help now. That's the attitude. I think WestAir has definitely helped me.

Researcher A: Do people agree with...

MB: Well going back, I was on the table here having an angiogram, thing stuck up the veins whatever you called it, and the doctor was saying, well I bad news for you, you got 3 arteries that are blocked. I said well at least you can do something with that, I won't improve breathing. Its good. I'm not gonna bloody well die emphysema then am I? Well at least you can do something about that you can't do sod all with the lungs. I'm the first person to ever say I'm looking forward to a, to a bypass. At one stage there you start thinking seriously about things that would take me a short way up, don't tell anyone else but I got things to see. Well I think there's probably other people truthfully if they probably also may have thought about it, but no one told me, I mean I was look at um, you know the blank, dark, reality was its wasn't a very pleasant way. I was gonna take a shorter way and quicker way.

FA: What is emphysema and can it be fixed with bypasses? Is there anything that can fix it?

MB: I was told early on I had emphysema...

FA: Yeah, but what is it? I want to know what exactly the signs.

Researcher B: Information like that should be in there?

FA: Yes.

MB: And so what breathing...

FA: You don't know what emphysema is?

Researcher A: I mean, its not really appropriate FA for me to say because neither Researcher B or I are medically trained people. However...

FA: What is COPD?

Researcher A: So these are questions you would like to see answered, yep and...

FA: How can you manage emphysema then? Do you know any managing skills for emphysema anyone? And what is there and like how does it differ from asthma? For some told I got both er, take your pick and my grandson just died of asthma, 3 months ago, at 33.

Researcher A: So, did other people feel so, FB you're saying that information there about how you can manage COPD?

FB: Yeah, that should be available to everybody who is diagnosed with it, the first week. I'm not talking six months down the track when you get in to see your specialist or when you...its not available within the doctor's room...

FA: You've got emphysema and that's it, you know, you're dead.

FB: Er, I wasn't handed out anything, or I don't think I was, it was years ago but I'm saying it a really frightening experience that I think if you are not left in the dark about it, its not so bad. Thats all I...

MC: With my wife, she used to um, go over and do exercises and and then swimming and er, it was you sit in a chair and they throw balls and do yoga, all conducted by a person that qualified and she used to look forward to that. I'm normally honest of people, so after about 10 years of my wife saying, she just give it away, she's finished.

FA: Its not a cure, but Yoga its, I've known...

MB: But it makes you...

FA: Its not cure but its...

MC: Its better than sitting home, talking about the wars.

FA: Its works because you can do it in the chair, and she might have been a... I do a few walks down there. I'm out of breath, so sit down or stand still, you know I mean so you in and do all of these things, just sitting. And its something you need to do, you need to keep, because I've got bad circulation and god knows what through not moving around enough and it's a vicious circle, and I'm not blaming anyone except myself. I just say I got the seven deadly sins, two words, what is it, gluttony and sloth.

MA: I'd like to ask you something.

Researcher A: Its best if you ask the group, that might be the way to go.

MA: I brought this up twice now, and I never got a answer yet. With the specialists and all the same. Why is emphysema classified as an old age disease? The simple reason is that its been left as...it doesn't come on you overnight, it just creeps up on you all the time. Once you get see the um, it creeps up on you. Why don't they do what they did years ago, to get rid of TB? X-Ray that person from 30 onwards and then work, work this out. I've over a fact that is over 300 people in this hospital or attached to this hospital, that are on gas but its costs a fortune keep them here going on that, and this whole disease has cost them millions. Whereas, without x-ray, what was I saying? They can do something for emphysema if you are under 50, there's a doctor that pioneered it in this hospital that can operate and give you at least another 5 to 10 years chance on your life, if they get you before 50. So why is the wait till about 70 years old?

FA: Well they got me when I was 30, and they didn't do a damn thing...

MA: Back then they didn't probably know what it was...

Researcher A: So it just gets what you're saying, it gets left and left and left basically.

MF: If I can just say something, just going back to M saying earlier, about when the disease is diagnosed or whether it is correctly diagnosed or not which is usually up to the GP level and because you get no information from the GP. They may give you a puffer and send you away and that's basically where it finishes and until you really get to a respiratory specialist, then you really can't get the treatment that you need for that matter, the information that you need if you are going to get it. Basically until you finish up in a ward like 4B, where you are being treated by the respiratory specialist then you've got some chance of maybe learning something. A classic example of that goes back to the meeting that we had to look at the formation of WestAir. And, a number of the people had never actually attended um, a specialist. They were diagnosed by their GPs and that's where it stayed and in fact, unfortunately we lost one of our members and here was the classic example. We lost him just this weekend just gone who we said at that meeting 'Look, get to see a specialist.' He was being treated by a GP who really wasn't treating him at all. He got emphysema, use the puffer, it's a death sentence, really go away, I don't want to know anything more about you.

MA: Well that seems to be a general thing with the GPs. They never want to refer you higher.

FA: Its not his responsibility, he doesn't feel responsible for you any more. Maybe we've been spoilt. Right from the beginning when we were kids. We're told that we gotta go and have a tooth out, or we gotta go do this or do that and we're waiting to be told to go to a specialist all right. Can we see a specialist without going to the doctors?

MF: Well you can't just do that. No, you can't, your doctor has to approve.

FA: No, that's right, and if you're not all that, I mean, I had an idea that I should have been having some specialist treatment or be seeing people that know a bit more and who did know more than the doctor.. You know you just don't know so, that ignorance is gone but on the other hand, we are left to, I found since being in the hospital now as to what it was years ago, you have to really ask questions yourself and find out for yourself. You have to do a lot more for yourself than you did years ago. Well as children, you shouldn't have to, your parents should be asking or whoever but now we gotta ask ourselves and learn to manage it ourselves. But we gotta be told that we can manage it ourselves because we are like, further back, we are far back generation where me, you know what I mean. Its certainly so different now, so different.

Researcher A: Well that's a very interesting point you've raised here R.

MA: But as you say, R is saying but we gotta know what questions to ask? What R is saying is right. To us, you gotta know the question to question to ask.

FB: I didn't even, I don't think I even know about emphysema up until he said the word, and then I just thought it was another word for asthma. I didn't know there was different things.

Researcher A: What do people do when they go to your GP? What do you, is there much of a too-ing and fro-ing in terms of asking questions or is it was a one-way ticket. How do people feel about that?

MA: The GP never wants to give any advice, because he thinks he's failing himself, where he's not. He's going to send you to the what-say, he would be doing a good turn, but honestly. It took about 4 or 5 years before she ever got to see a specialist here.

Researcher A: Right, so that was along wait. What about you R?

FC: I went to go in and see the doctor and asked if you're alright, need any medications, no problems here that's alright see you later.

Researcher A: Right, end of story?

FC: End of story.

MD: And not to always walk this way.

Researcher A: Sorry?

MD: Not to always walk this way because *sideways always when I feel right*, I don't have to see doctor, I take an oxygen pack. Some doctors prescribe an plus I have an antibiotic.

Researcher A: Right, is this through you GP or through your specialist?

MD: Specialist he always refer to GP he always write letters. Some specialist pumped me with 750mg for one little film. And I to tell them they're no good, and they put me on the gas. Because I know from old Doctor, I have a 100mg per day, and I come good. And the other one, he just pumped me with antibiotic, they want you to get rid of the sickness.

MC: That's alright. Once you get the GP to refer you to the specialist then they have consultations between themselves, backwards and forwards so until you go to the GP say refer me to the specialist, you're just wasting their time.

Researcher A: So can I just go back to...

FA: Make a note of that, make a note of that, there need to be cooperation between the doctor and the specialists. Conversation, communication, before you have any advice, before you gain any knowledge, before you can learn anything about your own condition. There has to be conversation, communication.

Researcher A: We made a note on the tape, so we can assure you that...

MA: Once your doctor refers you to the specialist, the specialist has gotta comply with the doctor.

FA: Supposedly yeah.

MA: He does, there's no two ways about that, by letter he don't call up. By that he tells him what's wrong.

FB: I wonder would the doctors refer you until you were up to 3 puffers a day or whatever, before you get referred to a specialist then you can go to a specialist and see them once a year. But you got that contact with someone that really knows what they are looking at. But it seems like you get your doctor just locked on until you get to a stage you've even got um, not phenomena but you have a chest complaint...

FA: You have to have something wrong with you until you get some treatment like being in hospital.

FB: ...so you can't do this or that. And then they refer you to see someone. There shouldn't be such a gap in that first.

Researcher A: Yeah, so getting to, knowing when you need to, go see a specialist.

FB: Yeah, but I think the doctors need educating on that its not us.

END OF TAPE ONE

FA: I didn't know that was I was doing, but I was, I was crying for attention and I got it. I wouldn't have got it otherwise.

MC: That's another thing there, I noticed that the drug companies haven't done too much in regards to the puffers and that all the what-say....

MF: Ventolin, Valium is what we all need.

FB: Gee, I can get that in the...

MC They haven't improved on that. Its been like that for the past ten years, and they haven't improved. I'll tell you what, that must eventually build up in your system. I was thinking it won't go out.

FA: And what does it do? Does it harm your system?

MC: Well, I'll tell you what, if you don't do what they tell you to do, you can be in big trouble. For the simple reason, if you don't wash you mouth out after you use it, and er, clean your teeth out, you'll be suffering with a real dry mouth and ulcers and lord knows what. You wash your mouth out on average 3-4 times a day, if you use a puffer.

FA: I use three of them.

MC: That, um, Ventolin, evidently is made by one company, what's all the other drug companies doing? There must be a profit in it.

MA: Not a large one.

Researcher A: So the questions that you need to know the answers to seem pretty basic. No, not basic, that's a very important question is probably a better word to use in terms of your, how the disease is going to progress, what you need to do when you first get it...

MC: We won't know.

Researcher A: Maybe these are the sorts of things that need to be discussed with people like yourselves but put in an information booklet, and then the, oh that's right, the other one that seems to be coming out quite clearly is about when to be referred to a doctor.

MC: You can end up going there with a hacking cough when you are 49, and that might be starting to get to a stage, and it gradually creeps up until you are about 65 or 70, then you're too old, they can't take anything out of your lung. If they get you before you are 50, they can operate, and shorten your lung and get rid of all the disease.

FA: Well they'll do anything after my age, you'd think. Cut my lung up.

MC: How old are you?

FA: Seventy-something. I'm 77 this year.

Researcher A: You're talking about the lung reduction surgery.

MF: I'll just say that, you can do it up until about 75 provided that you are in reasonably fit in other respects. Up to 55, lung transplants and you have to be very lucky to get that. With LRS, they'll do it up until about 75.

Researcher A: So...

FA: See, they could have seen me 10 years ago, and I might be in a different state of health all-together now. They could have done it when I was 65 or 60...

MA: Probably the way you've been living...

FA: I haven't. I haven't smoked for 15 years for one thing.

MC: They blame that on cigarettes, but many people get COPD and they haven't even smoked.

FA: And you see, I'm so sorry, I keep push, push, push. My father was a miner come from the north of England, I've just been back there, they've got the angel up there. Well, so many million died with their lungs and I mean, you know, you can't go on complaining going back, back, back, back, to when you were young and everything but I may think there is something in their make-up.

Researcher A: Could well be, could well be, and these are important things I would guess its, the hard part though is in terms of where you're at and where we're at with the booklet is. What to do now isn't it? And how you are best going to manage and deal with it. Tell me, whether the booklet of information, how open and up front do you think you need to be about, what I guess the bad news and good news of COPD?

FB: Anything to get any information that would help. I would be very grateful as a young elderly person if you know what I mean. I'm not an elderly person that is totally dependant on people, and I mean that is very sad when they're in. You've got to learn to manage yourself for as long as you can and once I feel I'm not managing myself, I know that the world won't manage me I know. You've got no, you lose your potential you know, you've got no potential, to be a old age person.

Researcher A: Right, can I just ask you about medicines and medications. What, this is a point that you raised Roy, and the various other people that raised it as well. Now, there seems to be some medications out there that don't do very much, you raised this as well G, and some that work quite well and others that maybe have some side-effects and so forth.

MC: You, well, you got the same trouble that's in this hospital, overdose of antibiotics right? Now you got super-bugs. I think the same thing can apply to this too. Because, there must a germ there that starts it, that's in your lungs, and they caused the what-say and as time has gone on, its become immune to the, Ventolin was in use 10 years ago, and its still in use now. Nothing else was a couple of...some little something that don't do nothing. But Ventolin is the main what-say...

Researcher A: The main thing, yeah. Do, what people think about that in terms of how open you need to be in terms of how open and up front in the booklet you need to be about this stuff.

FB: I think that the average person, not for myself but average person would consent, to have it laid out, as it is, no frills, no...

MD: No [?], nothing.

Researcher A: Except is that, is that information available at all at the present time? Up front, laid out information about medications?

MF: Some things you learn as you go along, but the side effects are there but, then its too late, not that its come to that.

FB: But also with the side effects, it doesn't happen to...I mean, you can take something and you'll have no effect, I take it and I've got a side effect. An average with any medication, you're going to strike that whether you got your...

Researcher A: Does anyone have booklets on medications? No?

MA: There is the occasional one when you go to the chemist with one in the pill box, um how to use it, what uses and some of the side effects perhaps.

Researcher A: Is that about it?

MA: Um, at one stage, I was working in the medical profession, out at Lyell Mac, I managed to get hold of an old library book that listed some of the things that um...all these chemicals etc.

Researcher A: Was that helpful?

MA: Yeah, it was. There was instructions, on at the time I read it and found out that the antibiotics with 3 people expired and they don't make additions from a simple antibiotic, 300,000 well this is with good odds to start with and I'm taking this particular antibiotic for Bronchitis or whatever it was. But generally, from people from the street, no. You would get no information. You get occasionally told by the chemist if you are taking this, don't drive, don't handle machinery and don't drink. That's about the only information you get. When you ask questions like 'What side effects?' or 'What potential if I'm taking that with this other drug?' and no one really wants to know too much.

Researcher A: How do you think it will be if you went to, say that information, lets say can I just pull out something from out of the hat right? Say, it turned out that Serevent you know, some people might be on Serevent, I don't know if I pulled out a bad drug but with Serevent, there was some information Serevent was of absolutely no use to you right? And there, it was written in this booklet that, I'm not saying that Serevent might not be useful but I'm just saying, use it as an example. And you went to your doctor, and your doctor was about to prescribe you Serevent and you had this information, what would it be like for you?

MA: That's a real good what-say. Then you can have a discussion with your doctor...

Researcher A: You feel as though you can have a discussion with your doctor?

MC: About what, why he gives it to you for. Otherwise he's just giving it to you and you take it. You don't know what it is and what its going to do or nothing. But, once you, you learn about it, you're asking 'Why are you giving me this?'

Researcher A: Alright, what about you R? What would it be like for you if you were that situation?

FC: I probably would be ask him all about it.

Researcher A: Right, right. Other people?

MC: I got this information from the pharmacy, and also where I was working at the time, about [?]. Which is a chemotherapy.

FA: Can't hear you love.

MC: Sorry, [?] which is a...chemotherapy, which is used for another treatment. Now this is where they 'ha and hum' and don't take notice and this particular thing is arthritis. When the doctor prescribes that for the next time I went back to get the information that was available on the half sheet, it wasn't full sized from the um, er, from the library, with potential to offer other things like that. She was able to carry a conversation and knew much or more what the doctor was doing in this particular...

Researcher B: Alright, keep going.

MC: And, well that was it. When you couldn't have a discussion, she was the person you we able to discuss on a level, but some people haven't got, or don't understand none of these things even if you do have the information. Because its in too technical terms. You don't understand some of these things.

Researcher A: Right, so it has to be in a basic, easy to understand...

MC: It just as dangerous because its going to upset your breathing, but not a word that going to upset your breathing that we can't understand.

MF: Can you really come and say what you're suggesting without leaving yourself open to all sorts of charges?

Researcher A: This is the other difficult...this is where you get hedged in from the other side...

MF: Yes, yes, I mean you might be able to indicate that there are certain side-effects that are documented so that's as far as I can think you can go.

Researcher A: I think just on that, I don't want to go on about too much about what we're doing but, with the Cochrane review information that would be included in this booklet. Basically you got the results of lots and lots of studies, that can be used to say 'Look, the evidence looks like this medication doesn't do very much or looks as though it does something or looks as though it does absolutely nothing, you know. So you've got that sort of information you can put in. Even so, its still tricky, you know, its still very tricky.

MB: It's a medical minefield...

MF: I would imagine, yes...

Researcher A: They're pretty wealthy companies lot of these...

MF: That's for sure, but I think as you were saying before, about just use Sarevent as a name. I think probably just about everyone who is on, the basic common list of puffers for a start. One of the best things, and I'm not to sure how they prepared it up on Ward 4B, but Respiratory Ward there is a board that has all of the puffer and their various forms and also in their categories. Whether they are preventers, whether they contain steroids or not, and all of the examples of the packaging as well too, which is excellent. But you gotta actually be admitted to Ward 4B before you ever get to find that information out, what is there and what is it used for.

Researcher A: And that's pretty damn confusing before you get to see what's going on with all these medications is it? Is that the list of them or is it fairly straight, people got a fairly good handle on that?

FB: Well I did.

MF: Well there probably about four different categories or there are 4 different purposes for using these things which in most cases, most people are, having them as treatments.

Researcher A: Right, G, what about you? How do you feel about all the medications? Are you clear about what they do and so forth?

MD: Yes, I got a book actually. About all the medicine, what it does, how you fix it up. With this other one, it didn't say, and the doctor gave it to me, oh yeah, this one will help, yes this is what you asked for, the specialist. Because I was getting like, woody legs, and I don't want to lose it because once I lose it, I won't be driving a car, and this, I did it then.

Researcher B: What is your book G?

MD: I got it from...

END OF TAPE 2
NOTE BY RESEARCHER B

While tape was being changed discussion was:

- *one participant said they had and used a book called something like A-Z of Medicines and another said they had one too*
- *the fact that patients want "all the information" about medicines, positive and negative*
- *that language needs to be very straightforward.*

FA: So I think future generations, you're going to have plenty of work, you'll never be out of work, you won't, you won't. Because all this going on since there are no other jobs. Kids will be too sick anyway to do factory jobs or any other jobs because they're be too fat, they won't be moving around enough. There all these electronic, network god knows what.

Researcher A: Particularly with...

FA: So I think gotta start with other things, you gotta come in from another level, the whole lot.

Researcher A: OK, with this stuff about, I just want to get a few things I'm interested to know whether they're... I think I you've probably answered some of these already R, I want to double check, just the idea of how COPD normally progresses in people. Is that an area you...

FA: I still don't know what COPD is.

Researcher A: Yes, so that taken on board, knowing what it is and how it progresses would be...J?

MF: The only time you get diagnosed with it is when you got it, and it's a thing that creeps up, it just doesn't happen overnight.

Researcher A: So is it all over then? Is it?

MF: Its like...

MD: You can't get rid of it.

FA: You can manage it. What we can aim for is the only thing I can hope for is being able to manage it, that's all. Like I just discovered I'm too old for an operation, so are you.

Researcher A: Right, OK. J, is there something you want to say there? OK, Marlene, how do u feel about this profession business? Is that an important part of the whole deal?

FB: Well it is the whole deal isn't it? I mean its going to progress. So you can't take it back so, you're looking forward but you do need to know what you are looking forward to, and how you can maintain your own level without falling down further.

MF: If I was going to say anything, that's about all you can do. You got to realise that it is a sentence but it can be controlled, it will deteriorate with time but given the right management, then you can lead a reasonably normal life.

Researcher A: Is that what you say to people when they come to WestAir?

MF: Yes, I think we gotta say that, um...unfortunately for most of the group now is happen is going back a couple of years ago we were involved in a meeting here. It was virtually said and it was the government that said it we were really past our use-by dates. And the focus was going from those who were suffering from COPD or lung diseases of various sorts to be shifted back to the younger generations, in fact even down to the level of children and that they were going to put as they have done through the um, Western what that name? General Practice. At one stage they had nurses who went out, there were are couple of them, who actually went out, visited patients in their homes,

and they did a fantastic job. We were brought in a few of us and it was discussed what was happening with the project and the Government was just turning the money off for that. It was going to be completely redirected and there were going to be clinics that were going to set-up within the general practice area. So they could pick up like something that was mentioned earlier, but they could pick-up the incidents of lung problems at a much earlier stage and while that's fine, it really left those some-what older, who were already identified with lung problems but were not going to get any better, with nowhere to go. Of course that's still, the case. I not sure how successful this move to the general practice has been by running clinics for 3 to 6 months and there one particular spot.

Researcher A: I've had some involvement with that and only one or two of those have actually survived.

MF: Yes, and I'm just wondering how long will it be before that's stopped and another thing is looked at.

MA: That's the Government policy, they're sharks.

MF: There no financial thing that gets chopped off.

MC: The put a coordinator in the what-say, goes for 6 months, the coordinator does an excellent job, and what do they do? Pull the rug out from under the coordinator, and everyone's left. Hopeless.

Researcher A: So does that mean if you...I'm

MC: Work it out this way. As J said, there's a few nurses that used to come around and so forth, and there's now got too much of a job for them, its too big. Linda used to go over and see us about every three months, now, well they don't come now but she ended up coming every twelve months.

Researcher A: Yeah, and then you need to still....

MC: It got worse.

FA: What's going to happen to your book?

Researcher A: Well, just getting back to the book, so that mean if you did have a good self-help book I guess if you like, but that's probably one the more valuable tools you can have, bearing in mind that...

MC: You would have more information that you got now.

FA: Yeah, like a manual. I reckon we can make use of anything. I've got a, I'm real proud of my, what you call it? I had it on the back page of your magazine.

MF: Gopher.

FA: Gopher. And I took me dog out this morning, it thinks its a Husky, it thinks its pulling me along, but like, that's good, but I mean, I get air but I don't really get any exercise, the dog gets the exercise, which it doesn't matter, I mean...

MA: Its like a lot of things, knowledge is power and power to yourself if you can overcome or help. If you are totally ignorant about things, you're kept in the dark.

MF: I think there is a lot of information out there but its all in little bits and pieces, as well too. Where it needs to be collated and put into a sort of thing you were talking about.

FA: And the doctor, why should the doctor bother to push to say 'Oh look out' learn this, learn that, look after yourself you know, I mean. He just said you got emphysema and that's it, you smoked didn't you? I mean why should he say well stop smoking, well I did eventually but it took, I knew I was gonna stop, and I did but like any, he could of said everyday stop smoking and until the time came I didn't.

Researcher A: You are going to be ready to receive that information are you? Are you going to be ready to take it in?

FA: The time comes when you do it, and I've got a lovely theory about it, I've got something I practice to and I did it. Like I knew it would come and the thing is, oh, I've lost me tread now sorry.

Researcher A: There are some good points there. I think...have you got any other things you want to...

Researcher B: No, I think probably people are getting a bit worn out now, but you know you were talking about like a manual, what should the booklet look like? Should it be a file or should it be stapled together or should be something were you can add new information you know, how much do you want? I mean you don't want a great thick...maybe you do, maybe you want a big thick...

FB: I do have a suggestion on the booklet and I got the original package that was given to me by WestAir last year. That would have been twelve months or something, now. I'd like to drop that into you because that's got every little bit that we're talking about here in that bag. They're basic, and its not frightening, look you don't want to be, I'm not saying don't be honest but not too honest. Don't say that the average person lives 10 years after so-and-so or not too old. You can't do that. Don't put it off either

Researcher A: That's where your input is going to be valuable because to know that, you use a fine line to...

FB: Others may not feel that way, that's how I feel...

Researcher A: Rest of us can guess, its only the people that actually know can really tell you how, you know. Look, I remember seeing a leaflet on cigarette smoking. You know, the smokers all said that they wanted a picture of a lung chopped in half with all the tar pouring out of it, you know the average person thinks 'My god, what a shocking picture.' But the cigarette smokers said 'No, put that picture in

the leaflet.' That's the sort of thing that gets off smoking, you know. So there it was, this leaflet I saw had this picture of a lung chopped in half.

FA: Its on TV. A lot of my grandchildren see them, and some of them are brilliant, you know really clever, and they smoke. But and its not a matter of brain, i just...

Researcher B: Some people have been pretty quiet, I'm just wondering from you, how much honesty you want in the...

FC: I want to say about that. It was only a short while ago I was told that I had COPD, but I've been on this oxygen for nearly three years, and I asked the doctor what COPD is said that's what is wrong with you, that's why your lungs keep on collapsing.

MD: I see what you mean, she solved the liver problem, the thing wrong is the lungs. He's got the brains, he a good man, a very good man. I got a grandson who will become doctor of science, in Brisbane this year. Because this computer here puts me on hold, six years back. I've been to nuclear medicine, twice, and I was ready to have an operation from Dr. Peacock. I come there never need to remind him.

MA: If you go out there in the corridor, go down the street, and if somebody walked up to them and ask 'Do you know what COPD is? You know what lung diseases are?' They probably come up with Lung Cancer and TB is the first that probably come to mind and that's about the limit. But everybody knows, no-one is aware of it, it's the fourth most expensive disease in the country.

Researcher A: Absolutely.

MA: Even the western community down here, around to the west, we've got the worst air. We've got the most people here with lung diseases including cancer...

Researcher A: We're big on lung disease.

MA: When they're opening up the new bit of stuff around the Port Adelaide and Rwater area there, this new industrial area...the parklands etc.

Researcher A: Yes, go on M.

FB: Why can't there be a centre like there's the diabetic centre next door and the epilepsy, why isn't there a centre for us? When your questions are answered. Alright we belong to a club and if I had a problem I went to you and said this and that, what would you think because you researched this and you've looked into it over the years I mean, but they do have centres for different things but we don't a centre. We have no back-up as when diabetics can go in and say I've got a certain problem with them...

Researcher A: So in generally speaking, diabetes and asthma and so forth and heart disease tend to do a lot better than COPD.

MB: I've noticed that all the hospitals around there was about, has this been an order from the government that they start look into this lack of emphasis and er, lack of emphysema. Starting to look into it. They just starting to wake up that it's a disease, and they're going to be spending millions on it.

Researcher A: Yes, it needs to be more of a priority.

ME: Yes just what that lady said, a clinic where you can go and see someone that knows something about the job, not a GP. A GP doesn't expect to know anything in that regard.

FB: Why should he? He says to himself, why should he?

ME: Its gotta go...

MF: You talk at all or have anyone that liases with the Lung Foundation Researcher A at all?

Researcher A: We have some contact with them, yeah some mainly down at repat.

MF: I just wanted you know to talking about you know, people in the street that Laurie I think raised a fair comment as well too. They have put out a paper, which is intended to, and I don't know if you are familiar with it to publicise their statement etc, which of course was intended to be pushed to Government and so forth.

Researcher A: They have to be by far the strongest opponents really, to try and raise the national profile...

MF: That's right, and some of those profile figures are quite incredible, whereas the Lung Foundation.

Researcher A: We're going to have to wind it up I think because....

END OF TAPE 3

Appendix 6 Summary of report on Focus Group 2 from Harrison Health Research , Harrison Market Research Pty Ltd, Adelaide

EXECUTIVE SUMMARY

From our perspective the hour and a half of discussion with the COPD patients and their carers can be distilled down to the following five key findings.

Key Finding 1: For the majority of participants, doctors and hospital personnel have been the main source of the information that they have acquired about COPD. For the most part the information seems to have been communicated verbally. There was not a lot of evidence that the patients who took part had searched out information on the subject.

A clear distinction needs to be made in relation to the two carers who were present. They appeared to be very well informed but their active involvement in a local support network is no doubt partly the reason for this.

Key Finding 2: During the focus group it was decided to present the participants with a fairly extensive list (please see appendix 1 and 2 for the two forms used during the focus group) of possible topics. These subject areas had emerged from previous discussions with patients and carers by the Clinical Epidemiology and Health Outcomes Unit.

The clear message that came out of this focus group is that the information people seek is very basic detail about the disease, the stages that are involved as it progresses and how they can best cope at each particular point in time with the consequences. In this context knowing about the likely impact of depression was deemed to be very important. So too were strategies for every day living even down to things like “how to take the exertion out of showering and making a bed”.

Key Finding 3: There was unanimous agreement among participants that the proposed COPD booklet should not only be easy to read but it should clearly specify the realities of the disease.

However, the consensus of opinion was that the information in the booklet should not be so confronting that it could be unnecessarily alarming for its readers.

Key Finding 4: Towards the end of the session participants were given an example of how the booklet might be written. In particular, they were invited to read and critique a page on the subject of 'Home Oxygen for COPD'.

The resulting comments were very positive and supportive. The view was that the commentary was well put together and that it had provided new insights to many people.

Key Finding 5: According to the participants they would have not hesitation about approaching their GP if they were to read about a new treatment for COPD.

Whilst we have some doubts about the validity of this outcome, the message to us is that the booklet should have an actual chapter (or sub heading at least) which gives patients and their carers both the "permission" and "confidence" to ask their doctor about issues that they feel are important to them.

Appendix 7 Style Evaluation Record Forms used by panellists

ROUND 1

How easy was this sheet to read?

Very easy Quite easy Quite difficult Very difficult

Did you learn anything from reading this sheet?

Yes, a lot Yes, a bit Very little Nothing

Would you talk to your doctor about *[topic of sheet]* after reading this?

Yes, definitely Yes, probably Probably not Definitely not

Please say why you would/wouldn't talk to your doctor

.....

[Space to record comments, explanations and discussion]

Topic /panellist/ date

ROUND 2

How easy was this sheet to read?

Very easy Quite easy Quite difficult Very difficult

What did you think about the style of the writing?

Too childish and simple About right Too complicated

What did you think about the amount of detail and information given?

Not enough About right Too much

How much of this sheet would you read if it came from the hospital?

All of it Most of it A bit of it None of it

Did you learn anything from reading this sheet?

Yes, a lot Yes, a bit Very little Nothing

Would you talk to your doctor about *[topic of sheet]* after reading this?

Yes, definitely Yes, probably Probably not Definitely not

Please give us any other comments on this article

.....

[Space to record comments, explanations and discussion]

Topic /panellist/ date

Appendix 8 Format interview guide and recording sheet

FORMAT PREFERENCES: INTERVIEW GUIDE

PARTICIPANT

DATE.....

POINTS AT START

- *Contains summaries of all treatments so there is a lot of information*
- *It will take some time to read and people might have to put it down and pick it up several times before they get to the end*
- *The idea is that people can read about treatments and then talk to their doctor if they want more information or want to try something from the booklet*
- *As more research is done, we could put out new summaries*

OVERALL QUESTIONS

How would you use this kind of booklet?

If you wanted to talk to your doctor about something from the booklet, would you take the booklet (or a page) with you, or would you remember the topic to bring up when you went to the doctor?

Would you like blank sheets included for your own notes? How important is it to put out new summaries as new research comes out?

We will give this booklet free to patients but as a guide to how valuable it would be to you, how much would you pay for something like this if it was for sale?

FORMAT ASSESSMENT RECORD SHEET

Format **Participant**

How convenient is this format for reading?

Very convenient

Quite convenient

Quite inconvenient

Very inconvenient

Would you find this format convenient to keep at home so you could look at it when you needed to?

Very convenient

Quite convenient

Quite inconvenient

Very inconvenient

Would you find this format convenient to take to the doctor if you wanted the doctor to look at something in the booklet?

Very convenient

Quite convenient

Quite inconvenient

Very inconvenient

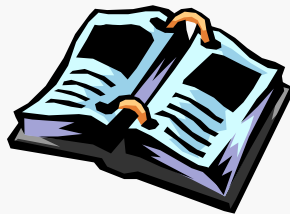
Appendix 9

Talking to your doctor about COPD
Clinical Epidemiology and Health Outcomes Unit. The Queen Elizabeth Hospital.
South Australia, 2002 (extract showing title page to page 44)

NOTE: This extract is included as Appendix 9 in the print copy of the thesis held in the University of Adelaide Library.

Appendix 10 List of tips given with manual

Tips for getting the most from your copy of *Talking to your doctor about COPD*



- As well as reading the booklet yourself, show it to family members or friends who help you manage your lung condition
- If you are too busy to read it all at once, you may prefer to read important parts first
- Show your GP the booklet – there is an order form in the front so the doctor can send for a copy if they want one
- Do talk about the information with your GP - mark one or two important points to talk about in one appointment

Appendix 11 Order form for doctor

COPD booklet study

Your doctor may like to have a copy of this booklet

Please pass this order form and reply-paid envelope to your doctor, so the doctor can order their own free copy of *Talking to your doctor about COPD*.

ORDER FORM

I am the doctor of (patient name) who has received *Talking to your doctor about COPD* as part of the COPD booklet study. Please send me a free copy of the booklet for myself.

Name

Postal address.....

.....

.....

Please post the order form using the post-paid envelope provided.

For information about the study, please contact Ms Melanie Harris (phone 82227933 or email melanie.harris@nwahs.sa.gov.au) or Dr Brian Smith (phone 82226531 or email brian.smith@nwahs.sa.gov.au) of The Queen Elizabeth Hospital and Health Service.

Appendix 12 Invitation to participate and reply form

COPD BOOKLET STUDY

Dear [name of patient],

I am writing to invite you to take part in a study being done by The Queen Elizabeth Hospital and the Flinders Medical Centre. This letter gives you information about the research. Before deciding whether you want to take part, you might like to talk to a friend, relative or your local doctor.

What is the study about?

The study wants to find out if the health of people with COPD gets better if they have a booklet about the disease. Different types of booklet are being tested.

Why have I been chosen?

You have been selected because hospital records show that you were recently in hospital with COPD, or that you attended a clinic for care of your COPD.

What happens if I take part in the study?

If you are interested in participating, please fill in the slip that comes with this letter and return it in the envelope provided, or call 8222 7933 to talk to the researcher. If you agree to take part, a researcher will contact you to arrange an interview time. In the interview the researcher will ask you questions about your health. This will take about an hour. After this, you will get a booklet. The researcher will visit you again 3 months after this visit and 12 months after this visit. They will ask the same questions at each visit.

What happens to personal information from the study?

Your personal details and answers will be kept in a locked cabinet at The Queen Elizabeth Hospital or The Flinders Medical Centre and will only be used for this study. Only the investigator and the researchers will have access to your name and address. Your personal details will be destroyed at the end of the study. Your name and address will not appear in any way in the results of this study.

What happens if I do not participate in the study or if I drop out of the study?

You are quite free to choose not to be part of the study. If you do join, you may drop out at any time. Staying out or dropping out will in no way affect your treatment at The Queen Elizabeth Hospital or The Flinders Medical Centre. If you continue with the study, this is greatly appreciated.

What are the benefits of the study?

The aim of this study is to find out if there are benefits for people who have COPD if they get written information about research on treatments. The study also wants to find out how people use booklets like this. Results will be published in the medical literature to help other groups to decide whether booklets will be useful to patients. The results might also help us to create better booklets.

What if I have questions?

If you have questions about the research, you can call Dr. Brian Smith (Investigator) or Melanie Harris (PhD candidate) on 8222 27933. If you wish to talk to someone at the hospital who is not part of the study, or if you want to make a confidential complaint, ring Paul Miller, from the Ethics of Human Research Committee at the Queen Elizabeth Hospital on 8222 6841.

If you choose to take part in this study, please complete the attached slip and return it in the postage paid envelope provided.

Yours sincerely,

Dr

Hospital:

Please complete this form and return it to the Queen Elizabeth Hospital in the envelope provided **or** phone Melanie Harris on 8222 6898.

Last name: _____

First Names: _____

Contact phone number:

Home () _____ Work () _____

Address: _____

Please tick appropriate box and return in envelope provided:

Yes, I am interested in participating in the study and I give permission for a researcher to contact me.

No, I do not wish to participate. Reason (optional) _____

Signed : _____

Appendix 13 Example of recruitment survey form

COPD Booklet Study: Evaluating forms of patient information

Please sign and hand this invitation to the patient if the patient meets the following criteria:

- severe or moderate COPD (FEV1<60% predicted OR breathlessness on exertion limiting daily activities)
- well enough to participate and able to give informed consent
- patient or carer reads English at basic level
- not part of another trial

SURVEY WEEK: reasons patients are not invited to the study

For the week 9-13 Feb, please complete for every patient who leaves without the blue invitation from their file.

- | | |
|---|--|
| <input type="checkbox"/> Not well enough | <input type="checkbox"/> Not COPD |
| <input type="checkbox"/> Too many other issues | <input type="checkbox"/> COPD mild only |
| <input type="checkbox"/> Cognition problems | <input type="checkbox"/> Does not read English |
| <input type="checkbox"/> Refused | <input type="checkbox"/> In another study |
| <input type="checkbox"/> Did not attend | |
| <input type="checkbox"/> Other (please specify) | |

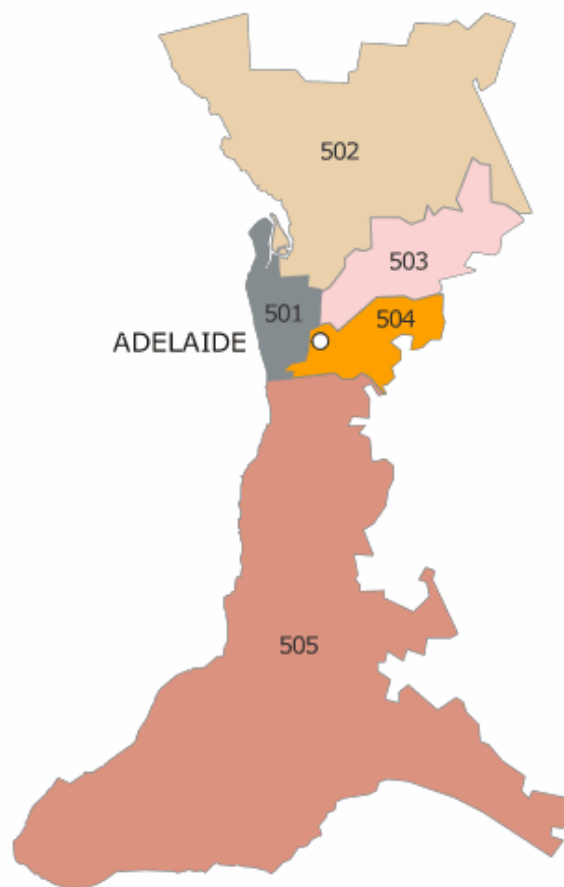
Please put this form in the tray provided



If you have questions, please contact Brian Smith or Melanie Harris (82227933)

Appendix 14 Recruitment areas and distribution of socioeconomic disadvantage

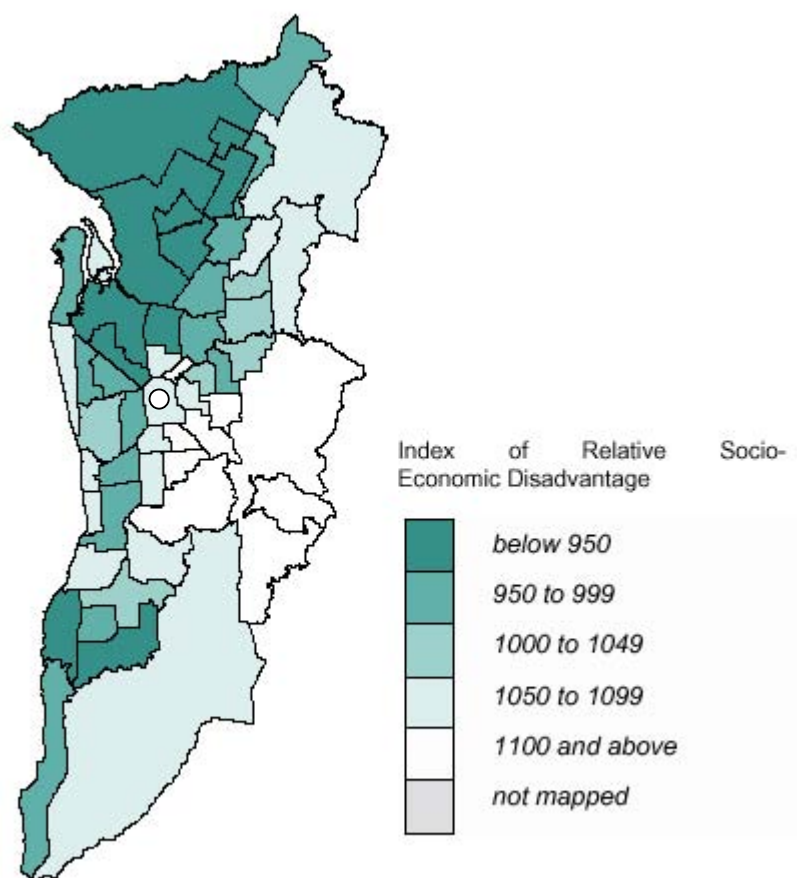
Recruitment areas corresponded with regions covered by two SA Divisions of General Practice. The intervention area corresponded with the Southern Division of General Practice, shown as 505 on the map below. The southern half of this area is comparatively sparsely populated with most participants coming from the metropolitan northern half. The control area corresponded with the Adelaide Western Division of General Practice shown as 501 on the map below.



Map showing Adelaide Divisions of General Practice.
White circle shows location of City of Adelaide.

(Map from Adelaide Divisions of General Practice http://www.adgp.com.au/site/index.cfm?module=DIVISION&state_code=SA)

Both recruitment areas included a range of socioeconomic conditions, as shown below.



Map showing distribution of Index of Relative Socio-Economic Disadvantage in metropolitan Adelaide area. (Hetzel et al 2004). White circle added to show location of City of Adelaide.

Appendix 15 Example of interviewer administered questionnaire: Questionnaire for 3 month interview

3 Month Form

Oxygen when interviewed? Y N

Date place of interview. Interviewer

Patient number.....Name

Address *if changed*.....

GP name, street, suburb *if changed*.....

If not yet collected:

Age started school.....left school.....If extra full time study, no. of yrs of extra study....

	The first questions are about the printed information that was given out. (show)	
1	Do you remember receiving the information? <i>(y=1, n=2, dk=9)</i>	—
2	Did you or your carer read any of the information? <i>(y=1, n=2, dk=9, N/A=8)</i>	—
3	<i>If read:</i> Did you/they read part or all of it? <i>(part=1, all=2, dk=9, N/A=8)</i>	—
- 4	<i>If read:</i> Did you or your carer learn anything from the information? <i>(y=1, n=2, dk=9, N/A=8)</i>	—
- 5	<i>If read:</i> How often did you or your carer refer back to any of the information after you had read it for the first time? never(1) 1 to 5 times(2) 6 to 10 times(3) more than 10 times(4) <i>(dk=9, N/A=8)</i>	—
- 6	<i>If read:</i> Did you talk about any of the information with your doctor? <i>(y=1, n=2, dk=9, N/A=8)</i>	—
-- 7	<i>If yes:</i> Did your treatment change at all because of what you talked about? <i>(y=1, n=2, dk=9, N/A=8)</i>	—
- 8	<i>If read:</i> Overall, how helpful was the information to you or your carer: very helpful (1) quite helpful (2) not helpful (3) <i>(dk=9, N/A=8)</i>	—
....	<i>If yes:</i> Do any of the following describe why you found the information useful?	
-- 9	I understand more about my lung condition <i>(y=1, n=0, N/A=8)</i>	—
--10	I understand more about my treatments <i>(y=1, n=0, N/A=8)</i>	—
--11	I felt more able to ask questions when I visit the doctor <i>(y=1, n=0, N/A=8)</i> <i>If other reason volunteered, enter here:</i>	—
	
	
	
	Some questions about you.	
	As far as you can remember, what was the date of your last :	
	<i>If influenza vaccination overdue at baseline:</i>	
(12)	influenza (flu) vaccination ___/___/___ (dd/mm/yyyy - enter available) never <input type="checkbox"/> dk <input type="checkbox"/>	p
13	bone density test ___/___/___ (dd/mm/yyyy - enter available) never <input type="checkbox"/> dk <input type="checkbox"/>	p

	I will read a number of statements which people have used to describe themselves. For each statement, please tell me how you feel right now at this moment by choosing "1 - Not at all", "2 - Somewhat", "3 - Moderately" or "4 - Very much" (<i>white card</i>).	
14		I feel calm —
15		I am tense —
16		I feel upset —
17		I am relaxed —
18		I feel content —
19		I am worried —
20	(<i>Change to cream card:</i>) I have enough information about my lung condition	
	Some questions about the GP that you see most often.	
	Please tell me how much you agree with each of these statements on this 7-point scale. (<i>cream card</i>) Very strongly disagree = 1 Strongly disagree = 2 Disagree = 3 Uncertain = 4 Agree = 5 Strongly agree = 6 Very strongly agree = 7 (dk =9)	
21	The doctor told me just what my trouble is	—
22	After talking to the doctor I know just how serious my illness is	—
23	The doctor told me all I wanted to know about my illness	—
24	I am not really certain about how to follow the doctor's advice.	—
25	The doctor seemed interested in me as a person.	—
26	The doctor seemed warm and friendly to me.	—
27	The doctor seemed to take my problems seriously.	—
28	I felt embarrassed while talking with the doctor.	—
29	I felt free to talk to this doctor about private matters.	—
30	The doctor gave me a chance to say what was really on my mind.	—
31	I really felt understood by my doctor.	—
32	The doctor did not allow me to say everything I had wanted about my problems.	—
33	The doctor did not really understand my main reason for coming.	—
34	This is a doctor I would trust with my life.	—
35	The doctor seemed to know what (s)he was doing.	—
36	The doctor has helped me deal with my worries about my illness	—
37	The doctor seemed to know just what to do for my problem.	—
38	I expect that it will be easy for me to follow the doctor's advice.	—
39	It may be difficult for me to do exactly what the doctor told me to do.	—
40	I'm not sure the doctor's treatment will be worth the trouble it will take.	—

	Now a quiz. (For quiz, score correct answer as 1, anything else as 0)	
41	What do you call your chest condition? (emphysema, COPD, COAD, or chronic bronchitis = 1, other = 0. Max score is 1)	—
.....	Which of the following can help you manage your chest condition?	
42	- Stopping smoking (y is correct)	—
43	- Reliever medications (y is correct)	—
44	- Vaccinations (y is correct)	—
45	- Exercise (y is correct)	—
46	- A sugar rich diet (n is correct)	—
47	- Drinking very large amounts of water (n is correct)	—
48	Sometimes people with your chest condition get very sick for a time. Which immunisations or vaccines might help reduce the risk of getting very sick? (pneumonia/pneumovax = 1, flu/influenza = 1. Max score 2 for this question only.)	—
.....	Which of the following symptoms show that you might be starting to get very sick with your chest condition?	
49	- Breathlessness gets worse (y is correct)	—
50	- Coughing up more phlegm (y is correct)	—
51	- Phlegm changes in colour (y is correct)	—
52	- Appetite for food increases (n is correct)	—
53	Is there any benefit in stopping smoking if you already have COPD? (y is correct)	—
54	When should you take relievers such as Ventolin, Bricanyl, Airomir and Asmol? (mention of regularly through a day OR whenever breathless is correct)	—
55	What is wrong with the lungs in diseases such as COPD, emphysema and chronic bronchitis? (mention of damage to air sacs OR blocking OR cough OR phlegm is correct)	—
55b	Do you smoke now? (y=1, n=2)	—
	<p>You have previously completed a questionnaire telling us about how you were feeling and how your lung disease was affecting your life. This is a follow up questionnaire designed to find out how you have been getting along during the last 3 months.</p> <p>When you are answering the questions this time I will tell you the answer you gave us the last time. I would like you to give your answer today keeping in mind what you said last time. For example, let's say that last time I asked you how short of breath you were while climbing stairs [give green card] and you said " 4 Moderate shortness of breath". If you were exactly the same today, you would answer 4 once again. If you were more short of breath you would chose 1, 2 or 3 and if you were less short of breath you would chose 5, 6 or 7.</p>	

I would now like you to describe how much shortness of breath you have experienced during the last 2 weeks while doing the five most important activities you have selected.

56 Please indicate how much shortness of breath you have had during the last 2 weeks while
[insert activity 1 from baseline] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose *[insert answer from baseline]* **[green card]**:

- 1. Extremely short of breath }
- 2. Very short of breath }
- 3. Quite a bit short of breath }
- 4. Moderate shortness of breath }.....
- 5. Some shortness of breath }
- 6. A little shortness of breath }
- 7. Not at all short of breath }

57 Please indicate how much shortness of breath you have had during the last 2 weeks while
[insert activity 2 from baseline] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose *[insert answer from baseline]* **[green card]**:

- 1. Extremely short of breath }
- 2. Very short of breath }
- 3. Quite a bit short of breath }
- 4. Moderate shortness of breath }.....
- 5. Some shortness of breath }
- 6. A little shortness of breath }
- 7. Not at all short of breath }

58 Please indicate how much shortness of breath you have had during the last 2 weeks while
[insert activity 3 from baseline] by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose *[insert answer from baseline]* **[green card]**:

- 1. Extremely short of breath }
- 2. Very short of breath }
- 3. Quite a bit short of breath }
- 4. Moderate shortness of breath }.....
- 5. Some shortness of breath }
- 6. A little shortness of breath }
- 7. Not at all short of breath }

59	<p>Please indicate how much shortness of breath you have had during the last 2 weeks while <i>[insert activity 4 from baseline]</i> by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [green card]:</p> <ol style="list-style-type: none"> 1. Extremely short of breath } 2. Very short of breath } 3. Quite a bit short of breath } 4. Moderate shortness of breath }..... 5. Some shortness of breath } 6. A little shortness of breath } 7. Not at all short of breath } 	
60	<p>Please indicate how much shortness of breath you have had during the last 2 weeks while <i>[insert activity 5 from baseline]</i> by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [green card]:</p> <ol style="list-style-type: none"> 1. Extremely short of breath } 2. Very short of breath } 3. Quite a bit short of breath } 4. Moderate shortness of breath }..... 5. Some shortness of breath } 6. A little shortness of breath } 7. Not at all short of breath } 	
61	<p>In general, how much of the time during the last 2 weeks have you felt frustrated or impatient? Please indicate how often during the last 2 weeks you have felt frustrated or impatient by choosing one of the following options from the card in front of you, keeping in mind that last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]</p>	
62	<p>How often during the past 2 weeks did you have a feeling of fear or panic when you had difficulty getting your breath? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]</p>	
63	<p>What about fatigue? How tired have you felt over the last 2 weeks? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [orange card]</p>	
64	<p>How often during the last 2 weeks have you felt embarrassed by your coughing or heavy breathing? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]</p>	
65	<p>In the last 2 weeks, how much of the time did you feel very confident and sure that you could deal with your illness? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [yellow card]</p>	

66	How much energy have you had in the last 2 weeks? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [pink card]	—
67	In general, how much of the time did you feel upset, worried or depressed during the last 2 weeks? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]	—
68	How often during the last 2 weeks did you feel you had complete control of your breathing problems with shortness of breath and tiredness? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [yellow card]	—
69	How much of the time during the last 2 weeks did you feel relaxed and free of tension? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [yellow card]	—
70	How often during the last 2 weeks have you felt low in energy? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]	—
71	In general, how often during the last 2 weeks have you felt discouraged or down in the dumps? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]	—
72	How often during the last 2 weeks have you felt worn out or sluggish? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]	—
73	How happy, satisfied, or pleased have you been with your personal life during the last 2 weeks? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [grey card]	—
74	How often during the last 2 weeks did you feel upset or scared when you had difficulty getting your breath? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]	—
75	In general, how often during the last 2 weeks have you felt, restless, tense, or uptight? -- last time you answered the questionnaire you chose <i>[insert answer from baseline]</i> [blue card]	—

Next appt (if arranged) Place.....

Date/...../..... Timeam/pm

Appendix 16 Samples of vignettes used in qualitative study





Appendix 17 Theme guide for Phase 1 of qualitative study

Interviewers explored the following aspects of behaviour in relation to the COPD

Evidence manual:

<p><i>History</i></p> <p>Describe diagnosis.</p> <p>What stage of the condition did you get the booklet?</p>	<p><i>Beliefs</i></p> <p>About yourself – your role, GP's role, specialists role in providing info and managing condition.</p> <p>What you can control</p>	<p><i>Facilitating/inhibiting factors (after decision)</i></p> <p>Things that help or get in the way once you have decided to do something to improve your health generally, and in relation to any changes you thought about /decided to make from the booklet?</p>
<p><i>Normative system:</i></p> <p>Other people who are important to you – what did they think of it? Are they involved in helping you manage?</p> <p>Family/partner</p> <p>Groups</p> <p>What you think your doctor wants you to do</p>	<p><i>Motivation</i></p> <p>Your values, drives (personal family), attitudes and emotions.</p> <p>Describe a time you asked or thought about asking the GP/specialist a question from the booklet. What made you decide to do it?</p>	<p>Anything else?</p> <p>Picture – to help you remember what you thought and did when you received booklet</p>

Appendix 18 Theme list for Phase 2 of qualitative study

Theme list for phase 2 of qualitative interviewing

1. Please tell me about what happened when you were diagnosed with your lung condition.
 - 1.1 *How long ago were you diagnosed?*
 - 1.2 *What type of information were you given then?*
2. Did you read the COPD booklet? (*Show vignette: Man or woman reading booklet*)

If no

3. Based on your experience of getting the book, what would you say might have made it difficult or impossible for you to read it?
 - Anything else?

If yes

4. What were your thoughts and feelings about the information in the book?
 - Anything else?
5. Did you feel that you needed to do anything in relation to your lung condition after reading the book?
 - Anything else?
6. What are your feelings about how easy it was for you to read and understand a book like this?
 - Anything else?

All

7. What do you believe are the advantages of reading a book like this?

If needed

- 7.1 Can you tell me a bit more about why you feel that way?

8. What do you believe are the disadvantages of reading a book like this?
9. Would you tell me about any people you think might disapprove of a book like this?

If needed

- 9.1 What about reading it through?
- 9.2 What about asking their doctor some of the questions?

10. Did you ask your doctor any questions from the book? (*Show vignette: Man or woman with booklet at Dr.s`*)

If no

11. Did you feel that you wanted to ask your doctor anything from the booklet?

If yes

12. Can you tell me about what happened?

If needed

- 12.1 Did you take the booklet with you?

All

13. What would you say might have made it difficult or impossible for you to ask some of the questions?

14. What do you believe are the advantages of asking your doctor some of the questions from the book?

If needed

- 14.1 Can you tell me a bit more about why you feel that way?

15. What do you believe are the disadvantages of asking the questions?

16. What are your feelings about how easy it is for you ask your doctor these kinds of questions?

17. Are there any other issues that come to mind when you think about someone with your lung condition getting a booklet like this?

Appendix 19 Sample transcript of in-depth interview for qualitative study

- *I When did you find out about your COPD?
- P It would be earlier this year I think. Yes, I went into Flinders and they said that I had it.
- *I Right. What had you thought before that?
- P I just thought I was out of breath and getting old and crotchety, actually.
- *I Did they give you any information then?
- P No. We got contacted then by the lass from your place and she went through it. I took the matter up with the doctor and the doctor gave me an inhaler and that's as far as its gone.
- *I Did you read the book?
- P Oh yes.
- *I Here is another man who has just got his book from the researcher. What were your thoughts and feelings when you read the information in the book?
- P Quite good in the general sense of things. To be quite honest, when I received the book I didn't have a clue what whatever-it-is was. So I didn't realise what it was all about. I had shortness of breath and I went into hospital for it. They sort of said, you now, you've got shortness of breath because you've got COPD but also I have ... emphysema, that 's the shot. And then they said that and went on to ask me about my smoking habits, which of course I gave up 35 years ago and they still say I have emphysema from smoking which I find very very difficult to understand or comprehend.
- *I And have they ...
- P They have done nothing.
- *I So nobody has tried to explain anything?
- P No. Well, they say that the mucus joins at the bottom of the lungs and never moves. Well, I don't know. If it stays there for 35 years it must be pretty good mucus. And I don't want to get rid of it. (laughs). I mean I was a heavy smoker. I'll admit it.
- *I Because you hadn't known much about COPD or emphysema, and then you got this book that's got quite a lot in it, was there anything that was a bit worrying, or were you reluctant to read on?
- P No no no .It was basically telling me what, what I am . And it's very basic. It doesn't go into the finer details but it does help you realise what COPD is.
- *I So as you were reading through, were you looking for more finer detail?
- P Yes. Well, perhaps I am silly but I like to know what's going on. That told me a certain amount, yes, but it didn't go into the real nitty gritty of what it's all about.
- *I And did it tell you how to get the nitty gritty?
- P Oh yes. I had to go back to my doctor and ask him so I did that and he said here you are have a puffer and you're alright now. So that was that. But getting back to the doctor, he's terrifically busy and time is of the essence. But he didn't tell me anything else, you know.
- *I Did you ask anything from the book?
- P No, I think most of it came out of my block. After reading that, questions came up to me. I mean they might correspond to those, but...But with my memory I don't remember those things.
- *I Did you take that along to the doctor?
- P Yes and I asked him if he watned one and he said no. And I asked him why not and he said because he already had one.

*I Here is our friend (picture). Can you remember any of the things that you did ask your doctor?

P Well, just general things like, why am I so short of breath, and what the COPD doing to me, and what should I be doing about it? And he came back with this new super whammy deluxe puffer thing, whatever it is, Spiriva. And he said this has just come out and it's the greatest thing since sliced bread so I said, right we'll try that. And I have and it's made a little bit of difference. I wouldn't like to say that... I mean when I first started on it I thought it did a lot better than its doing now. Because now, the last couple of days, I've got back to the stage where I'm huffing and puffing and puffing and huffing.

*I Have you still got some unanswered questions?

P Is there anything I can do to get rid of this thing. I mean everyone says no you can't but why can't I? I mean why go through life huffing and puffing all the time? What's the good of that? There's no quality of life in that.

*I You mentioned to me that the questions you asked your doctor weren't these ones in the boxes.

P No I didn't go through that.

*I I want to know a little bit more about why these questions didn't seem right for you , or whatever it was.

P Well, the whole trouble with me is that I read things and inwardly digest them and promptly forget them. I cannot comprehend the reading. If I hear it, yes I do. If I read it and hear it I have a greater comprehension and I know that that's the way to do it but just reading something I've got a tendency to skip over it and say that that means that, fair enough, and forget all about it.

*I If there'd been a tape with that would that have been helpful?

P Yes, that would have been a lot helpful.

*I Did you feel that you needed to do anything in relation to your lung condition after reading the book?

P Yes, just talk to the doctor about it.

*I What were your feelings about how easy it was for you to read and understand a book like this?

P I can read it yes but to understand it or to retain anything, I found it very difficult. But that's me. It's not the way that's written. Not at all. In fact it's quite well set out but I have a very good friend of mine that does the reading for me then we work together and I sort it out. To read that and inwardly digest, it would take me numerous, numerous, very numerous readings. And that's just me I've been like that all my life.

*I So have there been any books that have been right for you?

P There have been bits but they've been to do with work and I had to sort of belt them in with a sledge hammer. But no, other than that, no.

*I What about video?

P Yes. Video I could, because then you are getting sight and sound which is the ultimate way of having anything shoved into your brain.

*I What do you think would be the advantages of reading a book like this?

P For some people I think it would be very very helpful. As I said, to me... I read it, don't get me wrong. I was a good little boy and I read it.

*I Could it be helpful if family members read it as well?

P For her (wife) yes it was much more easy.

*I For people who are readers, what could be the benefits of reading the book?

P I can't help you.

*I What about disadvantages?
P I don't think so.
*I Would there be people who would disapprove?
P Oh there's people who disapprove about everything. Ask the greenies.
*I What could get in the way of people talking to their doctor about some of this material?
P No I don't think there's anything in there that's controversial or upsetting. It tells you what to ask your doctor. But me being me I don't do things.
*I Let's say you had decided to ask a question. What could have got in the way?
P He would sit and listen. He is a busy little boy but he's not that busy that he won't listen. He will listen and he's particularly good otherwise we wouldn't go to him. At least, I wouldn't.
*I Have you ever changed doctors to get one you were happy with?
P When we in another place, yes we did.
*I Would the busyness ever make you think you would ask the question another day or would you ask it anyway?
P Six of one and half a dozen of the other. If it was an important question yes I would ask him but if it was just something I wanted to know I would leave it til next time.
*I What do you believe might be the advantages of asking your doctor some of the questions from the book?
P That's a hard question. I suppose if the questions in the book had been thought out by someone who knew something about it. Whereas my questions have only been thought up by an old feller like me. I suppose, yes, you should ask the doctor the questions from the book but I don't work that way.
*I Are there any disadvantages of asking some of the questions?
P No
*I How easy is it to ask questions?
P Its easy. Its easy. He is terrific. Otherwise I wouldn't be attending.
*I Anything else you want to say?
P That's a beautiful book but a pet hate with books, mainly because looking at that publication, you have spent a lot of money on pages with hardly any printing on them, some with no printing on them, all good high quality paper, and terrific, but not necessary. I think that would have cost, I won't say how much but you could have done that on an A4 sheet with a photocopier and still got the same, not perhaps pretty pictures and that sort of thing but all the information. Which is what you want, not the pretty pictures. I'm afraid I have a pet hate, of brochures that come to this house and they are nice and glossy but they are a waste of ruddy money. And especially the government, they do it all the time. I know I used to work for them. Yes terrific, nice presentation but not necessary. If you had have put a glossy front on it or something but, no. That's only my opinion.
*I What about a tape or video? Should they be pretty basic as well, do you think?
P Oh no. You're going to different types now. You're getting the sight and hearing. No, that's different. You've got to gloss it a bit. It's got to be a bit of a glossy presentation. You couldn't go out with a video camera and take, you know, no. It's got to come thorough it's got to be a good clear speaking voice. Not some of these people that mutter. And you know lots of little... but that's in production and people that do that sort of production. That could cost more I know but you get more out of it than you get out of a book. It's a lovely book and if you'd

like to take it home with you , by all means. But that's me. I'm built that way.

*I You mentioned that after you'd had a look at that, you wanted to know more.

P Yes. After reading it, I still came back with the same question, what the devil is COPD, what does it do to me, how can I get rid of it. And I know everyone says you can't. But there must be something I can do to try and get rid of it. Maybe I won't get rid of it but I don't really want to have to start huffing and puffing all my life.