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UNIVERSITY OF SOUTHAMPTON

Faculty of Health Sciences

**The use of ambulatory oxygen in people with Chronic Obstructive
Pulmonary Disease**
by

Elisabeth Arnold

Thesis for the degree of Doctor of Philosophy

June 2012

ABSTRACT

University of Southampton

Faculty of Health Sciences

PhD degree

The use of ambulatory oxygen in people with Chronic Obstructive Pulmonary Disease

Elisabeth Arnold

Chronic Obstructive Pulmonary Disease (COPD) is a chronic incurable respiratory condition. Part of the condition is increasing lung damage which reduces the passage of oxygen from the lungs into the bloodstream. This means that some people with COPD have abnormally low levels of oxygen in their arterial blood (hypoxaemia). Increasing the percentage of inspired oxygen has been shown to reduce mortality in people with severe hypoxaemia.

Ambulatory oxygen (AO) has only been widely available for prescription in the UK since 2006, when the assessment and prescription of oxygen changed to a specialist service. But adherence to AO at home is still reported as poor.

This thesis sets out to explore the patients' perceptions of their AO system and how those perceptions may influence the use of the intervention. This body of work is divided into two phases. An initial qualitative grounded theory phase which interviewed 27 participants in their own home. This sought to uncover patients' perceptions of their AO, and how they used it. This qualitative phase uncovered that patients: found their AO system too heavy to carry, used their carers extensively to carry and manage their systems, were embarrassed to use AO in public, and could not recall instructions on specific use of AO.

A second quantitative phase sought to develop a questionnaire to discover if the perceptions uncovered in the qualitative study were held by a different cohort of similar participants. Five people were recruited to a cognitive interviewing study which was used to develop the questionnaire based on the findings from the qualitative phase results. A further 13 people were recruited to a pilot study to test the developed questionnaire in a different cohort of people with COPD. This quantitative phase recorded that the perceptions held by the qualitative participants were also shared by those in the quantitative phase. This thesis therefore describes a mixed methods study, looking at patients' perceptions and use of AO.

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DECLARATION OF AUTHORSHIP

I, Elisabeth Arnold

The use of ambulatory oxygen in people with Chronic Obstructive Pulmonary Disease

and the work presented in the thesis are both my own, and have been generated by me as the result of my own original research. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- where I have consulted the published work of others, this is always clearly attributed;
- where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- Parts of this work have been published as a qualitative study: Arnold E., Bruton A., Donovan-Hall M., Fenwick A., Dibb B. and Walker E. "Ambulatory Oxygen: Why do COPD Patients Not Use their Portable Systems as Prescribed?" BMC Pulm Med 2011; 1(9):1-7

Signed:

Date:.....

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Chapter One: An introduction to this thesis

As a clinical respiratory physiotherapist, the researcher has been involved with patients with Chronic Obstructive Pulmonary Disease (COPD) for many years. The use of supplementary oxygen in advanced COPD was established with the publication of two randomised controlled trials (RCT's) by the Nocturnal Oxygen Therapy Trial in America and the Medical Research Council Oxygen Trial in the United Kingdom. These two trials reported a decrease in mortality rates for COPD patients using oxygen for at least 14 hours per day and led to the development of long term oxygen therapy (LTOT), i.e. the use of oxygen on a permanent basis at home. Ambulatory Oxygen (AO) was used during the American trial because some patients used oxygen for 24 hours per day. Ambulatory oxygen involves the patient carrying a portable cylinder of oxygen, which allows them to leave their homes and still be able to access supplementary oxygen.

This thesis has been conducted during a time of change for the NHS in how oxygen for use at home is prescribed. In 2006 the guidelines for the prescription of oxygen changed (BTS 2006) and recommended that patients should be assessed for supplementary oxygen by specialist respiratory units within secondary care and not by general practitioners (GPs) which had been the case up to that time. New regional oxygen suppliers took over the responsibility for supplying oxygen equipment to patients in their own home, including ambulatory oxygen equipment, and for the first time AO became widely available for prescription. New prescription forms were introduced – Home Oxygen Order Form (HOOF), which was completed by the assessing clinician and sent to the oxygen supplier. The oxygen supplier collated all the oxygen usage information from each patient and sent it to the NHS Trust paying for the oxygen prescription. For the first time Trusts were able to assess the cost of total oxygen prescription for their patients.

At the time of writing (2012) the assessment for supplementary oxygen is changing again with the commissioning of specialist home oxygen assessment units within community NHS Trusts. This change has added an extra dimension to oxygen assessment as patients are now being followed up after the prescription of oxygen to assess adherence to the intervention. Indeed, many community NHS trusts are commissioning specialist home oxygen services (HOS), not only to assess the need

for supplementary oxygen in new patients, but to review every patient currently receiving oxygen at home and alter prescriptions according to clinical need and adherence. New assessment forms have been introduced HOOF A and HOOF B. HOOF A can be completed by clinicians who think a patient should have oxygen e.g. a GP or on discharge from hospital, but the prescription only lasts for 6 months. A HOOF B is a permanent prescription form for home oxygen and can only be completed by specialist prescribers. In this way it is hoped that all patients will be assessed for permanent home oxygen by a specialist service. AO can now only be prescribed on a HOOF B, i.e. by a specialist clinician. For the first time the prescribers will be responsible for both prescribing and assessing adherence to an oxygen prescription for both LTOT and AO. Home oxygen assessment services will also remove oxygen from patients who are deemed not to be using it.

The qualitative phase of this thesis was undertaken as part of a larger Department of Health funded project, via the HTD funding scheme (Health Technology Devices). The funded project comprised a series of work packages aimed at improving the design of and development a new generation of light-weight oxygen cylinders. The qualitative phase of this thesis made up one of the work packages looking at the patients' perception of their AO. The quantitative phase was undertaken independently by the researcher and self-funded.

This thesis is divided into chapters which describe the different areas covered by this body of work.

Chapter two introduces COPD, including a literature search around definition, diagnosis and pathophysiology. The chapter goes on to discuss the assessment and prescription of AO and the possible advantages of using this intervention.

Chapter three focuses on adherence in AO, and discusses the literature around adherence in COPD including three randomised controlled trials (RCT's) which have investigated this aspect of AO use. In line with the Grounded Theory study undertaken in this body of work, further literature searches were conducted as participant data was analysed so further literature is woven in to the findings in Chapter seven and the discussion in Chapter ten.

Chapter four explores the methodological underpinning of this thesis. It seeks to justify the use of the mixed methods approach used in this thesis and how it contributes to the robustness of this work.

Chapter five discusses the type of qualitative approach which was adopted to collect information from the participants themselves and investigates the background to Grounded Theory (GT) as this method and how it was utilised in this thesis.

Chapter six describes phase one, the qualitative phase of this thesis, and the use of GT to inductively collect and analyse patient data. In line with GT this chapter records a core category and a substantive GT theory (SGT) which seeks to explain the behaviour of the participants around the reasons for using or not using their AO system.

Chapter seven lays out a model which seeks to explain this behaviour, and the rest of the chapter employs the participants' responses to support this model.

Chapter eight marks the start of the quantitative phase of this thesis. The chapter explores the theoretical background to the production and pre-testing of questionnaires. It then goes on to discuss the background to the pre-testing methods employed in this thesis; cognitive interviewing (CI) and piloting.

Chapter nine describes the development of the questionnaire, through the use of the two separate research studies, one using cognitive interviewing and one using a pilot study in a different group of participants. The quantitative phase ends with the production of the questionnaire.

Chapter ten delivers an overview of the qualitative and quantitative aspects of this thesis, which are considered together in a final discussion of this body of work. This chapter goes on to explore the contribution of this thesis and the strengths and limitations of this work.

This programme of research provides a unique insight into the factors which patient perceives influenced their use of prescribed AO at home.

Chapter Two: COPD and AO prescription

2.0 Introduction

As stated in Chapter One, this body of work springs from a desire to understand what the patient with prescribed ambulatory oxygen (AO) perceives about this intervention and how those perceptions affect the individual's use of their AO at home. This work has involved people with COPD and therefore this chapter begins with an introduction to COPD including basic pathophysiology, clinical symptoms and treatment. It goes on to explain the prescription of supplementary oxygen in the treatment of advanced COPD and the clinical field tests used to assess this intervention. The chapter concludes by looking at the evidence supporting the current prescription guidelines (in 2012) and discusses the potential benefits of AO, which may not be detected by the current assessment used by healthcare professionals.

2.1 Chronic Obstructive Pulmonary Disease

COPD is an umbrella term used to describe a complex of different lung pathologies which are associated with the chronic inflammation of lung tissue. The most common cause of COPD is prolonged inhalation of noxious external particles or gas, such as cigarette smoke (Cornwell et al 2010), which causes progressive destruction and remodelling of lung tissue. This remodelling process produces an irreversible narrowing of the lung airways which impedes the ability of the lung to expel inhaled air normally or "airway obstruction" (van Eeden and Sin 2008:224). There is an increasing body of research which suggests additional causes for this condition. COPD can occur in people who have no smoking history. This is thought to be due to different aetiologies, for example damage done to the lung by childhood diseases which then cause increasing problems as the lung ages (Hodgson et al 2011), or as a progression of chronic asthma where the airways stop returning to normal between 'attacks' and become more permanently 'fixed', causing airway obstruction (Barnes 2011). More recently, the effect of environmental factors such as diesel fumes (Hart et al 2012) and air pollution (Peacock et al 2011) have been shown to be implicated in the development of COPD. There is emerging research into the effect of occupational gases and air particulates, suggesting that exposure to these factors increases the risk of developing COPD in existing smokers by 14-fold (Hodgson et al 2012).

2.1.1 Pathophysiology of COPD

The pathophysiology of COPD is believed to result from a chronic breach in the defence system of the lung. Inhaled noxious gas or particles produce a chronic inflammatory response in the endothelial and epithelial linings of the airways (bronchi) and parenchyma (alveoli) of the lung (Huertas and Palange 2011). The body responds to this inflammatory process through a complex process involving specific cellular and biological mechanisms which are recognised but not yet completely understood (Barnes 2011). Research speculates that it is an abnormal response in this repair mechanism which causes lung tissue to progressively remodel, resulting in a pathological lung condition which is irreversible (Yao and Rahman 2011).

The remodelling of lung tissue involves tissue changes at different levels of the lung. For example, where the lung inflammation and consequent changes affect the bronchial walls in the lung, the walls become thickened and fibrosed. This reduces the lumen of the bronchial airways and causes obstruction to airflow out of the lungs (Cornwell et al 2010). Where inflammation and repair affect the alveoli of the lung, the septa between the alveoli are destroyed, and the elastic recoil component of the lung parenchyma is destroyed (Salazar and Herrera 2011). Because COPD is an umbrella term covering diseases which cause obstruction of the airways, any one patient may have predominantly one area of lung affected or a range of different lung areas affected. The area of lung destruction/remodelling can cause different types of clinical characteristics, or phenotypes, for COPD.

Table 1 below describes the main phenotypes for COPD based on where in the lung remodelling has occurred. This is derived from Computer Tomography (CT) scans from two studies looking at COPD patients and describes the set of symptoms associated with lung damage in a type of lung tissue (Yao et al 2010, Pistolesi et al 2008).

Table 1: Main phenotypes in COPD and associated areas of damage and symptoms (based on Pistoletti 2008)

Phenotype	Pathophysiology	Signs and Symptoms
<p>Chronic Bronchitis 'type'</p> <p>Remodelling of the small airways predominantly</p>	<p>Increase mucus production</p> <p>Increase in the number and distribution of mucus producing cells (goblet cells)</p> <p>Disruption and destruction of cilia 'hairs' which causes decrease in sputum clearance</p> <p>Remodelling and thickening of the bronchial wall causing reduced airway lumen size in small (and some large) airways; causing obstruction to airflow on expiration</p>	<p>Chronic productive cough</p> <p>Wheeze</p> <p>Breathlessness</p> <p>Low arterial oxygen content</p> <p>High arterial carbon dioxide</p>
<p>Emphysema 'type'</p> <p>Remodelling of the alveoli predominantly</p>	<p>Destruction of the septa between alveoli</p> <p>Loss of elastic recoil</p> <p>Hyperinflation/gas trapping causing an increase in total lung capacity/lung volume</p> <p>Thickening of alveoli cause disruption to passage of oxygen into the arterial blood.</p> <p>Hypertrophy of neck muscles</p>	<p>Breathlessness</p> <p>Physically thin</p> <p>Wheeze</p> <p>Low arterial oxygen</p> <p>Barrel-chest</p>
<p>Chronic asthma 'type'</p> <p>Remodelling of large airways predominantly</p>	<p>Long-standing asthma becoming more permanent with fixed changes within the lung, which are irreversible or have a very small reversibility</p>	<p>Breathlessness</p> <p>Wheeze</p> <p>More asthmatic symptoms; diurnal changes in wheeze</p>

Patients may predominantly present with one type of COPD, or may have a broad, mixed picture of symptoms. A person's genetic ability to deal with the chronic lung irritation caused by cigarette smoke is being highlighted as an important part of the possible development of lung disease in smokers; especially since only 10-20% of smokers go on to develop COPD (Yao and Rahman 2011). This genetic susceptibility may decide not only if the person develops COPD but where in the lung this process is likely to predominantly occur and therefore what COPD phenotype the sufferer is likely to develop (Domagat-Kulawik et al 2011). Recently other system changes are being described as being part of the COPD condition. Muscle weakness and muscle bulk reduction is thought to be due to a chronic systemic inflammatory reaction in the patient, which 'overspills' from the chronic lung inflammatory process (Doucet et al 2010).

2.1.2. Definition and diagnosis of COPD

COPD is defined as a lung condition characterised by: "airway limitation that is progressive and not fully reversible with bronchodilators and associated with an abnormal inflammatory response of the lungs to noxious particles or gases" (Bellamy and Smith 2007:1380). As described above, COPD is a collection of conditions and therefore diagnosis does not depend on one single diagnostic test but relies on:

- The presence of airflow obstruction measured by spirometry.
- The patient's history of symptoms e.g. productive cough.
- Presenting physical symptoms e.g. altered lung sounds.
- The healthcare professional's clinical judgement.

(NICE guidelines 2010)

Spirometry is used to measure lung volumes, either dynamic (e.g. forced vital capacity) or static (relaxed vital capacity), and airflow rates out of the lung (e.g. forced expiratory volume in one second; FEV₁) (Booker 2009). The normal values for lung volumes and air flow-rates are not fixed, but have predicted values based on age, height, gender and ethnic origin. The diagnosis of obstructive pulmonary disease relies on the amount of air blown out of the lungs in one second as a percentage of forced lung volume (FEV₁/FVC) and results less than $\leq 70\%$ are positive for lung obstruction (NICE 2010). Table 2 demonstrates the categorisation of COPD on the basis of the

patient's airflow/ degree of lung obstruction compared to the normal recorded values as a percentage.

Table 2: NICE (2010) categories of lung obstruction based on spirometry

FEV ₁ /FVC	FEV ₁ % of predicted	COPD Category
≤ 70%	≥ 80%	Stage 1 (+ symptoms) Mild
≤ 70%	≥ 50-79%	Stage 2 - Moderate
≤ 70%	≥ 30-49%	Stage 3 - Severe
≤ 70%	≤ 30%	Stage 4 - Very Severe

2.1.3. Prevalence of COPD

COPD is fifth leading cause of death in the UK (O'Reilly et al 2010), and the second cause of emergency hospital admission in the UK (Calderon-Larrangia et al 2011). Jordan et al (2010) reported that COPD accounts for 1.4 million GP consultations and the 1 million in-patient bed days costing over £800 million per year in the UK.

The prevalence of COPD in the general population has been the subject of much debate over the last few years. This debate has centred on the known prevalence of COPD through data from Primary Care practices (people with a COPD diagnosis), and the potential prevalence if unknown COPD in the community is considered (people who may have COPD but have not been diagnosed). The importance of this debate has been highlighted by research suggesting that one of the risk factors for hospital admission is undiagnosed COPD (Calderon-Larranaga et al 2011). Simpson et al (2010) conducted a survey of an anonymised health database (QRESEARCH) which contains data from 422 self-selected General Practices (GP) from 2001-2005. The authors argued that the database is broadly representative of the primary care practices in the UK, although does not specify if they are inner city or rural practices or specify the criteria for self-selection for the database. This study included 51,804 patients and reported that the prevalence of COPD was 2.1% of this adult population. This study is concerned with diagnosed episodes of COPD and included 46 different

diagnostic codes for COPD, but not definitive diagnosis by spirometry. The authors confirm this might be a weakness of this study, i.e. they had no way of ensuring the COPD diagnosis was correct.

Frank et al (2007) looked at a general practice population of 2646 ever-smokers (had smoked at some time even if not smoking now), and 825 attended for spirometry. Of these, 163 participants had diagnosable COPD. The authors suggested that this gives a COPD prevalence of 4.1% for this population. A similar cross-sectional study of GP practice data by Jordan et al in 2010 looked at 20,496 people over the age of 30 years who had valid lung measurements. This study reported a COPD prevalence of 4.7% for this population. Of the 4.7% deemed to have a diagnosable COPD condition, 86.5% had no previous diagnosis of COPD. A classification of 'severe disease' was found in 25% of those people newly identified as having COPD. The need to identify these undiagnosed people has been spearheaded by the British Lung Foundation in its 'Missing Millions' campaign because evidence strongly suggests that early diagnosis and treatment can reduce hospitalisation and the economic burden of this condition (Hodgson et al 2011). O'Reilly et al (2010) estimated that there are approximately 3 million COPD sufferers in the UK, of whom about 2 million are still undiagnosed.

Hodgson et al (2011) and Simpson et al (2010) argued that the prevalence of COPD varies according to certain factors, specifically smoking rates and socioeconomic deprivation. So areas of high deprivation with high numbers of smokers have higher incidences of COPD. Simpson et al (2010) concluded that this translates into one in 32 people in socioeconomically deprived areas being diagnosed with COPD compared with one in 98 for people in more affluent areas. Hence COPD prevalence clearly depends on the population being sampled and the criteria used to confirm any diagnosis (Hodgson et al 2011). Traditionally the incidence of COPD was thought to be greater in men, but with increasing smoking levels in women this may no longer be true, additionally women appear to be more susceptible to the lung damage caused by smoking (Demeo 2011).

2.1.4. Clinical features and treatment

COPD is a complex heterogeneous condition, so not all patients exhibit the same clinical features. Individual symptoms will reflect individual lung and systemic pathology, but commonly patients complain of:

- Cough: related to increased production of mucus by the lungs (Barnes 2011).
- Wheeze: an indication of the chronic narrowing of the airways produced by inflammation and remodelling (Fromer 2011).
- Fatigue and muscle wasting: may be a multi-faceted symptom caused not only by breathlessness and reduced activity, but also by systemic peripheral muscle morbidity (Doucet et al 2010).
- Breathlessness: initially on exertion, but increasing to breathlessness at rest as the condition progresses; breathlessness may be due to different causes (e.g. differences in areas of the lung which are ventilated and those which are perfused, alveolar fibrosis, lack of fitness or anxiety), but low arterial oxygen level is believed to be an important cause of breathlessness in COPD patients (Albert and Calverley 2008).

There is no cure for COPD so treatment is aimed towards managing the patient's symptoms, in terms of bronchodilators, steroids and antibiotics to treat chest infections and pulmonary rehabilitation to improve/maintain exercise tolerance (Murphy et al 2011). Stopping smoking, so removing the lung irritation, has been shown to be vitally important in reducing mortality in COPD (Shaker et al 2011). Evidence suggests that pneumococcal and influenza vaccinations may reduce mortality by preventing infection (Croxtan and Bailey 2006). Long-term oxygen therapy (LTOT) also reduces mortality in patients with low arterial oxygen levels (hypoxaemia) (Albert and Calverley 2008) and is discussed further below.

2.1.5. Subjective breathlessness (Dyspnoea) as a clinical symptom in COPD

Subjective breathlessness or dyspnoea (defined as "the patient's subjective experience or sensation of shortness of breath and the discomfort associated with respiratory effort" (Heinzer et al 2003:87)), is one of the most common and disabling symptoms of COPD (Schlecht et al 2005). A growing body of research details the negative effects of breathlessness on quality of life, for example Martinez Frances et al (2008) who reported that the fear of breathlessness affects all aspects of the life of a

COPD patient and Eaton et al (2002) who described breathlessness as the single most distressing symptom for COPD sufferers. For health professionals, the presence of breathlessness in a COPD patient either at rest, or on exercise, is more likely to cause the initiation of/or change in medication than any other symptom (Upton et al 2011). Breathlessness in COPD may be due to low arterial oxygen level (hypoxaemia) (Albert and Calverley 2008).

2.1.6. Hypoxaemia

Research suggests that there are physical changes in the structure of the COPD lung, either in the ability of the lung to transmit oxygen to the functioning alveoli where oxygen transfer into the blood occurs, or in the alveoli themselves. This impedes the transfer of oxygen from the lung to the blood supply causing a reduction in the amount of oxygen available to the red blood cells. This results in low arterial oxygen levels or hypoxaemia (Yasuo et al 2011). Oxygen in arterial blood can be measured directly by drawing a sample of blood, and calculating the oxygen content or partial pressure of the oxygen (PaO_2) in the blood. Henderson (2008) cites normal arterial blood gas levels at 11-14kPa (80-100mmHg) and severe hypoxaemia at $\leq 7.3\text{kPa}$ (55mmHg). The percentage of oxygen saturation (SaO_2) in arterial blood can be measured indirectly by using an oxygen saturation monitor. These monitors are non-invasive and are well tolerated. Normal saturation level is above 96% (Henderson 2008).

2.2.0 Treatment of hypoxaemia with inhaled supplementary oxygen

Inhaled oxygen is used to correct hypoxaemia in COPD patients. Room air is 21% O_2 (or 0.2 fraction), by increasing the fraction of oxygen in the gas inspired into the lungs, more oxygen is available to be transferred from the lungs to the bloodstream (Croxtton 2006). Oxygen is frequently prescribed as a long term treatment for people with COPD and is prescribed on the basis of the level of oxygen in a patient's arterial blood at rest or/and on exercise (O'Reilly et al 2010). The rationale for the current prescription of oxygen to COPD patients is based on two trials conducted over 25 years ago which established a survival benefit in patients with severe arterial hypoxaemia at rest (NICE guidelines 2010), and which still form the basis of oxygen prescription guidelines in the UK today: The Nocturnal Oxygen Therapy Trial (NOTT)

in America in 1980 and the Medical Research Working Party Trial of Long-term Domiciliary Oxygen (MRC trial) in the UK in 1981

2.2.1. Long-term oxygen therapy (LTOT)

Under current guidelines (BTS 2006) long-term oxygen therapy is prescribed to COPD patients if the arterial oxygen level at *rest* falls below 7.3KPa, or below 8KPa if they have additional co-morbidities such as cardiac involvement (NICE 2010). Standard instructions to patients would be to use supplementary oxygen for at least 15 hours per 24 hour day; usually overnight and then additionally during the daytime hours. Home oxygen is usually delivered by a home concentrator which extracts air from the room and delivers oxygen (at about 96%) to the patient through a facemask or nasal prongs. The oxygen flowrate and duration of use are prescribed by the health professional who assessed the patient.

2.2.2. Ambulatory Oxygen (AO)

Some patients with COPD experience a drop in oxygen levels (desaturation) when they move around or perform physical activities. This could be as a progression of their low resting oxygen levels (patients who already have abnormally low resting oxygen levels) or could occur in patients who have a normal resting oxygen level (Moore et al 2011). Provision of AO is designed to address this exercise desaturation (NICE 2010). AO systems comprise a portable system which is designed to allow the patient to take supplementary oxygen out with them when they leave the house. AO can be supplied in two ways;

a. Cylinder oxygen - a cylinder of compressed oxygen is delivered on an 'as needed basis' to the patient. The flow of oxygen and the duration of use are set by the assessing clinician when the patient is assessed for their oxygen need. The cylinder is delivered with a shoulder bag allowing the patient to carry the system. These systems weigh some 3.5 kg at the time of this research.

b. Liquid oxygen (LOX) –where a mother large cylinder or 'dewar' is delivered to the patient and the patient decants the oxygen to a smaller portable cylinder weighing 2.7kg. The dewar is regularly changed by the oxygen supplier and the patient refills the

portable system themselves as necessary. To be given liquid oxygen the patient must have somewhere to store the mother tank safely, usually a garage or shed and be physically able (or have someone who is able) to refill the small portable cylinder as this takes some strength.

At the time of this research (until the renegotiation of the contract to the UK oxygen suppliers in April 2012) the supplier decides which type of AO the patient receives, after this time prescribers will be responsible for deciding on the type of equipment the patient will receive.

2.2.3. Current prescription of AO

Current AO prescription guidelines are based on the presence of exercise desaturation (SaO_2) in the patient (British Thoracic Society: BTS 2006). Traditionally the assessment for AO has been prompted by a fall in oxygen saturation by 4% to below 90%, during exercise (Lock et al 1991, for further discussion on this study see below). The updated COPD prescription guidelines (NICE 2010) state that two main groups of patients should be assessed for AO;

- Patients already on LTOT who wish to continue to use oxygen outside the house and are prepared to use AO i.e. patients who already have hypoxaemia at rest and so who would become more hypoxemic on exercise.
- Patients with exercise desaturation who on assessment, are shown to improve their exercise capacity or subjective breathlessness with supplementary AO and want to use it i.e. patients who do *NOT* have resting hypoxaemia but become hypoxaemic when exercising.

The prescription of AO involves clinically assessing the patient's potential response to any supplementary AO by using a walking test with and without AO and comparing any difference in terms of walking distance and subjective dyspnoea. Different health professionals may use slightly different formats but the clinical assessment below represents the assessment most frequently observed by this researcher.

2.2.4. Clinical assessment

The patient performs one walking test with saturation monitoring to establish the presence of exercise desaturation and their walking distance and subjective dyspnoea without oxygen is recorded. Allowing for a 30 minute rest between walks, the patient then re-performs the walking test with saturation monitoring and supplementary AO (at for example 1 litre per minute (1L/m) through nasal cannulae). The patient is closely monitored for any changes in exercise de-saturation, increases in walking distances and/or decreased subjective breathlessness when walking. An increase in walking distance by at least 10%, and/or a decrease in subjective breathlessness with oxygen could result in the patient being prescribed AO to take home and use as long as they are willing to use AO. These patients are termed 'responders'. Some patients do not increase their walking distances or feel less breathless with oxygen, and these patients are termed 'non-responders' and not prescribed AO as it is deemed to have no positive effect. Additionally prescribers are required to ensure that potential AO receivers are going out of the house on a regular basis.

Under the guidelines for AO assessment (NICE 2010), the oxygen flowrate prescribed for each patient, should be high enough to prevent a drop in oxygen saturations when walking i.e. should keep the patient's saturations at 90% or above. This may necessitate a further walking field test to ensure that the oxygen flowrate is sufficient to maintain the patient's saturation levels when walking.

2.2.5. Possible walking tests used to test exercise desaturation

At the moment there are three possible walking tests that could be used in an assessment for AO. There are no recommendations as to which test should be used but the six minute walk test (6MWT) is the most widely used clinically.

1. The 6Minute Walk Test (6MWT) (American Thoracic Society: ATS 2002)

During this field test the patient walks a 30 metre course. They are instructed to walk as if slightly late for an appointment but the patient can stop or slow down as they wish. The examiner talks to the patient every minute but only to tell them how much longer they have to go in terms of minutes left to stopping. Distance walked, subjective dyspnoea and oxygen saturations are recorded.

2. The Incremental Shuttle Walk Test (ISWT) (Singh et al 1992)

The ISWT is externally controlled by 'beeps' on a tape. The patient starts walking on a beep and has to complete the 10 metre course before the next beep is heard. The beeps become faster every minute and the patient has to keep up with the beeps or the test is stopped. Distance walked, subjective dyspnoea and oxygen saturations are recorded.

3. The Endurance Shuttle Walk Test (ESWT) (Revill et al 1999)

To perform the ESWT, the patient completes the ISWT first. Using the walked distance completed during the ISWT, the operator is able to work out the patient's sub-maximal work rate (VO_2) and from this the operator sets an endurance walking test at a % of the VO_2 recorded e.g. the operator may pick 30-80% of the ISWT results, depending on individual clinical judgement. The ESWT is another beep test where the beeps do not increase in speed but remain the same. The object of this test is to see how long the patient can maintain the set speed determined by the clinician. The operator records *time* taken from the start to when the patient can no longer continue.

2.3. Prescription of AO

To qualify for a prescription of AO a patient must demonstrate an improvement with supplementary oxygen i.e. walking at least 10% further on the chosen walk test or a reduction in subjective dyspnoea at the end of the test, when using AO. A further consideration for the prescriber is how much the patient is leaving their home. If they are not leaving home at all then prescribing AO is deemed to be unhelpful. If they are very active outside the house then liquid oxygen (LOX) which is considered a light-weight option may be prescribed. Potential reasons for not leaving the house are not always fully considered during the prescribing procedure. This can be due to many

reasons for example; time constraints or the healthcare professional being unaware of the impact of other co-morbidities, or lifestyle on the patient.

Patients who do not show any improvement in either walking distances or subjective dyspnoea are thought not to respond to oxygen and are not prescribed it. For patients who do 'respond' further walk tests with AO should be undertaken to ensure that the flow of AO is titrated to maintain their walking oxygen saturations at 90%, or above. Any information they may receive around use of AO is decided by the prescribing healthcare professional as, unlike for LTOT, there are no universally used recommendations for the day to day use of AO.

There is a growing body of research questioning these field tests, and the way they are used, and this is explored further in chapter three. The section (2.3.1) below explores the evidence for the current oxygen assessment and prescription guidelines.

2.3.1. Exploring the parameters for AO assessment and prescription

Research supporting the formation of the guidelines for AO assessment can be questioned. The report of the Royal College of Physicians on assessment and prescription of domiciliary oxygen published in 1999 by Wedzicha, used a study by Okubadejo et al (1994) as a reference for improvement in exercise tolerance through the use of oxygen. The study by Okubadejo studied the use of cylinders by COPD patients but is concerned with the provision of short burst oxygen therapy (SBOT) and LTOT provision rather than AO. However this study references a study by Lock et al published in 1991. The Lock et al study stated that it was published with the aim of providing the basis for prescription of AO. Therefore this study may be an important part of understanding the prevailing prescription parameters. Lock and his colleagues did not perform their own experimental trial but looked *retrospectively* at 50 assessments performed between September 1988 and March 1990 which resulted in the prescription of AO. Forty four of the patients had COPD. There are no research guidelines or operating procedures as the study looked at retrospective assessments so there is no way of knowing if all the assessments were done using the same criteria. Patients were assessed during a 6 minute walk test which was performed after two practice walks followed by two further walks; one where the patient carried a

cylinder of oxygen and one where they carried a cylinder of air. The authors reported only 27 patients had saturation monitoring performed on them as they walked. Twenty-nine patients completed a visual analogue score (VAS) to ascertain their perception of breathlessness before and after oxygen, but the authors do not say if VAS was recorded in the same patients who also had recorded saturation monitoring. Twenty-one patients improved their walking distances by 10% with oxygen and 14 improved on VAS, but again it is not clear if these were the same patients. The authors prescribed AO to 26 patients based on the results of their assessments. It is not clear if the recorded improvements in walking distances or VAS were in the COPD cohort or in the patients with other respiratory conditions. The authors claimed a significant correlation between improvement in walking distances and baseline saturations (although saturations were only recorded in 27 of the 50 assessments examined). The authors concluded that:

'We found a significant correlation between improvement in 6 minute walk test on oxygen compared with air and arterial desaturation which occurred on the baseline walk. This suggests that the degree of oxygen desaturation could be a useful indicator of those patients most likely to benefit from portable oxygen'

(Lock et al 1991:410)

This 1991 study appears to provide part of the basis for clinical AO prescription, but does not define specific desaturation parameters in the published paper. Interestingly the study recommends two practice 6 Minute walk tests before baseline assessment for AO and this is discussed further below. This study was completed before oxygen cylinders were part of the drug tariff and therefore patients had to pay for AO. The authors reported that patients were not using the equipment regularly at home but do not give any reasons for this.

The British Thoracic Society (BTS) published guidelines for the prescription of domiciliary oxygen in 2006 when the oxygen services in the UK changed and AO became widely available on prescription. Although they include a guideline of exercise desaturation as 4% desaturation to below 90% on oxygen saturation monitoring, they quote the research supporting this as Leach et al 1992 and Eaton et al 2002. The study by Leach et al (1992) did support the relationship between desaturation and the

benefit of AO in walking tests but did not mention a specific saturation as the cut off point for benefit. Eaton et al (2002) cited using the ATS cut-off point for exercise desaturation at 88%. It seems that the cut-off point for exercise desaturation may have come from completely different studies such as the use of saturation monitoring in respiratory disease (Chevannes 2003). This may be very important as clinically the guidelines have institutionalised the prescription of AO to exercise desaturators at 4% desaturation to below 90% on pulse oximetry, and there appears to be no research evidence supporting this cut-off point in the implementation of supplementary oxygen. It is hard not to agree with Tham and Anantham (2011) who argue that there is no robust evidential basis for the prescription of AO.

2.3.2. Other clinical studies

Other clinical studies have been conducted using the same parameter as Lock et al (1991) of desaturation at baseline. Some of these have demonstrated the same acute response to oxygen, in terms of improvement in increased walking distances and improvement in supplementary oxygen. Both Jolly et al (2001) and Leach et al (1992) found that there was an improvement with walking distances when the patient was given AO. In both studies at least two practice walks were completed before the participant was tested on oxygen. Leach et al concluded that participants should improve by at least 50% before being prescribed AO. This study also suggested that the distance to first stop during a walking test, may be a clinically important marker i.e. the first stop in terms of time/distance, made by the participant without oxygen / with oxygen, may be a more sensitive marker than the total 6MWT. Revill (2010) also found that participants improved with oxygen and agreed with Leach et al that the distance/time to first stop may be clinically important. On the other hand, a study by McDonald et al (1995) reports no increase in walking distances with supplementary oxygen.

A further differentiation may be between patients who use LTOT and in whom AO is prescribed to allow them to continue using oxygen during activities outside the house and people who have exercise desaturation only (Tham and Anantham 2011).

Research suggests that exertional desaturation portends a poorer mortality prognosis (Drummond et al 2008) so identifying these patients may be very important, but it is

unknown why some people with COPD demonstrate an acute response to supplementary oxygen whilst others do not. It is unclear if the non-response in some COPD patients is due to a physiological non-response, or the inability of the field tests to detect changes, or even if the field tests used are the right parameters to assess supplementary oxygen prescription. For example Fujimoto et al (2008) argued that the benefit of supplementary oxygen is in preventing an increase in pulmonary artery pressure, which would not be detected using the current assessment guidelines and field tests. Lacasse and Maltais (2005) suggested that there is a sub-group of COPD patients with exercise desaturation, in whom AO may be very beneficial but argued that at the moment these patients were difficult to identify. They comment that an acute positive response to AO does not appear to predict long-term usage and at present all are subjected to the same assessment tests for AO.

2.4. Potential advantages in using AO

The next section discusses the published literature around any benefits that the use of AO may confer on a patient. There is research suggesting that providing increased supplementary oxygen to desaturating patients confers a benefit, but the mechanism behind the cause of exercise desaturation remains unclear, and may be different in different people (Tham and Anantham 2011). Understanding the benefits may provide the basis for better AO assessment.

2.4.1. Benefits relating to Pulmonary Artery Pressure

Lack of oxygen in an area of the lung vascular bed, causes a constriction of the lung blood vessels to direct blood to other areas which better oxygenated (Fujimoto et al 2008). This blood vessel constriction has a feedback effect resulting in an increase in pressure in the pulmonary artery which in turn can cause damage to the heart as it tries to pump harder against the constriction in the artery (Fujimoto et al 2008). These same authors found that supplementary oxygen effectively reduced any increase in pulmonary artery pressure (Ppa), implying that oxygen affected the lung bed/cardiovascular system, which in turn improved the patient's exercise capacity. Weitzenblum and Chaouat (2001) found that an 88-90% resting saturation level was the threshold for increased risk of developing raised Ppa. This level would encompass most patients who require LTOT, but may not necessarily be identified in those who

intermittently desaturate only on exercise. These authors point out that the response to hypoxia is different in different individuals, which may go some way to explain the phenomenon of 'responders' and 'non-responders' to supplementary oxygen found in the studies cited above. This may also be an important consideration when prescribing supplementary oxygen to patients who only desaturate on exercise. Selinger et al (1997) found that removing oxygen from patients (already receiving oxygen) resulted in a rise of pulmonary artery pressure 2-3 hours after supplementary oxygen ceased. This suggests that to use inhaled oxygen to protect against a rise in Ppa, the patient would have to use oxygen every 2-3 hours. This was the one of the original tenets of prescribing AO, i.e. that it would enable the patient to maintain the beneficial effect of LTOT when away from the home (Pepin et al 1996). So in LTOT patients the use of AO may be to provide protection against the effects of hypoxia when they are away from their LTOT supply and performing activities. To prescribe AO on reduction in Ppa during exercise would require much more in-depth cardio-pulmonary based exercise testing, but may be a important indicator of need.

2.4.2. Benefits relating to dynamic hyperinflation

Casaburi and Porszasz (2006) argued that the importance of supplementary oxygen is in reducing dynamic hyperinflation during activity. Dynamic hyperinflation results from the severe airways obstruction experienced by people with COPD, which does not allow full emptying of the lung during expiration. The increase in respiratory rate during exercise increases hyperinflation, effectively causing the respiratory muscles to be at a greater disadvantage, and work even less well. This in turn increases dyspnoea and forces the patient to stop exercising. The authors theorised that supplementary oxygen reduces respiratory rate in exercise and therefore delays the need to stop exercise due to hyperinflation. Armann et al (2010) reached similar conclusions; that hyperinflation due to hypoxia, and excessive respiratory work, resulted in reduced exercise ability, so supplementary oxygen may allow a patient to exercise for longer. Miniata et al (2011) goes further and suggests that lung hyperinflation is particularly evident in an emphysematous COPD phenotype. Drummond et al (2011) identified this subset of COPD patients as a group that would benefit from AO as patients who may potentially improve their exercise tolerance with supplementary oxygen by decreasing hyperinflation. However this group of patients, who present with severe exercise dyspnoea but not always with exercise desaturation, would not qualify for AO under current oxygen guidelines (NICE 2010). Prescribing AO on the effects of

supplementary oxygen on dynamic hyperinflation during exercise would again require more in-depth cardio-pulmonary exercise training assessment, but that may result in better specific assessment and prescription of AO.

2.4.3. Benefits relating to quality of life

Two studies by Eaton et al (2002) and Nonoyama et al (2007) researched the effect of AO on quality of life scores in people with COPD. Both studies used cross-over methodologies, with participants using cylinder air and then cylinder oxygen or vice versa in a randomised order. These two trials employed two different validated health-related quality of life (HRQoL) questionnaires; the St George's Respiratory Questionnaire (Nonoyama et al study) and the Chronic Respiratory Disease Questionnaire (Eaton et al study). The studies reported that whilst Eaton et al 2002, found AO did confer positive results on quality of life status, Nonoyama et al 2007 found there was no benefit. The Eaton et al study recruited participants who had recently finished a pulmonary rehabilitation programme which is known to positively affect HRQoL (Ringbaek et al 2012), whereas Nonoyama acknowledges that his participants had not, so may have been more physically inactive. HRQoL has been demonstrated to affect all aspects of the life of a person with COPD, including physical activity (Kanervisto et al 2010), medication adherence (Agh et al 2011) and even mortality (Celli et al 2008), so any intervention that can positively affect HRQoL in COPD may be very important.

2.4.4. Benefits relating to exercise

There has been much debate over the use of AO to improve the effects of exercise. A Cochrane review of five RCT's concluded that there was little support for supplementary oxygen during exercise, but reported that COPD people could exercise for longer and have less subjective dyspnoea when using oxygen during exercise (Nonoyama et al 2009). This has been supported by a recent study by Dyer (2010), suggesting that AO improved the effectiveness of pulmonary rehabilitation in desaturating but oxygen-respondent patients, although this study has not been fully reported. This newer study may be an important pointer in the discussion over the effect of AO during exercise. The other studies reported by Nonoyama in the Cochrane review, did not assess participants for response to oxygen before starting the exercise

programme, they only included participants who had desaturated on exercise testing. It may be that better selection of candidates, according to what is now known about oxygen responsiveness, may have produced more definitive results. The small improvements found in participants using supplementary oxygen may support the theories of Casaburi and Porszasz (2006) that dynamic hyperinflation is reduced with the use of oxygen so patients can exercise for longer, which may be beneficial to COPD patients at home.

It is important to note that all the research assessing the effect of AO on exercise has used the same criteria as those used for AO prescription i.e. an increase in exercise tolerance, be it walking further or exercising longer, or desaturation markers. No researchers have explored the possibility of benefit to patients in terms of protecting from an increase in pulmonary artery pressure during exercise, which may be important to this patient group in terms of preventing cardiac involvement or further deterioration. For example, it may be important that AO enables a COPD patient to undertake a pulmonary rehabilitation programme whilst preventing a rise in pulmonary artery pressure during exercise.

2.4.5. Benefits relating to maintained mobility for oxygen patients

There is extensive research reporting the importance of maintaining function in terms of exercise capability in COPD patients. A systematic review of the effect of mobility in 6 RCT's which included 230 COPD patients concluded that loss of mobility was a contributing factor to increased mortality (Waschki et al 2011). Conversely, maintaining mobility and exercise tolerance has been shown to significantly decrease mortality in COPD (Ringbaek and Lange 2005; Garcia-Ayermich et al 2006). Reducing physical activity has been shown to be associated with decreasing HRQoL scores in COPD patients (Esteban et al 2011). It is thought that once patients stop going out and continuing enjoyable activities, their HRQoL scores fall. Fall in HRQoL has itself been associated with declining functional ability and increased risk of deterioration (Kanervisto et al 2010). Any intervention that can maintain mobility in COPD patients is an important part of the care of COPD patients, particularly patients with LTOT, as these patients tend to start limiting their activities outside the house to be near their oxygen supply (Ambrosino 2008). Theoretically AO should enable these LTOT patients to move out of the house with a safe, effective source of oxygen, allowing them to

continue activities in their community. However, we know that many patients do not use their AO systems as intended (Ringbaek et al 1999), but the reasons they choose not to use AO are not fully understood.

2.4.6. Summary of the potential benefits of AO

- AO may help to relieve pulmonary artery hypertension especially in patients on LTOT, which may be a very important consideration in allowing the patient to move safely away from their home oxygen supply.
- AO may help to relieve dynamic hyperinflation in some COPD patients during exercise so potentially help them to exercise longer and more comfortably.
- AO may help improve HRQoL which may be an important factor in maintaining patient activity away from home.
- AO may help with exercise but more research is needed to confirm.
- AO may be helpful to maintain mobility in patients and therefore improve their risk of mortality.

2.5. Potential disadvantages to using supplementary oxygen

It is known that supplementary oxygen can incur some disadvantages, although the extent to which these affect people using AO alone is unclear.

2.5.1 Oxidative Stress

The body has complex cellular processes to ensure that oxidants are constantly balanced by anti-oxidants. Oxidative stress occurs when there is an imbalance in this control system, either through an increase in oxidants (such as might be associated with hyperoxia), or a decrease in production/ effectiveness of anti-oxidants (Carpagnano et al 2004). The effects of oxidative stress depend upon the size of the imbalance, with a cell being able to overcome small perturbations and regain its original state. However, more severe oxidative stress can cause cell death, and has been associated with a number of diseases. Some patients with COPD have been found to be affected by increased oxidative stress (although it is unclear if this is

because they produce excessive oxidants, or are unable to increase the supply of anti-oxidants). It is therefore possible that exposing them to more oxygen in the form of AO may increase their potential for oxidative stress. Carpagnano et al (2004) report some evidence that oxidative stress increased in 23 COPD patients after breathing 28% oxygen for one hour. Foschino-Barbaro et al (2005) found that increasing an anti-oxidative (N-acetyl cysteine) prevented a rise in oxidative stress in patients with COPD. Oxidative stress has been associated with an increase in pulmonary inflammation and exacerbations in some COPD patients, which would have a negative effect on the morbidity and potentially the mortality of people with COPD (Barnes 2000).

2.5.2. Problems with hypoxic drive

In healthy individuals, the stimulus to breathe is related to an increase of the waste gas carbon dioxide (CO_2). However, some patients with the extensive lung damage that causes hypoxic COPD have a build up of the waste gas carbon dioxide (CO_2), resulting in a condition known as hypercapnia (Cornwell et al 2010). It is thought that over time, people with hypercapnia become less sensitive to higher levels of CO_2 and rely upon sensitivity to a low oxygen level to trigger a breath (Barnes 2011). It is known that giving oxygen to hypoxic patients who also have hypercapnia, may reduce their respiratory drive, producing drowsiness or even unconsciousness which would increase their hypoxia even further. This has been reported in hypercapnic patients receiving LTOT or uncontrolled oxygen in hospital (Lazic et al 2008). It is unknown if the same problem occurs in AO patients who are receiving oxygen, as this group receive oxygen while mobilising and therefore ventilating their lungs better; but awareness of the problem should be a consideration in the prescription of all oxygen.

2.5.3 AO confers no benefit

The published research around the use of AO is currently inconclusive. Nonoyama et al (2009) reported on five RCT studies looking at the use of AO in exercise and they reported that despite small improvements in some studies the overall results were inconclusive. A systematic review of short term ambulatory oxygen by Bradley and O'Neill (2005) reported similar findings. They found that in some single case studies

oxygen appeared to confer a benefit during exercise, but that further work was needed to identify the specific sub-groups of COPD who might benefit for AO.

2.5.4 Summary of the potential disadvantages of AO

- Supplementary AO may increase oxidative stress in COPD patients increase their risk of inflammatory exacerbations.
- AO may increase hypercapnia in some patients with hypoxic COPD.
- AO may not confer any advantage on the exercising hypoxic COPD patient.

Unanswered questions

The research presented above demonstrates that there are still many questions to be answered about the use of AO and how it is prescribed. The NICE 2010 and BTS 2006 prescription guidelines are un-evidenced (Tham and Anatham 2011) and prescription is based on the idea that these guidelines (increased walking distances, reduced subjective dyspnoea) definitively identify responders who would benefit from AO. However it is unknown if this is true, and whether full cardio-respiratory assessment looking at the effects on AO on pulmonary artery pressure and dynamic hyperinflation during walking may be better markers of the need for AO prescription.

2.6 Summary

COPD is an incurable progressive disease which can cause extensive lung damage. This damage can interfere with the transmission of oxygen into the patient's blood stream, resulting in hypoxaemia. Supplementary oxygen has been shown to improve mortality in those patients and is prescribed to patients who qualify under the guidelines. AO is prescribed both to patients who qualify for LTOT (so have low resting saturations) and to patients who do not qualify for LTOT but demonstrate desaturation on exercise. Prescription of AO is based on the results of field tests where walking

further or feeling less breathless with AO would identify a 'response' to oxygen. However these guidelines are un-evidenced, and there is little research on assessing potential recipients of AO for other benefits such as reduced pulmonary artery pressure during exercise. The next chapter explores the research in adherence to AO in patients with COPD.

Chapter Three: Adherence to AO in people with COPD

3.0 Introduction

This chapter considers adherence in COPD patients to both treatments generally and then to supplementary oxygen. The three quantitative trials which looked specifically at AO use in a domiciliary setting are then presented and discussed. The chapter goes on to discuss the possible effect of the current AO prescription guidelines on adherence. It then questions what is not known about AO particularly from the perspective of the person using AO and ends with a rationale for the research undertaken in this thesis.

3.1 Adherence

For healthcare professionals prescribing AO to the responding patient, the fact that walking distances or subjective dyspnoea improves on assessment may equate to assuming the patient will definitely use the intervention to help maintain outside activities. However clinically it is evident that whilst some patients use AO, others do not, and this observation is supported by the research evidence discussed below. Understanding why patients may decide to use or not to use AO is crucial to prescribing effectively.

Christenson (2004) suggested that despite all the advances in modern medicine, the effectiveness of any intervention relied on the willingness of the patient to follow the required medical regime. He described this as the 'Achilles heel' of the medical management of any condition, covering the taking of prescribed drugs, attending appointments and undertaking any required lifestyle or behavioural changes. He defined adherence as

'The extent to which a person's activity or behaviours coincide with advice or instructions from a healthcare advisor intended to prevent,

monitor or ameliorate a condition' (2004:3)

Non-adherence to medicines in long-term conditions appears particularly problematic. These patients have to self-manage their medications on a day by day basis with medical intervention aimed at maintaining health and prevention of deterioration, not curing. It is well documented that adherence to medication in chronic conditions is generally poor (Hahn et al 2008). Research suggests that adherence in chronic diseases may run at between 40-60% (Vestbo et al 2009) and that non-adherence may directly contribute to increases in hospital admission and mortality rates (Butler et al 2011). The reasons for this non-adherence may be myriad, but research has suggested that complexity of drug regime, the presence of side-effects, lack of perceived benefit and lack of support for the patient may all contribute to non-adherence (Protopopescu et al 2009).

3.2. Adherence to COPD medications

Within COPD, patient adherence to medication is also thought to run at a 40-60% (Agh et al 2011). COPD is a complex chronic condition where patients may be managing several different treatment modalities in one day, such as multiple inhalers, nebulisers, oral drug regimes and supplementary oxygen. This is without any additional medication for any co-morbidities. Complexity of drug regime may also be a factor in adherence in COPD; Yu and colleagues (2011) found that just simplifying the regime in terms of using combination inhalers instead of separate ones improved adherence to medications in COPD. George et al (2005) found COPD patients were influenced by their perception of the perceived benefit from an intervention, so that if it was perceived as useful they persevered with using it. A qualitative study by Chen et al (2008) supported the findings by George et al, and found that COPD participants used the medications they felt they needed on a day by day basis. This day to day variability in symptoms and medication use may affect use of all medications including supplementary oxygen. Lopez-Capo (2010) found that how patients felt in the first few hours of the day may dictate medication usage for the rest of the day.

3.3. Adherence to supplementary oxygen

Oxygen is a drug and may be part of a complex daily drug regime. It is useful to look at adherence to LTOT because the prescription of LTOT ensures the patient is told a specific number of hours per day during which they must use their LTOT. So there is a parameter against which to measure adherence. The research studies which have explored patient adherence to home oxygen, have suggested that adherence to LTOT is around 50% (Cullen 2006). An adherence study by Pepin et al (1996) put LTOT adherence for 15 hours of oxygen per day at 45% in a cohort of 930 COPD participants. This appears to suggest that even interventions which have been shown to improve mortality are difficult for patients to adhere to. Different researchers have ascribed this low adherence to different factors such as; fear of dependency, length of time using the equipment, problems with the equipment itself and outside activity (Cullen 2006, Ringbaek 1999).

3.3.1 Adherence to AO

Exploring adherence to AO is a much harder concept than LTOT because there are no specific rules for use. Studies which have reported on AO have adopted 'use outside the home' as the criteria for judging AO adherence and have used cylinder usage as a means of establishing the level of adherence. Some studies have reported on adherence in AO together with LTOT and these have been mostly quantitative in design; for example Kampelmacher et al (1998) in a survey study of 528 LTOT participants found that only 20% said they were using their AO outside the home. These respondents cited non-adherence due to feeling shamed at being seen with oxygen, or felt they had impaired mobility due to the weight of the equipment. In another questionnaire study by Ringbaek et al (1999) with 125 participants with LTOT; 45 had mobile units. Of those 45 participants with AO, only 17 used them outside the home. The reason cited for not using AO was the weight of the AO equipment.

A qualitative study by Earnest (2002) used in-depth interviews to explore adherence in 27 COPD participants using both LTOT and AO. Although adherence to LTOT was the main focus of the paper, the author described emerging themes around using AO,

including embarrassment at being seen with oxygen, fear of dependency on oxygen, burdensome AO equipment and using AO to manage symptoms away from home. The author concluded that in his opinion, symptom management was the most powerful motivator in oxygen usage. If participants felt oxygen helped them to relieve breathlessness, then they used it. If the participant did not feel any benefit, in terms of relief of breathlessness, then they struggled to incorporate oxygen as part of their treatment regime. The patient's belief in the effectiveness of an intervention to improve symptoms is a common theme in general medication adherence literature (Christenson 2004).

3.3.2 Adherence to AO in a domiciliary setting

Ambulatory oxygen was developed to allow patients who use LTOT, or who desaturate on exercise, to continue to use their oxygen when away from the home. Three studies; Lacasse et al 2005, Sandland et al 2008 and Moore et al 2011, all used RCT's to examine the use of AO in a domiciliary setting. These three studies are summarised in table 3 below and discussed in the next section.

Table 3: Studies designed to investigate the domiciliary use of ambulatory oxygen

Authors	Study	No:	Findings and Conclusion
Lacasse et al 2005	A one- year randomised three-period cross-over trial; pts randomised 1. an oxygen concentrator at home with no AO, 2.oxygen concentrator +AO, and 3.oxygen concentrator + compressed air. Each arm was 3 months + 1 month wash-out. Gas titrated to prevent desaturation below 90%, delivered with OCD Pts picked up cylinders themselves. Patients selected for study were those thought 'most likely to benefit from AO'. <i>COPD pts had resting hypoxia and LTOT for 3-12 months</i> <i>No previous use of AO</i>	24	POM: HRQoL, 6MWT and use of cylinders No improvement in the oxygen group compared to the air group was found in terms of HRQoL score Pts went out of the house three times more without cylinders than with cylinders, so study stopped pre-maturely
Sandland et al 2008	Randomised 8-week double blinded placebo-controlled trial of cylinder air vs. cylinder oxygen, Pts had completed 7 week PRP. Gas delivered at 2l/m. Baseline ISWT/ESWT/HRQoL, Cylinder usage and domiciliary activity recorded. <i>COPD pts with either hypoxic at rest and using LTOT or had exercise hypoxia</i> <i>No previous use of AO</i>	20	POM: cylinder use away from home, HRQoL score No significant changes in domestic activity or HRQoL for either cylinder oxygen or air (POM). Worsening of HRQoL score on cylinder air. Increasing cylinder oxygen usage outside the home (in minutes per day) over 8 week trial period.
Moore et al 2011	12-week parallel double-blinded randomised trial of cylinder air versus cylinder oxygen. All gas delivered at 6l/m via OCD. Cylinders provided with trolleys and pts instructed to use during activities that made them breathless inside/outside the house. <i>COPD pts with/without exercise hypoxia but with exercise dyspnoea</i> <i>No previous use of AO</i>	139	POM; Number of cylinders used, B/TDI, HRQoL, HADS No difference in B/TDI or HRQoL between oxygen and air groups Initial laboratory improvement in 6MWT with oxygen usage 50% reported difficulties with equipment 28% felt cylinders helped

POM=primary outcome measure, HRQL= Health related quality of life score, CRDQ= Chronic Respiratory Disease Questionnaire, ISWT=Incremental shuttle walking test, ESWT= Endurance shuttle walking test B/TDI=Baseline/Transitional dyspnoea PRP: pulmonary rehabilitation programme, OCD: oxygen conserving device, LTOT: long-term oxygen therapy, 6MWT: 6 minute walk test.

3.3.3. The AO domiciliary trials in more depth

1. The study by Lacasse and colleagues (2005) recruited COPD participants who had been on LTOT for 3-12 months but did not have AO. No reason is given as to why these participants who qualified for AO had not been prescribed it, but the authors say that these participants were recruited because they were deemed 'most likely to use AO' (Lacasse et al 2005; 1034). The authors state that they needed to recruit 43 participants to give a 90% chance of showing a statistically significant difference in CRDQ score, but in fact only 24 participants had completed the trial. Oxygen was titrated (on a 6MWT) to maintain saturations at 90% and delivered through an oxygen conserving device (flow rate was not recorded in the study details). No practice walk tests are recorded. Participants picked up their own cylinders from the research centre. It is unclear if this is normal practice for Canada where the trial was conducted. Cylinders weighed 3.5 kg and they were carried by the participant. The study included a one month wash-out period (no treatment received) between each active arm when participants presumably did not receive any ambulatory cylinders. It is difficult to know how the authors thought the participants would cope with this period if they needed AO, or if they coped well without cylinders, why they should start using them again once they had entered the next phase of the study. The experience of having to cope with subjective dyspnoea has been reported in other studies where patients have developed coping strategies to allow them to cope with breathlessness outside the home (Williams et al 2007) and this may affect their use of an introduced cylinder. It has been suggested by this researcher that if a patient does not feel they need AO this will influence their use of AO (Arnold et al 2011). The Lacasse study was stopped early because patients were not using their AO outside the house, but it is difficult not to conclude that the parameters of the study itself contributed to participants not using AO consistently. In a later publication Lacasse and Maltais (2006) acknowledged that patients established on LTOT are less likely to leave the house, so this may have affected the results.

The authors do not comment on the use of a cross-over trial in COPD patients, but the progressive and unpredictably nature of the condition could mean that participants were physically better or worse during different parts of this study.

2. The study by Sandford et al (2008) included COPD participants who also did not have AO at home, despite some of them receiving LTOT. Exercise desaturation was

defined using the ISWT, no practice walk tests are recorded although the author said that participants were familiar with the test following a pulmonary rehabilitation programme. The participants were assessed at baseline and then were randomised into receiving either an air or oxygen cylinders at home for 8 weeks. Each cylinder weighed 3.1 kg and delivered gas at 2l/m. The authors record giving 'standard advice' on using AO, but do not say what that advice constituted. Backpacks were given to participants to help them carry the equipment, but there is no record of the acceptability of this carry system. Although of the 32 patients randomised to the trial arms, nine withdrew citing weight and aesthetics of the equipment or exacerbation. Daily activity was recorded with an activity monitor on a belt worn for 12 hours daily for 7 consecutive days. The authors do not record when within the 8 week study, the 7 days continuous monitoring occurred and this may be significant, particularly as the study itself recorded increasing use of oxygen cylinders towards the end of the study period. A self-reported diary was used to record time away from home. The authors found no difference between oxygen and air in cylinder usage in domestic activity or HRQoL, although there was an increase in oxygen cylinder use outside the home, as the study continued. The authors report that cylinders were changed during regular visits by the investigator but there is no information on how often those visits occurred, or if participants ever ran out of gas and had to wait for refills. The authors do not comment on the ethics of the use of air cylinders with patients on LTOT, which is against current prescription guidelines, but would have occurred in the randomisation of participants. It is unknown how this may have affected the results, if participants did not use the air cylinder because it did not help. It may be that since these LTOT participants were not already in receipt of AO they may have been assessed as not leaving home enough to warrant a prescription and this would have affected the results of this study. Sandland also acknowledged that delivering the gas at 2l/m may not have been sufficient to maintain saturations in desaturating participants and this may have affected their results.

3. Moore et al (2011) performed an RCT of 139 stable COPD participants. Unlike the other domiciliary studies cited above, it recruited participants who were breathless on exercise, but only some of the participants had exertional desaturation and the potential importance of this is discussed further below. The authors do not comment on the cause of the exertional breathlessness in the non-desaturators, so this could have been caused by muscle de-conditioning which would not necessarily have show any improvement with supplementary AO. Participants had no existing home oxygen

support and so had no experience of AO. Exertional desaturation was demonstrated by using the 6MWT (below 88%) and was found in 35% of participants. No practice walks are recorded. Cylinders weighed 4.2 kg and trolleys were given to the participants to help with carrying. The gas was delivered at 6l/m through an OCD. The study method was similar to the Sandford et al study above, in that participants were assessed at baseline then randomised into either an air or oxygen intervention to receive at home. The authors reported in one part of the study that no recommendations were given to the patient on the use of the gas cylinder at home, and in another paragraph report the participants were asked to use the cylinder during any activities provoking breathlessness. Self-reported diaries and activity monitors were used to establish activity level and gas usage. The authors report no difference in cylinder usage or change in Quality of Life scores. It is interesting to note that 50% of the participants reported difficulties with the apparatus; either poor portability or trouble with the regulator on the cylinder, which may have affected usage of the equipment. The authors themselves suggest that 6l/m gas delivery is high but it was adopted to try and alleviate breathlessness. However it was delivered through an oxygen conserving device so whether this would have affected the participant's perception of flow and exercising ability is not discussed. OCDs are devices which interrupt the inspiratory flow of oxygen from the cylinder so it only flows during inspiration. This is thought to lengthen the life of a cylinder by only allowing gas delivery during inspiration. However research has shown that an interrupted flow of oxygen to a patient may result in lower oxygen saturation levels than when continuous flow is utilised (Palwai et al 2010). These same authors also reported that OCDs were highly variable and could actually contribute to limitations in exercise ability.

Moore et al (2011) recruited patients with exercise breathlessness but not necessarily exercise desaturation, whereas most of the earlier studies have recruited patients with exercise hypoxaemia, but do not necessarily state if the patient felt breathless on exercise or if they were oxygen responders. Each study is concerned with assessing if oxygen makes any difference in terms of AO cylinder use. Yet we know (Sandland et al 2008) that not all COPD patients actually respond to additional inspired oxygen. So it is not surprising that studies show a wide variation in results. The difference in the perspective of how patients perceive their breathlessness, the cause of their breathlessness and the ability of supplementary oxygen in relieving that breathlessness may be crucial to understanding not only the efficacy of AO within COPD, but also why patients who have been prescribed it, do not use it.

3.3.4. Summary of domiciliary trials

- Three trials with three different protocols.
- Different levels of desaturation were used for each study; the Lacasse study only included participants already on LTOT, so desaturated at rest, the Sandland study included patients on LTOT and those who desaturated by 4% to below 90% on exercise saturation monitoring and Moore used 88% as the desaturation level, including participants who did desaturate and those who did not.
- No practice walks were recorded in any of the studies above and the importance of this is discussed further below.
- No trial recorded the instructions, if any, which were given to participants regarding use of AO. This may have been important particularly considering some study participants had managed without AO up to the time of the trial.
- Barriers to use included weight of the equipment, aesthetics of the equipment and lack of benefit.

3.4. The importance of these three studies as a collective whole

These three quantitative RCT's examined the use of AO at home, and are, in fact, the only published studies that could be identified looking at the use of AO at home. All three concluded that AO had limited benefit in domiciliary use, but this bears further investigation. All three used clinical field tests to establish the presence of exercise desaturation in the recruited participants at baseline. All three recorded disappointing results in terms of use of AO in a domiciliary setting. However what does emerge from all three trials is that exercise desaturation at assessment, did not appear to predict the use of AO at home. This is important; if the presence of exercise desaturation at rest does not predict usage, is that because:

1. The parameters for clinical prescription are not able to discern patients in whom AO would be beneficial over time, particularly those with only exercise desaturation and who do not qualify for LTOT.

Or

2. Patients are choosing to use or not to use the intervention for individual reasons.

The following section explores the research around the field tests used in the assessment of AO. As discussed in chapter 2, the field tests used in the assessment guidelines are un-evidenced (Tham and Anatham 2011), and a growing body of research is questioning whether these field tests themselves contribute towards non-adherence in AO users. The reasons why the assessment for AO may directly affect adherence to AO use at home is discussed further in section 3.4.1.

3.4.1. Use of field walking tests in assess AO effect

Clinically the six minute walk test (6MWT), the incremental shuttle walking test (ISWT) or the endurance shuttle walking test (ESWT) are tests used to assess suitability for AO prescription. Clinical practice (as viewed by this researcher in four different oxygen assessment centres) is to do a baseline test without oxygen and then a second test with oxygen to assess any improvement in walking distances or subjective dyspnoea. However, it is well documented that these field tests have a 'learning effect' i.e. that participants improve their walking distance by practising the test before a baseline is established (Morante et al 2005). The current clinical guidelines stipulate a improvement in walking with supplementary oxygen of at least 10% is required for possible AO prescription (BTS 2006), but Leach et al (1992 p784) suggest that the 'learning effect' in the 6MWT may be as much as 17% between walks 1 and 3. McKeough et al (2011) reported that there is an identifiable learning effect with both the ISWT and the ESWT and that the ISWT should be repeated twice before *and* after an intervention and the ESWT should be repeated twice post intervention. This suggests that if only one pre-assessment walk is used, any improvement may not be due to supplementary oxygen but to the patient improving walking distances purely through a learning effect from walk one to walk two. The use of the first stop point identified by Leach et al (1992) and Revile et al (2010) may be a more important marker than walking distance in six minutes or shuttle walking distance because it may more closely reflect a patient's home pattern of movement (Eisner 2011). This is

important as if oxygen is prescribed incorrectly because a patient improved their walking distances through a learning effect, then AO may not be useful at home and so be discarded by the patient.

3.4.2. Sensitivity to desaturation

There is a growing body of research exploring how sensitive these field tests are to changes in oxygen saturation. Chatterjee et al (2010) found that participant saturations fluctuated over the course of 3 repeat 6MWT tests performed over three different days. Their study reported that 58% of stable COPD participants demonstrated a desaturation to 88% in one 6MWT, but that only 30% of the same cohort demonstrated desaturation over 3 6MWT tests with continuous SaO₂ monitoring. This may be due to the training effect mentioned before but Chatterjee et al suggested that the 6MWT itself may only have moderate reproducibility for AO assessment. This opinion differs markedly from Morante et al (2005) who reported that the 6MWT was an effective method of establishing the presence of desaturation in COPD participants. Interestingly Morante et al study tested 3 6MWT on the same day, but used 85% as the desaturator point, unlike any other study reported here. It is unknown if the ISWT/ESWT has been tested for reproducibility for desaturation in AO assessment. Turner et al (2004) found that the 6MWT and the ISWT were comparable in terms of sensitivity to desaturation, whereas Lewko et al (2007) argue they are not. Lewko and colleagues contend that the ISWT induced much greater exercise desaturation than the 6MWT where the patient walks at their own pace and stops and starts as necessary. Revil et al (2010) argues that the ESWT is more sensitive to saturation levels because the participant does not stop, which they may do in the 6MWT.

Another important consideration here is the accuracy of pulse oximetry itself. Milner and Mathews (2012) claim that the standard deviation for any pulse oximeter is $\pm 2\%$, this could mean that a patient's saturations are incorrectly recorded. Additionally these authors found that in a sample of pulse oximeters being used in 29 different hospitals, a significant proportion were inaccurate to a level of 4%. The assessment for AO depends on accurate pulse oximetry not only to detect desaturation but also to ensure levels of oxygen are titrated correctly to prevent desaturation. Pulse oximeters may not be accurate enough to perform this task.

3.4.3. Titration of supplementary oxygen to prevent desaturation

The studies looking at the effect of supplementary oxygen on walking distances have used different protocols for delivering that supplementary oxygen. Leach et al (1992) and Jolly et al (2001) both titrated oxygen levels upwards during the study and found that higher levels of supplementary oxygen appeared to result in better walking outcomes. However other studies for example Sandland et al (2008) delivered all oxygen at 2l/m, despite the patient's level of desaturation, and these authors note that not titrating oxygen levels may have been a problem in their study

Clinically the titration of supplementary oxygen to prevent desaturation is an area of practice which is often not addressed. Healthcare assessors observed by this researcher blamed time constraints for not re-assessing patients to ensure prevention of desaturation if they had responded positively to oxygen. Patients were routinely prescribed 2l/m of oxygen flow for the AO equipment. This may negatively impact on the use of AO at home as the patient may still be desaturating despite using supplementary oxygen, if the oxygen flow is inadequate.

3.4.4. Do walking field tests reflect functional ability?

The issue as to whether walking field tests reflect functional ability is an important consideration in the use of tests to determine AO prescription. If these field tests do not reflect functional ability then any improvement in walking distances with AO may not reflect a useful increase in functional ability at home, and may also help explain why patients may not find AO beneficial. There is no definitive answer although there has been much debate about the usefulness of walking tests in determining functional levels. Glaab et al (2010) argued that the 6MWT and the ISWT were valid tests for reflecting a patient's life activities. They based this argument on the fact that both tests are symptom limited which may accurately reflect a patient's lifestyle. Lewko et al (2007) and Eisner et al (2011) suggested that the 6MWT may be better than the ISWT at detecting the patient's functional capacity. They suggested this because in the 6MWT the patient is allowed to stop and start as they feel necessary. These authors maintained that this is a better assessment of usual daily activities rather than the maximal exertional assessment associated with the ISWT.

Taking a different perspective, Morante et al (2005) conducted an experimental study of 37 COPD patients which compared oxygen saturations recorded during a 6MWT and during 24 hour continuous monitoring at home. The authors reported that patients did not record such low saturations during home monitoring as they did on the 6MWT. From this the authors argued that patients with COPD avoid becoming breathless in their ADL's and so do not achieve the levels of breathlessness or desaturation recorded during set exercise field tests. Fussel et al (2003) also found that 18 participants desaturated on the 6MWT whereas only 3 of the same participants desaturated on continuous ambulatory monitoring at home. Viera et al (2011) following an experimental study of 35 COPD patients concluded that an improvement in the 6 MWT with AO, i.e. an acute response to oxygen, did not predict an increase in outdoor activity at home.

A lack of association between field tests and functional activity may be an important aspect of prescribing AO from field tests. However valid and reliable they may be, these tests may not reflect the daily life experience of COPD participants in terms of desaturation or exercise dyspnoea. If a patient desaturates on a field test but is not achieving those levels of activity, desaturation, and breathlessness during home activities they may not use AO.

3.4.5. Summary of the use of field walking tests in AO prescription:

- 6MWT/ISWT are the most used field tests for prescribing AO, even though endurance testing may be more sensitive to change.
- There is a 'learned effect' as part of all field tests.
- This learning effect could account for any increase in walking distance

3.4.6 Implications for adherence to AO

The section above explored the area around the prescription of AO and how that clinical prescription may itself be a reason why AO is not successfully used by some patients in the community. Research suggests that the desaturation levels which are recorded in the 6MWT or ISWT, and which prompt AO prescription, may not be reached by COPD patients at home (Morante et al 2005). In this case COPD patients may feel no benefit from AO and stop using it. Only performing one field test before testing with supplementary oxygen, may mean that any improvement in walking distances is due to a learning effect rather than from an improvement due to AO (Leach et al 1992). Again this may equate to patients not feeling that AO is helpful and discontinuing use at home. Not titrating oxygen levels to prevent de-saturation when walking may mean that patients do not feel it is beneficial, and so discontinue use. George et al (2005) argued that COPD patients use an intervention that they think is beneficial. Patients who are assessed for AO will have experienced subjective breathless and may have developed their own coping strategies which, up to the time of assessment, will not have included AO. Patients need to find enough benefit from AO to carry a cylinder of oxygen around with them. It is hard not to conclude that the present assessment for AO may not be able to detect or predict enough of a concrete

benefit for COPD patients to use AO at home. Tests to identify the potential benefits of AO described in 2.4 would require in-depth cardiovascular assessment.

3.5. What is not known about the USE of AO by patients

Little is known about what happens to a COPD patient once oxygen has been prescribed. As Myers and Midence (1998) argued, the majority of work on adherence has been designed to give researchers and clinicians a more theoretical knowledge of adherence, what remains unknown is the patient's perspective of the factors which influence adherence to a treatment. Research suggests that AO is not well used by patients to whom it is prescribed, despite response at assessment (Tham and Anantham 2011). Croxton and Bailey (2006) had previously argued that the underuse of AO by patients and the reasons for this underuse needs further research. These authors went on to advocate research into AO both in terms of clarifying the benefits of AO to COPD patients and how patients use AO, as a priority for medical researchers. This call for more research into the use of AO has been echoed by others (Nonoyamo et al 2007), Drummond and Wise (2007) and Albert and Calverley (2008). The latter suggested that whatever the clinical benefit AO has on the performance of COPD patients, what remains largely unknown is how patients use AO in their day to day lives, and what effect AO has on people's capacity to function. Katsenos and Constantopoulis (2011:6) described this lack of knowledge as an 'enormous void that must be confronted'. Presently any understanding of patient's use of AO is based on quantitative survey studies and one qualitative study which were focused on LTOT use. These studies have not provided an adequate picture of patients' beliefs about the use of AO at home.

3.6. Rationale for this PhD programme of work

The provision of AO, on prescription, in the UK has been viewed as an important reflection of the quality of care provided to patients with COPD. The freedom of healthcare professionals to prescribe it to appropriate patients has been seen as vital to improving COPD healthcare (Ambrosino et al 2008). Despite some of the continuing uncertainties around the clinical efficacy of AO and its prescription for COPD patients, it is currently part of UK national clinical guidelines for the treatment of patients with COPD. Until we as healthcare professionals, have a greater

understanding of how patients, who are prescribed AO, decide to use it at home, we will be at risk of prescribing an intervention which may not be used. Researchers have highlighted this lack of knowledge as an important gap which needs addressing. The prescribing of AO can be directed at ensuring patients will derive the maximum benefit from this intervention. This study seeks to address this lack of knowledge.

Therefore the rationale for this research rests upon the following:

1. The need for clinicians to understand why some patients decide to use their prescribed AO whereas others decide not to use it.
2. The need for a greater understanding of the patients' perceptions of AO.
3. The need to understand how those perceptions affect an individual's use of AO.
4. The need to identify any barriers to use that may have been experienced with AO.

This study moves away from the previous research focus on how AO improves patients' physical performance and instead explores how patients use their AO in their daily lives and what factors or issues appear to impact on their use of AO.

The research objectives of this study are:

- to understand from the patient's perspective, what issues they have around using AO.
- to identify the patient's perception of the system.
- to gain insight into the processes that appear to affect how patients use this intervention.

The research question underpinning this study was:

What do people with Chronic Obstructive Pulmonary Disease (COPD) and prescribed ambulatory oxygen (AO) perceive as the advantages and disadvantages of their system and how do those perceptions affect their use of the AO system?

Chapter Four: Methodological Overview

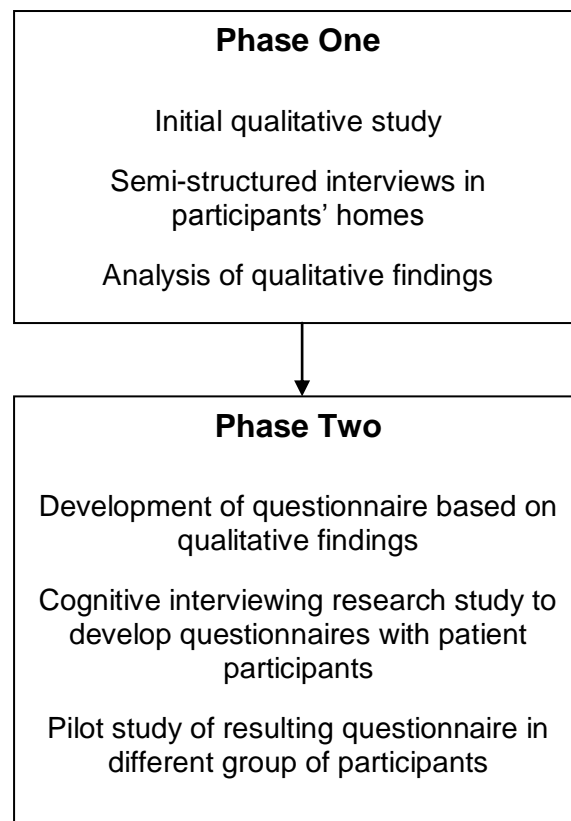
4.0 Introduction

This chapter summarises the two research phases which make up this thesis, and details the aims of each of these phases. It describes the ontological, epistemological and methodological approaches which underpin research in general and explains the researcher's individual epistemology. The chapter goes on to clarify the choice and justification for the research approaches, both qualitative and quantitative, employed during the different research phases of this thesis and ends with an overview of mixed methods research.

4.1 Summary of this research

The goal of the researcher is to explore the patient's perceptions of AO when using, or not using, this intervention at home. The first research phase used a qualitative approach to identify what patients themselves actually thought about their AO systems by interviewing them in their own homes. The second research phase evolved from the findings of this qualitative research phase. Here a quantitative questionnaire was devised in order to ascertain if the perceptions of the quantitative participants were also found in a larger cohort. This combination of qualitative and quantitative methods produced a mixed method research thesis. Figure one below depicts how this thesis has been conducted.

Figure 1: to demonstrate the research phases used in this thesis



4.1.1 Justifying the combination of qualitative and quantitative methods

Combining qualitative and quantitative methods is a source of academic discussion which is explored further below. In this study the approaches were combined to ensure the research question was answered as fully as possible. If the study had finished after phase one then any findings would have applied only to a small local population. In order to generalise the results to a larger COPD cohort, phase two was thought to be an essential part of the research process. Using both research approaches in this way is supported by the arguments of Walker et al (2010) that the weaknesses of one approach are offset by strengths of the other, so the findings from a smaller in-depth inductive qualitative study can be confirmed, or not, in a larger population. This ensures that the identification of perceptions which any affect the use of AO will have strong generalisable foundations.

4.1.2 Phase One

The aim of phase one was to explore what patients perceived about their AO system, and how those perceptions affect their use of AO. In order to explore these perceptions, it seemed essential to ask the patients themselves to explain their views about the equipment, their perceptions of its usefulness and why they had decided on a specific course of action regarding its use. This supports the argument of Lees (2011) that it is only by asking the patients themselves that allows healthcare professionals (HCPs) insight into patient experiences. The rationale for the methods used is discussed later in the chapter but a deductive approach involving a pre-presumed hypothesis was deemed inappropriate and an interpretative approach using in-depth interviews was the research method employed here to collect the information needed to answer the research question.

4.1.3. Phase Two

A Cognitive Interviewing study (CI) and pilot study were employed to develop a questionnaire based on the findings of phase one. This questionnaire was designed to explore if the beliefs found in the results of phase one, were also present in a larger cohort of COPD patients using AO. The aims and methods employed in each phase are summarised in Table Four below.

Table 4: The two phases of the research

Phase	Aims	Method
Phase one	To develop and clarify the research question while exploring patient's perception of their AO equipment by carrying out in-depth interviews with patients prescribed AO	In-depth interviews to collect the experience information inductively from participants
Phase two	To develop a questionnaire based on the results on the in-depth interviews, designed to present the views of the phase one cohort. Pilot that questionnaire in another group of participants, so that the final questionnaire is ready to be disseminated.	Using cognitive interviewing techniques to develop a questionnaire based on the findings from phase one and ultimately to deductively confirm the findings from phase one.

4.2 Ontological, epistemological and methodological issues

Crotty (1998) argued that before adopting methodologies and methods to answer any research question, it is important to understand what the researcher believes in terms of how knowledge is known and what kind of knowledge does the researcher believe is attainable. Birks and Mills (2011) suggested that how knowledge is known for the researcher i.e. the researcher's philosophical position, informs the methodological approach and the method used to obtain the research data and to analyse it.

4.2.1 Research Paradigms

Philosophical beliefs about the world and how it is known are often portrayed in terms of 'paradigms'; which are described as human constructions (Guba and Lincoln 1999) or views about how the world is perceived (Annells 1996). The idea of a 'paradigm' which reflected a particular 'world-view' was suggested by work of Thomas Kuhn in 1962. These paradigms describe how a researcher may view the world and their beliefs about how knowledge is created (Morgan 2007). Sandelowski (2004) suggested each paradigm includes distinct views on;

1. Ontology: a view of reality
2. Epistemology: views of knowing, principally how something is known and the relationship between what is knowable and the knower
3. Methodology: views about methods of inquiry

A paradigm is, therefore, a set of beliefs held by the person/researcher which define how the person looks at the world, his or her place in that world and how he/she can acquire knowledge of that world. However paradigms are not established immutable truths, they are not fixed; they represent possible truths as to how the world may be viewed by an individual (Guba and Lincoln 1999). Paradigms have evolved, and continue to evolve, over time as new thoughts and theories about the nature of the world and how knowledge is known and acquired have emerged. For example, Annells (1996) argued that up to the 1980's the prevailing paradigm was positivism i.e. reality is assumed to exist through immutable laws. This philosophical view held that the researcher was an objective observer and recorder of the participant's reality but separate from it. This view is now associated with a quantitative research approach (Castillo-Page et al 2012). Over time different viewpoints have emerged as researchers question how they see the world and how the voice of participants within their research are represented. For example, Constructionism holds that reality is multiple mental constructions or realities which collectively exist, so the researcher actively helps to create a reality with the research participant (Willig 2001). Positivism and constructionism could be said to represent the two extremes of a continuum of research 'positions' which could be adopted by a researcher.

Table Five below describes a range of the epistemological positions held in healthcare research today, and describes what the researcher who subscribes to these epistemological position believes to be the ‘truth’ about attainable knowledge.

Table 5: the most common paradigms in healthcare research, with positivism and constructionism shown as examples of extreme positions based on Cohen and Crabtree (2007)

<p>Realism _____ Relativism</p> <p>Positivism _____ Constructionism</p> <p>post-positivism interpretism subjectivism</p>	
<p>Positivism could be seen as:</p> <ul style="list-style-type: none"> • There is a real world/reality outside and apart the person • Researchers can know this world/reality and accurately describe and explain it • Researchers can compare their explanations against objective reality which allows for verification, and prediction • The world is imperfectly known but can be known better through research 	<p>Constructionism could be seen as:</p> <ul style="list-style-type: none"> • Reality is mentally constructed inter-subjectively • We cannot separate ourselves from what we know, who we are and how we understand the world • Researcher's values are inherent in all phases of research • Research findings or knowledge are created through negotiation of meaning between research and participants

Traditionally research approaches using an epistemology of realism (e.g. positivism) are associated with uncovering a knowable reality or truth through methods using verification, usually through the use of numbers, as in quantitative work (Castillo-Page et al 2012). Qualitative work has been more associated with interpretative epistemologies, and relies on textual data which aims to understand the meaning of human action (Carter and Little 2007). Table six below summarises some of the broad differences between qualitative and quantitative approaches

Table 6: The differences between qualitative and quantitative research approaches based on Castillo-Page et al (2012)

	Quantitative Approach	Qualitative Approach
Ontology	Realism	Relativism
Epistemology	Objectivism: knowledge is external truths	Interpretism: knowledge within individual values, culture and experience
Research participant	Held separately from research process, knowledge collected from participant	Part of the research process, knowledge is integral part of person
Knowledge gained	Explanatory, predictive	Understanding of actions, meanings
Knowledge gained	Generalisable	Specific
How knowledge is gathered	Deductively –theory confirming or falsifying a theory	Inductively- any theory emerging from collected data

4.2.2 Paradigms and Mixed Methods Research

Most of the discussions around the use of qualitative and quantitative approaches have been from researchers passionately advocating one specific approach over another, so much of the academic opinion around paradigms and their uses have been written from specific epistemological positions. Carter and Little (2007:131) described this as epistemological ‘fundamentalism’, where researchers become entrenched in

one epistemological position which, they argue, can never be changed, modified or combined with any other method. Mixed methods research which involves mixing the research approaches traditionally associated with either qualitative or quantitative research, has highlighted these arguments. For example, Denzin (2010) as an opponent of mixing qualitative and quantitative research argued that the two approaches represent such different world-views and corresponding research approaches that they cannot be compatible within one study. A researcher who believes that there is one external reality and uses a positivistic epistemological approach in their research, could not then argue that s/he holds, for example, a constructed view of a multiple reality for another part of the research. On the other hand Wuest (2011:7) talks about the importance of moving between the “silos” of epistemological position and using a “toolbox” of approaches, and Searle (1995:25) suggests that philosophical differences should not be regarded as problems but rather resources for helping people understand how they view the world.

For researchers holding philosophical views at the extreme ends of the continuum (diagram 1 above) it is difficult to see how a mixed methods approach could be reconciled. For example, constructionism at its extreme would mean there would be multiple realities where each one is equally valid, and positivism at its extreme would mean there is only one external reality. More researchers are questioning if the apparent division between qualitative and quantitative research really is insurmountable. Trochim (2006) argued that the two approaches are not as divided as they may appear; both can use numeric and written data; quantitative research can be used as exploratory in nature, qualitative research can be used to confirm hypotheses; and qualitative research can be successfully employed using an objectivistic epistemology (Greckhamer and Koro-Ljungberg 2005, Lomberg and Kirkevold 2003, Moore 2010, Birks and Mills 2011).

Using both research methodologies allows researchers to utilise the rich tradition of both approaches to benefit a research study and more fully answer a research question (Johnson et al 2007). Within health research, Lees (2011) argued that mixed methods research allows the researcher to work most effectively in exploring and representing patient experience by using an integrated approach of qualitative and quantitative approaches. Mixed methods research has enabled the researcher to

address the complexities of healthcare in a more realistic way, in that several studies have been able to combine for example, not only the effectiveness of an intervention through a randomised controlled trial but also explore how participants used that intervention, giving a more useful rounded picture (O'Cathian 2009; Doyle et al 2009). In line with any other methodological approach, academics stress the importance of researchers articulating why they used a mixed methods approach within any research study.

4.3 The philosophical position of this researcher

Many qualitative researchers insist that researchers must state their epistemological position because this increases the validity of the study and ensures the study is methodological correct (Crossan 2005; Carter and Little 2007; Porter 2007; Koro-Lyungberg et al 2009). Perhaps the most useful reason for explaining a researcher's epistemological position is that paradigms indicate a shared understanding or set of values to which other researchers can relate, and this in itself can help judge the quality of any research (Wutich et al 2010).

This researcher believes that the world is a 'knowable' place and the decisions people make are 'real' and are based on emotions and psychological processes which are 'real' and have definite qualities and properties albeit complex and contradictory processes, but which can be objectively understood by another person i.e. the researcher (Ratner 2008). The researcher believes that when a patient says, for example, they are unable to lift something, they are truthfully revealing their reality and that can be objectively recorded. This is supported by the arguments of Searle (1995) who maintained that because social reality exists and is shared and understood between people, objective judgements could be made about society and its processes. This researcher believes that the participant can be held independently from the researcher and the participant's knowledge can be objectively obtained from them, whilst striving to eliminate interference or influence from the researcher. However the researcher also acknowledges that research is, to some extent, subjective and that another researcher undertaking the same research may produce a different picture of the participants (Duncan and Nicol 2004). She agrees with Kirk and Miller (1986) who argued that this subjectivism does not preclude the existence of a knowable truth which can be sought and obtained from research. This implies that the researcher has

an objectivistic view of the world, but she also acknowledges that although reality exists it cannot be just 'known' but can be increasingly known through research. She also believes that the knowledge required to understand that reality more fully, can be gained from people who have experience and views of that reality. She believes that social phenomena exist in an objective world and would therefore describe herself as a critical realist. Table 7 and 8 below describe the effect of the researcher's epistemological position on this various aspects of this research.

Table 7: The effect of the researcher's philosophical position on phase one and phase two of this thesis

Theoretical perspective	Phase One	Phase Two
Ontology: reality to be known	<ul style="list-style-type: none"> Participant's experience of AO equipment derived from their perceptions of using the system 	<ul style="list-style-type: none"> Participant's experience of AO equipment derived from their perceptions of using the equipment
Epistemology: how that reality can be known	<ul style="list-style-type: none"> Using an approach to collect the participants' experiences of an AO system - words providing access to the truths that govern their use of AO. 	<ul style="list-style-type: none"> Using an approach to collect the participants' experiences of an AO system - words providing access to the truths that govern their use of AO
Methodology: how the researcher can get this knowledge	<ul style="list-style-type: none"> In-depth interviews to inductively <i>collect</i> the patient's experiences objectively in phase one Using an analysis approach which allows theory to be produced inductively from the patient data 	<ul style="list-style-type: none"> Questionnaire study to collect information from questions set by researcher i.e. closed format Using numerical statistical analysis to confirm the findings of perceptions

Table 8: Effect of the researcher's objectivistic epistemological position on the phase one and phase two (based on Birks and Mills 2011)

Epistemological influenced areas	Phase One – Qualitative Study	Phase Two - Quantitative Study
Relationship between researcher and participant	<p>Separated</p> <p>Method used which allows collection of data from the participant</p> <p>Researcher maintains distance from participant</p>	<p>Separated</p> <p>Researcher does not influence participant or data collection in this postal questionnaire</p>
Representation of participant's voice	Voice not represented individually but examples of experience are collected from individuals to develop theory from collected data inductively	Voice not represented individually but examples of experience collected from participant and generalised through statistical analysis
Methods employed to represent quality in the research	Grounded Theory method employs objective representations of quality in terms of: Fit Work Relevance and Modifiability	Employs objective methods of validity for questionnaires e.g.; face error, measurement error, processing error

4.4 Choosing the research methods used in this thesis

4.4.1 Phase One

Within qualitative research there are several different approaches which could be adopted to provide the data to answer the research question. This was not a study concerned with ethnicity or biography or case study so these approaches were unsuitable. An approach which allowed participants to talk about their experience was thought to be most fitting for this project, because it was important to understand why participants had acted as they did with regard to their AO systems (Starks and Trinidad 2007). Within qualitative research design three approaches were considered. Discourse analysis, Phenomenology and Grounded Theory (GT); all of which offered approaches which could have been used to explore the research question. Discourse Analysis was rejected as this was not a study attempting to understand how participants might use language to construct their reality. Phenomenology could have been used to answer the research question, as the study involved exploring the lived experience of each participant in using AO. However as phenomenology does not normally go on to build a theoretical model (Jirwe 2011), GT was chosen as the research method.

GT offers the researcher the opportunity to explore the connections between patient experiences and how they may have influenced their social actions (Stern 2007). GT allows the researcher to develop explanatory theory about social processes based on the data acquired inductively from patients (Starks and Trinidad 2007). Other reasons for deciding to employ GT include;

1. GT offers an approach which adopts an objective reality for qualitative research through the classic GT framework (Moore 2010). This approach suited the researcher's philosophical position as discussed above at paragraph 3.3.

2. Clinically GT is a well known research approach which can inform practical intervention and further research (Wuest 2011). This phase one qualitative research study was part of a larger funded project exploring ways to redesign oxygen cylinders for COPD patients. Being able to produce some theory as to why patients may use or not use the AO systems they had been prescribed, would be a valuable part of that larger project.

3. GT allows for a broad area of exploration of relevant social processes and helps to describe key experiences. GT helps the researcher understand what is significant and what influences participants (Wuest 2011).

4. GT has a defined structure and analysis procedure for directly deriving substantive theory from patient data (Kelle 2007). This structured approach was thought helpful to a novice researcher.

5. GT has been used widely in healthcare research, as Wuest argued “Grounded theories assist health professionals to better understand what is significant, and the ways that social and structural conditions influence how people manage. Most importantly for practice professionals, grounded theories suggest points of intersection, that is, times, places, and ways to change individual practices, alter procedures, and shift policies” Wuest (2011:2).

GT is a method which had developed and evolved since its development by Glaser and Strauss in the in the 1960's. The type of GT employed in this study, is explained and discussed further in Chapter 4 (4.2).

4.4.2 Phase Two

The objective of phase two of this study was to confirm and, if possible, generalise the findings derived from the qualitative interviews performed in phase one within a different cohort. The questionnaire was therefore designed to be test the responses of the qualitative cohort (as opposed to exploratory) and used as a method of triangulation to increase the validity and generalisability of the qualitative interview study findings (Denzin 2010). This meant collecting information from potential COPD participants using AO, across a much larger geographical area. It would be physically impossible to hold individual interviews or focus groups throughout the UK, because of the time and distances involved. However the researcher needed to collect information from this larger cohort, so it was thought that a questionnaire based on the results of the phase one qualitative study would enable the researcher to obtain data on the experiences of AO users further afield. The development and piloting of that questionnaire is described in chapters eight and nine. This thesis ended with the production of the questionnaire and did not go onto use the questionnaire to collect more data.

4.4.2.1. The use of questionnaires in this research

There is ongoing general debate around the use of questionnaires within healthcare research (Marshall 2007). Questionnaires are extolled for their ability to gather large amounts of information from participants in a generalised format. Conversely doubt exists that all participants understand each question equally, which may undermine the results (Boynton 2004). This debate is more fully addressed in Chapter Eight of this thesis. Questionnaires were used in this research to allow the researcher to gather information from a different cohort of participants (although due to time and financial limitations only a pilot study was conducted in phase two).

4.4.3 Philosophical perspectives for phase two

The researcher has already stated her objectivistic epistemological position above. Questionnaires can be used to collect data in different ways. Questionnaires using open-ended questions, where the respondent supplies an individual answer could be used in a more interpretivistic way and to gather new data. On the other hand questionnaires using a closed answer format, where question and answer formats are pre-determined by the researcher, collect information more objectively. This type of questionnaire would be firmly placed within a positivistic philosophical paradigm as described at 3.2.1 above. The results are collated numerically and analysed statistically. Questionnaires represent a deductive positivistic approach to data collection, and are placed within a quantitative framework (Carter and Little 2007). This type of closed questionnaire was used in this research, as the aim was not to explore or collect new information from the respondent. Questionnaires are discussed in more detail in chapter eight.

Phase two involves the use of cognitive interviewing techniques to develop a questionnaire based on the results of the qualitative findings of phase one. As Willis (2005) explained; cognitive interviewing in questionnaire development has been shown to improve the user-friendliness of a questionnaire. It achieves this by rounds of interviews with participants using the developing questionnaire. This helps to ensure that the question and answer formats are answered as the researcher intended, and that they are as comprehensible as possible. This in turn promotes the successful completion of the questionnaire so the researcher can collect the maximum amount of

useful data. Phase two ended with the piloting of the questionnaire after the cognitive interviewing study finished.

This research thesis therefore used a combination of quantitative and qualitative methods (mixed methods study) to answer the research question. Mixed methods research is considered in more depth from 3.5 below.

4.5 Mixed methods research

Although considered a new type of research methodology by some authors (Doyle et al 2009) mixed methods research (MMR) has a long history of being used by researchers as a way of strengthening the validity of a study and its results. Using mixed methods in this way was termed 'triangulation' and proposed by Campbell and Fiske in 1959 (Burke et al 2007). Other academics have supported the use of mixed methods to improve the results of a study. For example, Morgan (2007) suggested that triangulation could encompass mixing not only methods but also different researchers looking at the same data, and using different data sources as all being legitimate ways a researcher could gain further insights and knowledge into the area under study.

The current form of mixed methods research goes further than just verifying research results in that supporters suggest that quantitative and qualitative methodologies can be used as co-existing essential parts of one research study (Morse 2010). This has caused an increase in the academic debate into what actually constitutes a mixed methods research study and arguments both for and against its use as a '3rd research method paradigm' (Burke et al 2007).

4.5.1 Definition of mixed methods research

There is a wide variation of opinion as to what constitutes a MMR study. Johnson et al 2007 (p119-121) lists 17 different definitions of MMR gained from the leading supporters of the MMR movement. They suggested that this diversity is because the MMR field is relatively new, that it is still evolving as a research method and that not having a fixed definition allows the methodology to continue to evolve. The range of

MMR definitions could perhaps be best illustrated by two definitions at either end of the scale.

- MMR is a practical approach to research where there is a combination of qualitative and quantitative research approaches, which capitalise on the strengths of both whilst offsetting the weakness (Walker et al 2010), and this is how mixed methods research has been traditionally viewed (O’Cathain 2009).
- MMR is a new methodological approach which arises from a pragmatist paradigm and includes both narrative and numerical data (Teddlie and Tashakkori 2009).

There is intense academic debate about the use of mixed methods as a new research paradigm. Proponents laud this approach as enabling the pragmatic researcher to gain better insight of the area under study by using different methods (Lees 2011).

Opponents reject the idea of mixing qualitative and quantitative approaches under the banner of the ‘3rd research paradigm’ because of fundamental differences in their philosophical paradigms (Denzin 2010). Within healthcare research the use of mixed methods as a research design is increasing (Doyle 2009). This could be due to the perception, as Lees (2011) suggested, that researchers want to use different methods to better understand all aspects of patient care, and are using mixed methods research to achieve that goal. This research uses a mixed methods approach to improve the study design and ensure the researcher is able to generalise the findings from the phase one qualitative study in a larger cohort of participants.

4.5.2. Justifying the use of a Mixed Methods approach

There are several reasons why a MMR approach may be adopted by a researcher Bryman (2007). A list of the different ways mixing methods may be used in one research project have been summarised in Table Nine below;

Table 9: Ways in which mixing methods have been used in research generally

Concept	Use within MMR
1.Triangulation	This is the most traditional use of mixed methods research (Denzin 2010), where a different approach is used to corroborate or increase the validity of the findings from another type of study e.g. using surveys to corroborate the findings from an interview study
2.Development	Where the researcher uses two approaches to expand elaborate or enhance the research, by using different methods e.g. using interviews to expand the understanding around the results of a survey (Bryman 2007)
3.Complementary	Where the research may help to develop one study by using aspects from another approach e.g. sampling methods (Doyle et al 2009)
4.value for exploring complex social realities	Could enhance capacity to understand social complexities and contexts of social experience (Mason 2006)
5. Answering the research question	MMR helps to allow the researcher to answer the research question more fully by providing a greater range of repertoire of tools to meet the aims of the study (Doyle et al 2009)

In this thesis mixed methods have been employed to develop the research. A quantitative survey was used to explore if the qualitative study findings were found in a much larger cohort and so develop the whole research study.

4.5.3. Mixing methods within a study

How mixed methods are used and presented within any study differs considerably. To clarify this, a typology of mixed methods research has been developed by different authors (Doyle et al 2009). For example, Leech and Onwuegbuzie (2009) produced an explanation of how mixed methods could be used, and this is documented in Table 10 below.

Table 10: Different ways a mixed methods study could be conducted (based on Leech and Onwuegbuzie 2009)

Fully Mixed Methods Study	<ul style="list-style-type: none"> • Qualitative and Quantitative approaches run CONCURRENTLY • Dominance can be given to one approach or equally to both approaches
Partially Mixed Methods Study	<ul style="list-style-type: none"> • Qualitative and Quantitative approaches run SEQUENTIALLY • Dominance can given to one approach or equally to both approaches

Table 10 shows that mixed methods could be fully integrated with a mixing of research methods from defining the research objective, collection of data, analysis and inference. Whereas a partially mixed study usually involves a qualitative and quantitative study being conducted sequentially. The emphasis of the study on one type of method, either qualitative or quantitative may also be important. Burke Johnson et al (2007) argued that in a mixed methods study, equal weight should be given to both the qualitative and quantitative methods employed. The apparent dominance of quantitative methods in some studies, e.g. as questionnaires and then interviews, has led some authors to posit that MMR is actually post-positivism disguised as mixed methods as the overall study is guided and dominated by a quantitative framework (Morse 2010, Hesse-Biber 2010). On the other hand Doyle et al (2009) describe mixed methods studies where the quantitative/qualitative aspects were not equally weighted and suggested that this is an acceptable mixed methodology. Other authors suggest that integration of different methodologies only at the interpretation stage of a study would be acceptable as a partially mixed method design (Leech and Onwuegbuzie 2007).

4.6. Mixed methods in this study

4.6.1. Is this research mixed methods?

This thesis uses a qualitative inductive approach to collecting data in phase one and then a deductive approach to explore the extent to which those beliefs are present in a different cohort of phase two participants. This was done by designing a questionnaire based on the findings of phase one which could be ultimately disseminated in a different cohort of COPD participants. So this thesis may be considered to be a mixed methods study. However, this thesis finished with the production of the questionnaire because of the unexpected amount of time taken to complete the cognitive interviewing study. Although the pilot study collected data from 13 participants using the questionnaire that was done to ensure the questionnaire performed adequately in collecting the relevant data.

A further viewpoint is also worth considering. As stated above, the researcher places herself in an epistemology of objectivism and uses a qualitative method (GT) with an objectivistic approach to conduct the inductive qualitative study in phase one of this study. The second phase of the study used a deductive quantitative approach which uses a positivistic epistemology to discover an objective truth. So in terms of epistemology the researcher has not mixed methodologies and has performed the thesis with a consistent objectivistic epistemology but has used different methods to answer the research question.

The researcher has described this as a mixed method study because it combines a qualitative approach to inductively explore the perceptions of patients themselves and then a quantitative deductive approach to pilot a questionnaire to establish if those beliefs were held by participants in a different population. This is consistent with the majority of the definitions of mixed method research, the practical combination of a qualitative *method* with a quantitative *method* within the same study (Leech and Onwuegbuzie 2007).

4.6.2 Status of the different approaches used in this study

This study does not give equal status to the qualitative and quantitative methods employed. This study is a partially mixed methods study which uses the different research approaches sequentially. Phase one of the study rests on qualitative methods to collect and analyse the data and formulate a substantial GT theory. The phase two questionnaire was not being used to explore further possible answers but to determine if the presence of the beliefs already recorded were held in a larger population. Therefore the study is driven by a qualitative method and uses a quantitative method to determine that the beliefs found in phase one are, or are not, present in a larger cohort of participants.

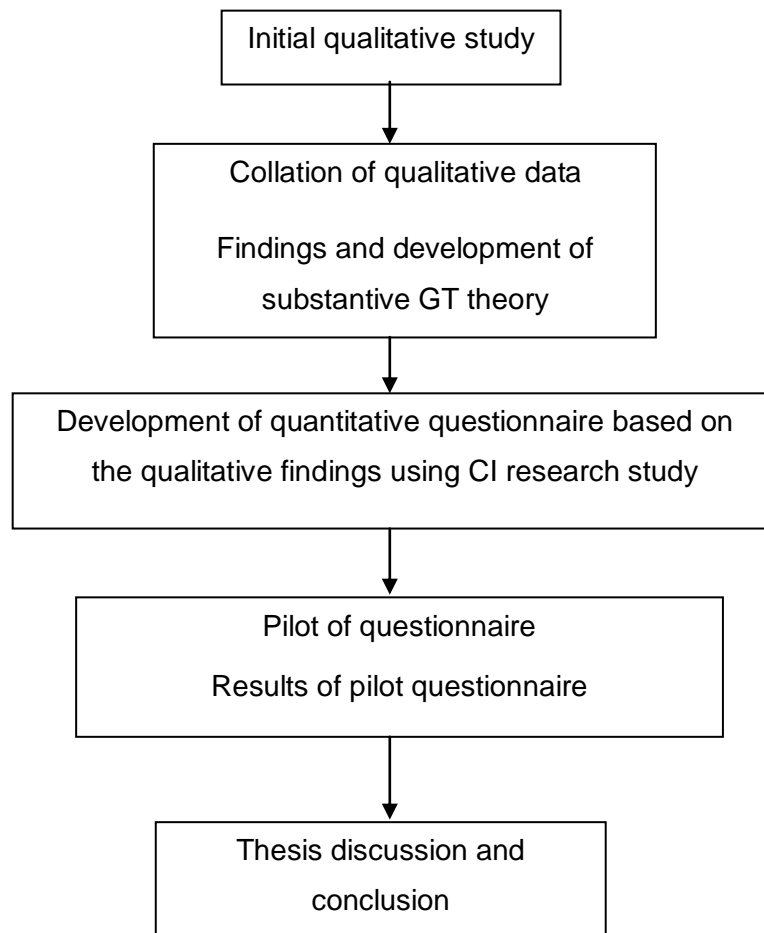
4.6.3. Does a using mixed method approach enhance this study?

Mixed methods were used in this study to determine if the findings from phase one participants were found in another group of participants, and therefore increase the generalisability of the research results and more fully answer the research question. The qualitative phase allowed the researcher to explore the perceptions of the users of AO and determine a substantive GT theory around what influences the use AO on a daily basis. This phase involved a local cohort of participants, so may have uncovered locally held problems or beliefs about AO. Developing a quantitative questionnaire in phase two enabled the researcher to explore if those perceptions were held in a different cohort of participants, which strengthened the findings of this research. The results from the pilot study are presented here.

4.6.4. How methods are mixed in this study

Within this thesis, research methods are mixed in a sequential pattern. The thesis begins with a qualitative phase and ends with the development and piloting of a quantitative questionnaire based on the interpretation of the data obtained from the inductive qualitative research. The final discussion and conclusions within the thesis are derived from a combination of the qualitative and quantitative data. Figure Two below describes the sequential position of the qualitative and quantitative methods used in this study.

Figure 2: Representation of the mixing of methods in this thesis



4.7 Credibility of a mixed methods study

All research needs to justify the methodology, approach and results (Birks and Mills 2011). Given the differences in the definition of mixed methods research it is probably not surprising that this research genre has yet to develop a standard method of establishing the credibility of a mixed methods study. For example; Dellinger and Leech (2007) proposed a whole 'validation framework' (VF) for assessing the credibility of a mixed methods study. The framework draws on the concept of 'construct validity' which they suggest should be defined as a judgement of how much the study and theoretical rationale results in judgements about social structures under study. Teddlie and Tashakori (2009) rejected this, arguing that this framework is very much in its infancy and further work on developing standards for credibility and validity in MMR needs to

be done to improve its validity as the 3rd research paradigm. They proposed a system of “inferences which denote good quality research” (2009:306). In this proposal the researcher determines the validity and reliability of the qualitative and quantitative parts of the study individually, using the recognised validity criteria for the qualitative and quantitative work undertaken. Validity of MMR only becomes important at integration of the two approaches. Table 11 below details the validity ‘inferences’ advocated by these authors, together with the questions that need to be asked to fulfil the ‘inferences’ described as desirable. Inferences nine and ten are in italics to emphasise the stage of integration of the two approaches used in MMR.

Table 11: Credibility in MMR studies based on Teddlie and Tashakkori (2009)

Qualitative/quantitative research inferences	Question to be asked to ascertain validity
1. Design suitability	Was the study method appropriate for answering the question?
2.Design fidelity	Were the design components implemented adequately?
3. Within-design consistency	Do the design components fit together?
4.Analytic adequacy	Are the data analysis techniques adequate for answering the question?
5.Interpretative consistency	Do the conclusions follow the findings?
6.Theoretical consistency	Are the conclusions consistent with current knowledge?
7. Interpretive agreement	Would other researchers reach the same conclusion given the results?
8.Interpretative distinctness	Are the conclusions plausible given the results?
Integration of MMR study	Integration of MMR study
9. <i>Integrative efficacy</i>	<i>the degree to which each strand of the MMR study is integrated into a theoretical whole, to provide a fuller understanding of the study area, consistent or inconsistent</i>
10. <i>Interpretative correspondence</i>	<i>the degree to which the MMR study supports the use of an MMR design</i>

Actual measures of MMR credibility have yet to be widely accepted, and Teddlie and Tashakkori (2009) produced the list of inferences above as a guide for researchers. They agree with other academics that inference 1-8 can be used and is similar to

tenets of validity which already exist for quantitative/qualitative work. However inferences 9 and 10 are specific to the mixed methods approach.

There is little discussion, to date, in the literature around specific validation criteria for mixed methods research beyond using a mixed methods approach itself to help validate the findings of both approaches used in the research study. Cresswell and Tashakkori (2007) suggest the most important aspect of any mixed methods research study is that the two research approaches are integrated and connected in some way.

4.8. Tenets of validity used in this mixed methods study

This thesis consists of a qualitative GT phase and a quantitative questionnaire research phase. The qualitative phase was designed to uncover how participants perceived their AO; the quantitative phase was designed to develop a questionnaire to test those beliefs in a different cohort. The quantitative phase ended after the pre-testing stage before the final questionnaire was used in a research study. This makes it difficult to achieve the integrated efficacy suggested by Teddlie and Tashakkori (2009) in table eleven above. However the design of the two study phases follows, in the researcher's opinion, a logical pathway and using both qualitative and quantitative methodologies enhances the study. So the study does display interpretative correspondence as suggested by Teddlie and Tashakkori (2009) in table 11 above.

The results from both phases are considered together in the final discussion in chapter ten which supports the arguments of Cresswell and Tashakkori (2007) that the two phases are integrated in some way. An overview of the whole MMR study is reviewed in chapter ten.

4.9 Summary

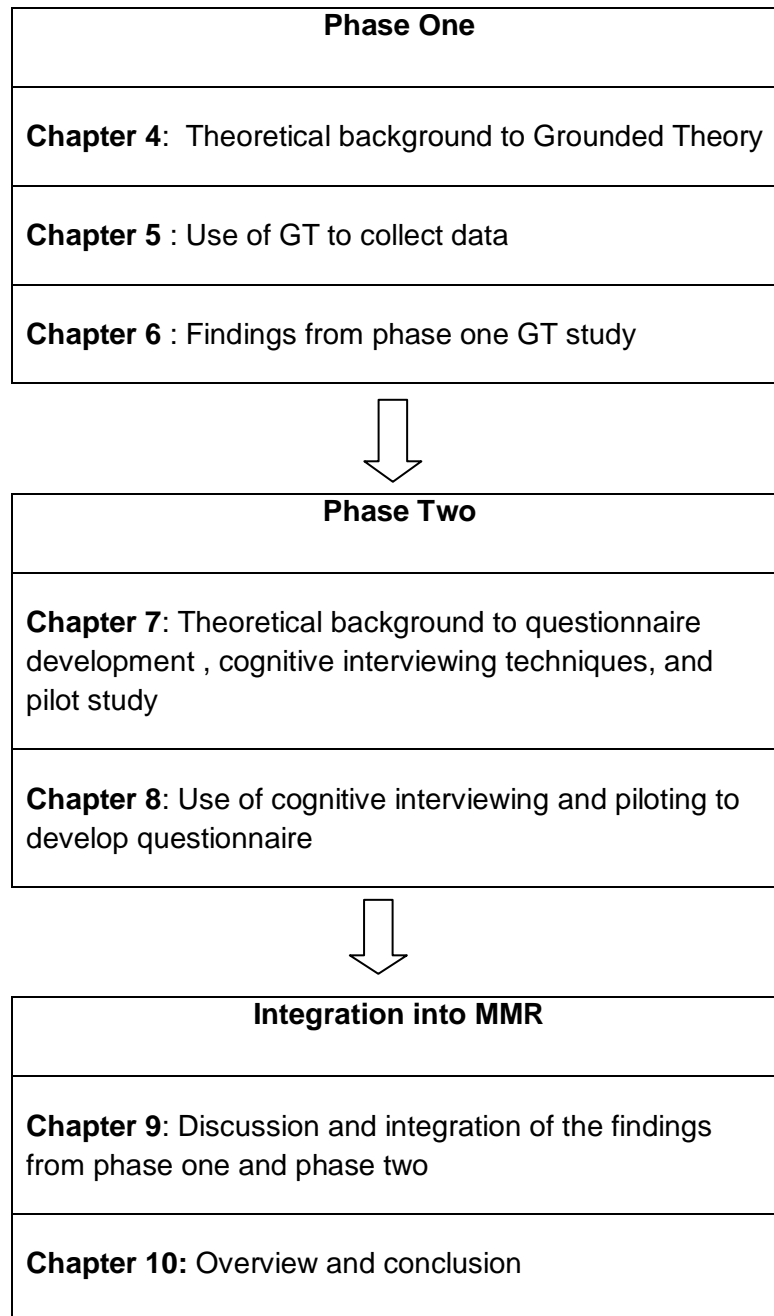
This study is divided into two phases:

Phase one is inductively driven using interpretative approaches to conduct in-depth interviews to collect information from participants about their experiences of AO. The use of GT approach reflects the researcher's objectivist epistemology in data collection.

Phase two is a deductively driven using a questionnaire to collect information from participants further afield. This thesis is described as MMR because it combines a qualitative inductive method and a quantitative deductive method.

Table 12 below, is designed to show how the rest of this research project is laid out in this thesis in terms of phases and what they contain

Table 12: the layout of the phase one and phase two in this thesis and their integration into a mixed methods study



The next chapter describes the background to Grounded Theory as the method selected for collecting and collating patient data.

Chapter Five: Grounded Theory Method

5.0 Introduction

Grounded Theory (GT) was the qualitative method chosen to collect and analyse the data obtained inductively from the study participants. This chapter describes the background to GT, and the rationale behind the choice of the GT approach adopted for this qualitative phase. It then continues by explaining how this method was used to conduct this research phase. GT research aims to understand what is happening in a social setting. It aims to produce not a description of what is happening, but an ongoing conceptual theory which will explain what is happening (Hunter et al 2011). There are three basic versions of GT, but here an adapted GT approach was chosen to construct a substantive theory from the data inductively collected from the participants.

5.1 The Background of Grounded Theory

GT was first described by Glaser and Strauss in 'The discovery of Grounded Theory' published in 1967. Glaser and Strauss held that social theory could be produced from inductive qualitative research by using a 'tool-bag' of systematic approaches to the data which could be validated (Chiovitti and Piran 2003) and which could be used by both qualitative and quantitative researchers (Glaser and Strauss 1967). The development of this method of inquiry was seen as a very important development in qualitative research, as in the 1960's, qualitative research was striving to become an acceptable scientific research methodology; but one which rejected the 'a priori' deductive research methodology adopted by quantitative researchers (Annells 1997).

Glaser and Strauss suggested that GT was a "strategic method" and compared it to statistical analysis (Glaser and Strauss 1967:21). They suggested that GT collected facts which could be "replicated as comparative evidence either internally (within the study) or externally (outside the study) or both" (Glaser and Strauss 1967:23). They introduced a collection of fundamentally new research approaches e.g.

- taking a naïve approach to the research subject by allowing theory to emerge from the research participants.
- not performing *detailed* literature searches prior to starting the study as the researcher was not using research to prove or disprove an already constructed social theory (a prevalent use of qualitative work at the time).
- fracturing of data into codes or categories, (the constant comparative analysis of data).
- theoretical sampling, and the conceptualisation of the emerging data into theory.

(Glaser and Strauss 1967)

Although never specified by Glaser and Strauss in 1967, the original version of GT is viewed as working in an objectivistic framework where a reality is waiting to be discovered by an objective detached researcher (Birks and Mills 2011). In the last four decades, the world of qualitative research has undergone major changes which reflect the on-going and in-depth academic debates on how knowledge can be known, and the position of the researcher to the researched. Such developments have had an impact on GT and how it is applied, and these are discussed more fully below.

5.1.1 Changes in GT

A split occurred between the original authors and a new version of GT was published by Strauss and Corbin in 1990. This new version adamantly rejects the positivistic foundations of the original GT which holds the researcher detached from the researched, and proposed a more constructionist approach for a GT study, which holds the researcher as an active participant in the construction of the data (Mills et al 2006). However the authors retained the methods of original GT: fracturing of data and the constant comparative method of data analysis. Walker and Myrick (2006) suggested that Strauss and Corbin appear to have adopted both constructionist and objectionist assumptions in that they incorporate constructionism as an ontological perspective i.e. they believe in the “researcher as a passionate participant” (p193) but retain the positivistic approaches of the original GT approach which they cite as being, for example, constant comparative analysis.

How these differences are viewed or adopted seems to be open to a wide variety of opinions. Glaser was highly critical of the Strauss/Corbin method maintaining that their method of data analysis forced the data into pre-existing categories rather than allowing the codes/categories to emerge from the data itself (Glaser 1992). He maintained that Strauss and Corbin had developed “not just a different method of GT but rather a completely different method” (Glaser 1992:77). Other researchers suggest that the “Strauss/Corbin method is too programmatic and formulaic” and “may distract the researcher” (Duchscher and Morgan 2004:611), whilst others, applauding the changes, suggest that “Strauss and Corbin provide a clear explicit framework, which some may prefer to Glaser’s more open method” (McCallin 2003:205). Hall and Callery (2006:261) suggested that any differences between the Glaser method and the Strauss and Corbin method are “merely semantics”.

5.1.2 The development of a constructionist version of GT

The advent of an overtly constructionist version of GT by Charmaz in 2000, further highlights the theoretical philosophical differences with the original version of GT. Charmaz (2000) states that her version of GT, together with later versions of Strauss and Corbin’s GT, rests on a foundation of symbolic interactionism, which emphasises the co-construction of meaning through dialogue between researcher and researched (Birks and Mills 2011). Charmaz (2000) contests that constructionist GT constructs an image of a reality not the truth of a situation. However, despite having fundamental philosophical differences with the original GT, Charmaz, as with Strauss and Corbin, advocated the use of many of the basic analytical approaches of the original GT, together with suggesting that the axial coding of Strauss and Corbin could also be used by the researcher “if they wished” (Charmaz 2006:60). Charmaz’s method of GT could be seen as a synthesis of the analysis methods advocated by both Glaser and Strauss and Corbin.

Academics argue if GT, as it was originally termed and defined, can exist within a constructionalist framework. On one hand some reject positivism and its objectivity absolutely and so embrace constructionist GT as the way forward (Thomas and James 2006); whereas others, such as Greckhamer and Koro-Ljunberg (2005), argued that a constructionist GT researcher *co-constructs* data, so does not collect objective data from the subject and therefore the data are not grounded in participant experience.

This suggests any theory produced by constructionists is, therefore, grounded in the process of making the meaning of the data and cannot produce theory around the social process under study. Others suggest that constructionist versions of GT still used methods of analysis, such as the constant comparative, a method of analysis – which they argue is objectivistic in nature, so renders the concept of ‘constructionist’ GT invalid. What is less clear is why constructionist qualitative researchers such as Strauss, Corbin and particularly Charmaz wish their methodological approaches to still come under the name of ‘Grounded Theory’ since it philosophically differs so much from the original objectivistic GT concept. Thomas and James (2006), argued from a perspective of rejecting objectivism completely in qualitative research, suggested that it is because qualitative researchers still desire the approval by the scientific or medical community, and the title of ‘GT study’ may confer that. They go on to suggest that although Charmaz’s constructionist version of GT moves the debate about GT ahead generally, its insistence on still being called GT “stunts and distorts the growth of qualitative inquiry”. But Charmaz (2009) argued that GT should be seen less in terms of a strict methodology and more as a developing model of enquiry, with the consistent use of the constant comparative analysis method as a mode of interrogating data. But the use of an objective process in data analysis and development of theory does seem counter-intuitive to a constructionist approach. Especially as in the original version of GT (Glaser and Strauss 1967), the authors emphasised the objective nature of the constant comparative method of analysis, specifically comparing it to statistical analysis. Despite the nuances of the academic arguments, constructionist versions of GT are used widely in healthcare research (Licqurish and Seibold 2011).

5.1.3. Effect of epistemology on version of GT adopted in this study

Carter and Little (2007), Birks and Mills (2011) and Hunter et al (2011), all argued that it is the researcher’s epistemological position that influences the type of GT employed. The original version of GT reflects this researcher’s objectivist position in the key epistemological areas described by Carter and Little (2007):

- the relationship between the researcher and participant is separate and that the researcher strives not to influence the participant or the collection of data.
- reality is waiting to be uncovered as objective truths by the researcher.
- individual voices are not represented, but examples of the experience are collected from participants and theory produced by the researcher.

- the quality of the research is assessed using objective methods of validity such as Fit and Work.

Table 13 below compares some of the approaches to the handling of data advocated by Glaser, Strauss and Corbin and Charmaz in their various versions of GT. Apart from Strauss and Corbin's axial coding which is a framework designed specifically to direct the researcher to look for characteristics which define categories (completely rejected by Glaser as forcing data), there are many similarities in all three different GT procedures.

Table 13: The differences/similarities between the three main types of GT

Glaser/original method (1967)	Strauss & Corbin (S & C) method (1998)	Charmaz method (2006)
<p>Constant Comparative method: PHASE 1 Fracturing of data into open codes (1st part of phase 1)</p> <p>PHASE 2 Substantive coding(2nd part of phase 1) Looking for links between codes to form categories Developing emerging categories which link and developing properties of primary core category to sensitise researcher to connections between categories and properties</p> <p>PHASE 3 Advanced/Theoretical coding, using coding families to hone categories Integrating and developing conceptual ideas of previously coded concepts so theory can emerge</p> <p>Memoing throughout to allow researcher to develop concepts</p> <p>THEORETICAL SAMPLING Analyst decides what further data to collect in order to help theory emerge</p>	<p>Constant Comparative method PHASE 1 Fracturing of data into open codes + dimensionalising category's properties by structural questioning, flip-flop, conditional matrix(techniques for enhancing Theoretical Sensitivity)</p> <p>PHASE 2 Axial coding (connections between categories) 'coding paradigm' to sensitise researcher to categories and properties. Developing categories, properties, sub properties and dimensions Patterns of connectivity Conditional path</p> <p>PHASE 3 Selective coding- selective coding and integration around a core variable Use of conditional matrix (also used with axial coding)</p> <p>Memoing: to serve as a reminder Several different kinds-</p> <p>THEORETICAL SAMPLING To maximise opportunity to compare events, to determine how a category varies in terms of property and dimensions</p>	<p>Constant comparative method PHASE 1 – Initial Coding Fracturing of data into codes =coding with words that reflect action. Line by line coding. Coding incident to incident / In vivo codes</p> <p>PHASE 2 Focused Coding Synthesis and explain larger segments of coding derived from line by line coding above Axial coding – (as in Strauss and Corbin)if researcher wants to use it Re-examination of initial data coding</p> <p>PHASE 3 Theoretical coding Using coding families such as Glaser does; to develop conceptual ideas of the data to allow theory to emerge</p> <p>Memoing as in Glaser, throughout analysis to help develop and explore codes and categories</p> <p>THEORETICAL SAMPLING To further exploration of tentative categories allowing more data and memoing which is more analytical</p>

5.2. Elements of a GT study

There are specific aspects of any GT study which are widely acknowledged to be necessary before the study can be considered as GT (Cutcliffe 2005; Stern 2009; Jeon 2004). This list is not exhaustive and to some extent depends on the texts followed by the researcher, for example Glaser (1992) maintained that researcher's should not conduct in-depth literature searches before starting their research, but this criterion is not included in other texts on GT (Birk and Mills 2011). This study represents an **adapted** GT study because it uses the objectivistic approach consistent with original version of GT (commonly known as Glaserian GT) but does not include all the features of a Glaserian GT study (Glaser 2007). For example, the researcher conducted a literature search before the study began, but continued with a more in-depth literature search as the study continued. So the method has been adapted to meet the researcher's requirements to undertake this GT study within a modern healthcare setting. What has and has not been included in this study is discussed further below.

5.3. Elements of this adapted GT study

The researcher's objectivist approach means that the researcher is treated as removed from the participants as an unbiased collector of data which is waiting to be uncovered. The data is treated as objective data collected inductively from the participants. As said above, this position is consistent with the original version of GT developed by Glaser and Strauss, by now usually called Glaserian or original GT (Kelle 2007). But the researcher has adapted this approach to fit her research needs. The next section describes the aspects of this study which are adapted from the original version.

5.3.1. Literature searches

A literature search was conducted before starting the research. This is probably the area most contested within GT studies generally. The original GT held that researchers should approach the area of study with 'abstract wonderment' (Glaser 1992:22), and should not even have decided on a research question (Cutcliffe 2005). However in medical research, studies have to be approved according to an ethical

code laid down by the Government (Department of Health 2001) and this requires the identification of a specific research question, a background literature search, identifying the participants and the method of research to be used (Cutcliffe 2005). Researchers have argued that Glaser and Strauss's original position is naïve, and that a literature search can sensitize the researcher to processes occurring in their area of research which may be beneficial to the theoretical sensitivity demanded within GT (Charmaz 2003). However the literature is itself confusing, with Moore (2010) reporting Glaser recommended researchers should sensitise themselves to the area under study, whilst Glaser (1998) advocated that *in-depth* literature searches should only be carried out when the study is nearly completed. The conflicting aspects of GT here are the need to balance not having any in-depth knowledge which may influence the researcher to look for specific concepts within the data, the need to be theoretically sensitive to what is important in the data, and the needs of developing a robust ethics application.

The researcher did have some clinical experience of COPD patients as a population and therefore was not completely unaware of some of the problems they faced generally. Indeed some of this experience was used to produce a frame-work of questions for the participants in this study, which may not have been possible otherwise. But the researcher had no experience at all of talking to COPD patients about their experiences with AO, and had no knowledge of the psychosocial factors underpinning the decisions of the participants regarding AO, so did not know of any specific problems which may have occurred when using an AO system. However her clinical knowledge did sensitise her to problems that patients with COPD may experience. Literature searches towards the end of the study are discussed further below.

5.3.2. Sampling as the *start* of the study

Classical GT advocates the use of theoretical sampling at the beginning of a GT study. Defined as the 'process of data collection for generating theory whereby the analyst collects, codes and analyses his data and decides what data to collect and where to find it in order to develop his theory' (Hood 2007:160). In the light of 'abstract

wonderment' theoretical sampling is a logical participant selection process but again within the confines of the modern research ethics requirements for this kind of study, theoretical sampling was not strictly possible. Having said that, some researchers contest that (at the start of a study) 'purposeful sampling'; (a decision to sample specifically according to pre-conceived, but reasonable, set of dimensions worked out in advanced of the study), is comparable with theoretical sampling (Stanley and Cheek 2003). Indeed, within qualitative research literature the two terms are often used interchangeably, particularly where researchers may go to groups where they believe the maximum amount of data will be accessed (Glaser 1997). However, Coyne (1997) contests that the difference between theoretical and purposeful sampling (at the *beginning* of a study) is that in theoretical sampling the researcher may have some idea of where to sample but NOT what to sample for, or where it will lead.

In qualitative research generally, the 'best' sample size is not readily identifiable although there is a general agreement that the bigger the sample the more variety of experience and data which can only enhance a study's findings (Barnett 2005). Stern (2009:69) suggested that there are no 'hard and fast rules' for sample selection in Glaserian GT but in this study the researcher followed the advice of Starks and Trinidad (2007) who suggested that for a GT study a wide range of participants with experience of the phenomenon is very important. Morse (2007) suggested that GT begins with convenience sampling to find participants who have had experience of the process under study. This recommendation was used to identify a group of participants who had knowledge of the phenomena under study i.e. had a diagnosis of COPD and had been prescribed AO. But, within that group of potential participants, the recruiter's knowledge about the participants can be used to pick cases purposefully to be included in the sample Moore (2010). So there is a combination of convenience and purposeful sampling at the start of this GT study.

5.3.3. Theoretical sampling used *within* this study

Theoretical sampling is used with a GT study to steer the collection of data to look for examples of categories (Glaser and Strauss 1967). It directs the collection of subsequent data (Holton 2007) with the aim of trying to explore specific areas under study, so any gaps in the data could be addressed and explored (Birks and Mills 2011). Glaser and Strauss suggested that theoretical sampling should look to recruit

participants from different areas and working in the 1960's they were able to enter different research fields with little negotiation compared to the modern demand of ethical review (Moore 2010). However this aspect of theoretical sampling was not pursued in this study and the theoretical sampling here was concerned only with the selection of potential participants within the original sample.

In line with original GT, theoretical sampling was employed to look for participants who could provide the data which could specifically inform the emerging categories in the study. This was done by utilising the knowledge of the respiratory nurse in the respiratory centre. She knew many of the participants and so could guide, in a general sense, the researcher towards those who had different social backgrounds or may be using their AO system in a different way. This was done in a tiered way with the researcher analysis and contrasting each transcript over a series of several participants before deciding on the direction of new collected data and trying to recruit participants with specific experiences. This follows the sampling strategy suggested by Moore (2010). New data could then be compared and contrasted with existing and other new data through the constant comparative analysis process. This allowed a category and its connections to be more robustly investigated (Stacks and Trinidad 2007).

5.3.4. Theoretical sampling at the *end* of the study and Formal Theory development

Theoretical sampling at the end of a study is a means of continuing and refining the area under study, and producing Formal Grounded Theory (FGT). Here the researcher develops a substantive theory for one area and moves to another research area to explore if the same beliefs are true. For example are the reasons for becoming a nurse the same as the reasons for becoming a physiotherapist? Theoretical sampling has not been performed in this study to date. Glaser himself states that producing formal grounded theory is “not mandatory” (2007:110).

5.3.5. Development of an interview framework

Within interviews a semi-structure interview guide is often used to aid in asking questions (Kvale 1995). Glaser's directive to asking questions in interviews was that

the researcher must not ask a direct question because that may force the emergence of data (Glaser 1992). Duffy et al (2005) suggested that a semi-structured interview approach is consistent with an original GT approach as it allows the researcher to ask general topic questions but has enough flexibility to explore in depth. This is important because within GT the direction of asked questions change as the researcher analyses the data from previous participants. As the researcher seeks more information on an aspect of the study or seeks to explore categories that are emerging from the data, the questions change (Duffy et al 2005). Within this study the semi-structured interview schedule was developed to explore and understand the participant's use of AO, but changed as new areas arose which, in the researcher's opinion, were important to answering the research question. However this approach of moulding the questions to uncover areas of concern is supported by Glaser (1998) and Birks and Mills (2011) who argued that for a problem to be of relevance it must come from those for whom it has significance.

5.3.6. GT Analysis

Within GT method the use of constant comparative analysis is well documented (Cutcliffe 2005). In this approach data are collected and analysed concurrently, with the researcher 'fracturing' the data collected from the participant, iteratively exploring the data for ideas raised by the participant. These ideas can then be coded and constantly compared with new data from successive participants, so that the data inform further data collection and analysis (Birks and Mills 2011). Bryant and Charmaz (2007) suggest that the constant comparative method allows reasoning to be extrapolated from participants and their data to form conceptual categories. Further discussions of the analysis used in this study are detailed in the section below on coding and category formation. The coding and categorising of data is regarded as the defining analysis procedures of the GT method (Jeon 2004).

In recent years computer applications which help to organise collected data have become available to the GT researcher. There is an on-going debate as to the usefulness of these computer programmes. Birks and Mills (2011) argue that as most researchers are now computer literate, using a computer to assist in the management of collected data is a logical step. Programmes can aid in the coding and categorisation of large amounts of data and allow researchers to conceptualise data in

terms of diagrams, all using the same tool. Holton (2007) suggested that using a computer to aid analysis of data may be problematic. She contends that using a computer programme could produce huge numbers of codes and prevent the researcher from recognising the intuitive links in data which are fundamental to GT development. Hesse-Biber (2007) agreed and further suggested that computer analysis may isolate the researcher from the intricate task of developing codes and categories, because on a computer it may be a matter of moving files without a thorough thought process. She argues that GT analysis is not a single analysis event but woven into the whole research project, which may not be evident from computer analysis. In this study all coding was done by hand. This was because the researcher was more comfortable handling the data by hand than on a computer programme.

5.3.7. Coding procedures

Original GT suggests that the initial phase of the constant comparative analysis is called open coding and consist of two parts; part one is the initial fracturing of data and part two is called substantive coding. This followed by a further coding procedure called advanced or theoretical analysis. This study employed open, substantive and theoretical coding as described further below. Birks and Mills (2011) contested that all coding techniques are a combination of inductive, deductive and abductive thinking by the researcher.

- **Inductive reasoning:** “a type of reasoning that begins with a study of a range of individual cases and extrapolates pattern from them to form a conceptual category”
- **Deductive reasoning:** “A type of reasoning which starts with the general or abstract concept and reasons to specific instances”
- **Abductive reasoning:** “A type of reasoning that begins by examining the data and after scrutiny of these data, entertains all possible explanations of the observed data and then forms hypotheses to confirm or discount the data until the researcher arrives at the most plausible interpretation of the data”

Definition of deductive, inductive and abductive reasoning (based on the Sage Handbook of Grounded Theory glossary 2007: 603).

1. Open coding

As the transcript is read the text is broken up as bits of data which are pertinent to the research. Text can be coded line by line or by several lines of text which describe an event in the text (Duchscher and Morgan 2004), or by 'text segments' which are pieces of text which are similar in some way or relate to an incident (Kelle 2007). The codes for these text segments are written in the margin of the page. Each transcript is coded separately to avoid contamination or bias from previous transcripts. The codes are then recorded separately and the researcher begins the process of continually comparing and contrasting these codes to the previous and subsequent codes, as part of the constant comparative method.

2. *Substantive coding*

During selective coding the codes derived from the open coding analysis of the text are developed by looking for links between the codes. At this stage Strauss and Corbin used axial coding, which is a strategy that tries to identify the properties of a developing category by asking what affects this category. Glaserian GT requires the researcher to move backwards and forwards within the coding data, asking questions of the data and looking for possible links between the codes to form categories. The researcher looks for codes which enlarge a category and those which negatively impinge on category formation (Holton 2007). The researcher allows the meaning of the categories and links between categories to emerge from the data itself. Glaser suggests that the researcher should have some sensitivity for the theory which may be arising from the data (theoretical sensitivity) but maintains that this arises from immersion in the data and the process of constant comparative analysis (Walker and Myrick 2006). Kelle (2007) suggests that theoretical sensitivity requires the researcher to have some insight into what is happening in the data, and the ability to make something of that insight.

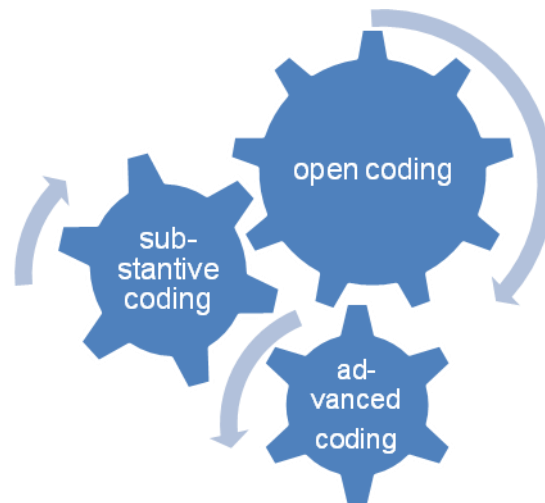
3. *Advanced /Theoretical coding*

This is the final stage of the Glaser's constant comparative analysis techniques. Glaser describes theoretical codes as terms which describe possible relationships between categories to help form theory. Glaser suggests using theoretical families to help form theory for example; 'cause', 'condition', 'consequence', 'covariance', 'contingencies' and 'context' could be applied to possible links between substantive codes to help the

researcher look for relationships within the data (Kelle 2007). But Kelle (2007:209) goes on to suggest that for most novice researchers applying theoretical coding can be confusing, and proposed the application of 'common-sense' to codes and categories, so the researcher can identify topics within the data and form categories and links between them. This researcher does not have a background in sociological or psychological theory, so this study uses a common-sense approach to category formation and links between categories to develop theory. Glaser (2001) argued that theoretical codes could be drawn from other research to help situate the GT study within a theoretical body of knowledge. In this light, literature searches at this point would be useful.

The three types of coding occur together throughout a study, as new data is collected and analysed in comparison with existing material. Birks and Mills (2011) suggested data analysis should not be thought of as a linear process but as an interconnected approach. Diagram 3 below represents how the coding process is interconnected.

Diagram 3: The interconnectedness of stages of analysis in GT



5.3.7.1. Types of reasoning in GT analysis

There is disagreement between academics as to which aspects of reasoning; inductive, deductive and abductive, are used in different versions of GT. For example, Birks and Mills (2011) contest that all types of GT use all three types of reasoning, whereas Reichertz (2007) argues that classical GT does not use abductive reasoning because of Glaser's insistence that all codes and categories emerge from the data. It is difficult to see how abductive reasoning as defined above, does not come into original GT analysis at some stage because in this researcher's experience, ensuring all the codes and categories emerge from the data still requires all possible explanations of that data to be employed in category linkage, the production of a core category and theoretical sampling. So for example the researcher can identify relevant experiences inductively from an individual's collected data, and then deductively compare that experience to another participant's data. The analyst can then abductively extrapolate that experience to help in the formation of a core category such as an 'advantage or disadvantage' even though the participants have not used that classification. Within this study abductive reasoning was employed to help formulate the theory arising inductively from the data.

5.3.8. Theoretical sensitivity

Mills and Birks (2011:59) defined theoretical sensitivity as "the ability to recognize and extract from the data, elements that have relevance for the emerging theory". In the original version of GT, Glaser and Strauss (1967) maintain that theoretical sensitivity

was the ability to see insights in the area under study and understand their relevance to any theory development. Glaser himself acknowledged that this was a difficult concept to grasp and introduced the concept of 'coding families' (Glaser 1978). These were to help the researcher by looking at, for example, causes and consequences within the data. This in turn was thought to help researchers look for links in the data analysis between substantive codes and the more abstract theoretical codes (Kelle 2007). Since this researcher has no training in GT methodology and is not a sociologist or psychologist, links between substantive and theoretical codes were looked for from a common-sense viewpoint. This is supported by the arguments of Kelle (2007) who maintained that categories and their links could be identified by drawing on general common-sense knowledge. However the researcher's clinical knowledge of patients with COPD (although not in a home setting) did sensitise her to understanding some of the aspects having breathlessness as a symptom.

5.3.9. Theoretical saturation

Theoretical saturation is the term employed by Glaser and Strauss to describe when a no new codes are being produced to inform a category (Birks and Mills 2011). Hood (2007) suggests that theoretical saturation occurs when no new data is being collected from participants. Thorne (2011) argues that theoretical saturation is just an excuse to stop collecting data, particularly within healthcare research where every new participant has an individual story. Within this research, the suggestions of Hood (2007) were followed, but every effort was made to ensure the categories were explored as much as possible. Some categories were saturated very quickly but the researcher continued to collect information about those categories, often looking for negative cases because the category was saturated so quickly.

5.4. Memo writing

The constant writing of memos is important to the GT method. Memos are the notation of ideas about codes and their connections which occur to the analyst during the coding procedure (Jeon 2003). The writing of memos sensitises the researcher to what is happening in the data and aids the researcher in formulating theory and within classical GT, it is a key part of the analytical process (Walker and Myrick 2006). Birks and Mills (2011:41) also underline the importance of memo writing and suggest that

writing memos can increase the researcher's theoretical sensitivity during the study but also emphasise the importance of producing an 'audit trail' using memos to record why decisions were made during a study. Examples of the extensive memo writing that accompanied this study are documented in appendix. In this study all memoing and sorting of memos was done by hand.

5.5. Core category formation

Within original GT, core category formation is achieved through comparative analysis and a combination of inductive, deductive and abductive reasoning (Birks and Mills 2011). The core category is central to the data and accounts for a large proportion of the variation in behaviours found in the area under study (Birks and Mills 2011). Glaser described core categories as having "grab" (Glaser 2007:103). He argued that it can be abstract, but must still have relevance and fit, which are both products of the comparative analysis process. Core categories may be concepts abstracted from the minutiae of the research itself as far as time, place or person is concerned, but must recognisably explain the meaning of the data being studied (Cutcliffe 2005). In this study a core category was identified.

5.5.1. Generation of Theory

The aim of GT is to produce theory emergent from the data (Kennedy and Linguard 2006). Some researchers suggest that most GT studies do not produce theory at all (McCallin 2003). They produce only 'descriptions' of the process under study and while this may be acceptable as qualitative descriptive analysis research, it should not be labelled as GT (Cutcliffe 2005). Cutcliffe (2005) contends that a classical GT study should attempt to identify an underlying basic psychosocial process, which helps to give an overall explanation of what is happening in the data, which reflects the 'fit' of the findings with the field under study. It has been suggested that all GT studies should articulate what kind of theory they are aiming to produce (Jeon 2003). Glaser (2001) has suggested that GT can produce substantive GT (SGT) theory and formal GT (FGT) theory. Birks and Mills (2011) explained that substantive GT theory is a theory which relates to a specific phenomenon in a clearly defined group of participants. Whereas formal GT is a theory which is applicable to a different number of substantive areas, so for example are the reasons for becoming a physiotherapist also found in

people becoming nurses? This study sought to produce a substantive theory about AO use, developed inductively from the data collected from the participants in this study cohort.

5.6. Literature searches towards the end of the study

Original GT advocates that literature searches are conducted later in the study as the theory comes to light. This is to avoid the researcher becoming immersed in the relevant literature rather than the data from the participant (McGhee et al 2007). Within this study a basic literature search on the aetiology of COPD and the prescription of AO was performed before the study began to support the ethics submission. Further literature searches on emerging issues were performed once theory began to emerge from the data. Relevant research is woven into the findings (Chapter seven) and discussion (Chapter ten). The researcher found this a useful process as the literature search on COPD and AO, done at the beginning of the study, actually had very little bearing on the respondent's perception of their equipment. Undertaking literature searches as the theory emerged did mean that the researcher was not pre-sensitised to any similar issues around patient's perception of use, which was evidenced in other research. Therefore the researcher had no pre-conceived ideas about any possible findings from this research study.

This study utilised other methods used within GT studies but which are not specific to any particular type of GT.

5.7. Using interviews for data collection.

Interviews have become a popular way of collecting data within a grounded theory approach (Birks and Mills 2011). However, interviews have advantages and disadvantages compared to other methods of data collection. Opdenakker (2006) argued that interviews allow the researcher to explore issues in depth, adapt questions and clarify ambiguity. Conversely, the interview relies on the participant's verbal ability and may be subject to the bias of the researcher or the respondent not wanting to share information. Hewitt (2007) argued that observation provides a direct access to

the phenomena under study that does not rely on the participant's verbal ability or on self-reporting, but records behaviour in a situation. Mowatt (2012) points out that observational studies also have disadvantages in terms of the time they take to complete, that they are also subject to observer bias or ignorance, and may not be feasible in some research situations. Within this study individual interviews were chosen as the means of collecting the relevant information from the participants because the researcher wanted to explore why participants decided to act as they did and therefore asking in-depth questions seemed to be an approach which would collect that information. The researcher acknowledges that an observational study may have been a useful adjunct to this study given the differences in actions between the participants but exploring the apparent advantages and disadvantages of AO seemed more suited to verbal dialogue.

Interviews are often seen as epistemologically neutral (Miczo 2003), but Lowes and Prowse (2001) suggest that interviews should be seen as a purposeful data-generating activity which is characterised by the particular philosophical position adopted by the researcher, and that that position should be clearly stipulated in a study. The arguments around how a qualitative interview is constructed broadly reflect the different approaches of the objectivism and constructivism ends of the epistemological spectrum.

5.7.1. Epistemological position of the researcher in the interview

This researcher believes that although participants are obviously involved in an interview interaction, the researcher has set the agenda and the questions for the interview and therefore the participant cannot co-construct the research. This researcher agrees with the arguments of Kvale (1996), that knowledge exists in the relationship of the person with the world and the interviewer is trying, through conversation, to elicit that knowledge from the person in the relationship. This researcher believes that it is possible to achieve objectivity in collecting data, an objectivity which sees alternative viewpoints and can interpret experiences in a meaningful way (Lowes and Prowse 2001), and so the 'identity' of the researcher holds no importance (Hewitt 2007). Cassel (2005) suggested that from an objectivistic epistemology the interviewer asks questions and attempts to avoid any 'contamination' or influence of the data collection or collected.

5.7.2. Power/ethical issues

All interactions involve a power perspective which may affect the outcome of the interaction.

- In a research interview the researcher may be seen to have power because they may be perceived by the interviewee as being a professional, a researcher, healthy, having specialist knowledge, asking the questions and taking away the results of an interview (Nunkoosing 2005).
- The interviewee may be seen as having power because they are the holder of the knowledge which the researcher is seeking, and they choose how much of their knowledge to reveal or withhold.

By holding the interviews in the participant's own home, the participant has more power in deciding who will be present, and it allows them to feel more comfortable in deciding what to reveal. However it could be argued that by having the interview in the participant's home, the interviewer is allowed to make judgements about the participant's circumstances and home life. The participant may reveal more than they intended to the researcher. It is incumbent on the researcher to be sensitive to the interviewee's responses and discard personal material that is obviously not part of the research question. The researcher must also be aware of issues that may cause guilt or anxiety and the interaction between the participant and any carer who may be living in the house.

5.7.3. Gender, class age and race issues

Within all interactions, gender, class race and age may play a part in affecting the interaction between participants. Obviously it is not possible to do anything to alter those factors, but a sensitive awareness of these issues is important, particularly where they impinge on linguistic usage by either interviewer or interviewee. In this study a middle-aged, middle class, Caucasian woman who had not experienced lung problems or chronic ill health asked the questions.

5.7.4. Trust issues

Interviews proceed when the interviewee feels confident to reveal to the interviewer his/her life experiences, and the interviewer can facilitate trust and communication with the interviewee (Manderson et al 2006). Setting the scene for an interview by briefing and debriefing the interviewee helps to engender trust in the interviewer and facilitate conversation (Kvale 1996).

5.8. Validity issues within a GT study

Within the world of qualitative research there is an ongoing controversy (Angen 2000) on how to achieve validity in studies, and this mirrors the general argument within qualitative work of the opposing views of positivism/objectivism versus constructionism. Arguments around validity are concerned with whether the knowledge produced by qualitative work can be legitimately judged and if so, how? (Mays and Pope 2000) Qualitative researchers themselves cannot decide what the criteria for judging quality should be (Cutcliffe and McKenna 1999), and this has led to the formation of two opposing camps whose views are based on the opposing philosophies cited above. The criteria for validity used in this study are based on those advocated in the original GT (Glaser and Strauss 1967), but the researcher has also incorporated some aspects of validity which have developed in importance since GT was first developed and these are discussed further below.

5.8.1. Validity within this GT study

Here validity is defined as an accurate representation of the aspects of the phenomena that this account is describing, explaining and theorising (Hall and Callery 2001). Maggs and Rapport (2001) suggest that much of the dependability of a qualitative study rests on its adherence to the chosen methodological approach. This study has adopted an objectivism stance and therefore the reliability and validity standards by which this study should be judged, reflects this philosophical position and methodological congruency. The measures for judging a GT study devised by Glaser and Strauss are discussed below. However this study, as has already been explained, is an adapted study and therefore does not rest *just* on the criteria that Glaser and Strauss originally suggested for GT (Glaser and Strauss 1967) but also incorporates

tenets for credibility accepted by the modern qualitative world. This is discussed further below. The criteria of original GT are:

- **Fit:** categories must be readily applicable to and indicated by the data under study and emerge from the data. The developed core category must fit with the social problem under study and be able to explain most of the variation in behaviour used to address this problem.
- **Work:** must be meaningfully relevant to and explain the behaviour under study. The developed core category must work with the emerged and emerging categories so they are related.
- **Relevant:** theories should be relevant to the area under study. The developed core category must be relevant to the data and account for the variation in the behaviour used to address the problem.
- **Modifiable:** theories produced may go through changes as other theories emerge.

Original GT focussed on procedures for verification of data which reflected its objectivistic position. Lomberg and Kirkevold (2003:197) suggest that within an objectivistic epistemology 'fit' is reasonable measure of validity as it gives the possibility of 'external judgement', of 'facts' from the participant. Original GT held the researcher to be separated from the subject, and was not thought to influence the research process (Hall and Callery 2006). However, no researcher in today's research arena can be ignorant of the discussions around the use of other forms of validity, which could be used in a qualitative study.

5.8.2. Respondent validation

Respondent validation is seen as a means of enhancing internal validation within a study (Johnson and Wakefield 2004). Interviewing participants for the second time, to confirm their original views, is not part of original GT, but has been advocated by other GT academics (Birks and Mills 2011), and is thought to fit comfortably with an

objectivist epistemology (Cho and Trent 2006). Respondent validation is supported by many researchers as being an important technique for establishing credibility in a qualitative study (Mays and Pope 2000). However, this is a source of some controversy within qualitative research, as other researchers argue that the patient's perception may have changed over time, they may not remember what was said or they may not see the overall study, just the interview with which they were involved. This study has used respondent validation as the researcher wished to ensure the validity of the study as suggested by Johnson and Wakefield above.

5.8.3. Methodological congruence

Methodological congruence has been included as a marker of validity and reliability because it is in line with the more modern demands of validity within a qualitative world (Birks and Mills 2011). This research has been undertaken from the researcher's stated objectivistic stance. The employment of an original GT approach, albeit adapted for this study, is congruent with that stance.

5.8.4. Negative Cases

Emphasising negative cases, i.e. cases or subjects that differed from everyone else, is another means of addressing the internal validity of this study (Morse 2007). This author argues that within GT, negative cases are integrated into the emerging theory. They form part of the theoretical sampling procedure, where patients with alternative experiences or perceptions are actively sought out, in order to explore a phenomenon more fully.

5.8.5. Reflexivity

Reflecting on the effect of the researcher on the research process has become to be seen as an important part of qualitative research study, emerging from constructionist qualitative research as part of the social construction of knowledge (Hall and Callery 2006). Reflexivity, they suggested, is defined as reflecting on the influence of the investigator on the participant and the research process. Reflexivity was not part of qualitative work when classical GT was introduced and so never explored by Glaser and Strauss at that time. Mills and Birks (2011) argued that although Glaser apparently

rejected reflexivity because it lead to 'reflexivity paralysis' (2001:47) what he actual was rejecting was becoming immersed in the production of the study rather than the analysis of the data from the participant. Birks and Mills (2011) argued that whatever the epistemological position of the researcher, they should be 'reflexive'. These authors suggested that objectivistic researchers should reflect on their detached position both with the subject and on the data analysis. Hall and Callery (2006) emphasised that theoretical sensitivity which is part of the original GT calls for researcher knowledge and this should be reflected on. For these reasons the researcher has included a section on reflexivity in this thesis.

5.8.6. Generalisability of this study

A criticism of qualitative research by the scientific community has been its apparent inability to transfer the findings of a study to a more general population (Mays and Pope 2000). However this is rejected by qualitative researchers who argue that if an aspect of psychological functioning is independently evidenced across many people, then probably the same functioning is present in across most people in the same situation (Lamiell 2001).

In this study, the research from other relevant studies (COPD, AO or as comparison for relevant behaviours) have been interwoven with the findings in Chapter 6. This constant comparison demonstrates the potential transferability of the findings from this study (Chiovitti and Piran 2003). However the generalisability of this study, both in terms of using a piece of prescribed equipment outside the home, and the model of behaviour which was produced by this study, require further comparisons to larger patient cohorts.

5.9. The validity of this qualitative study within a mixed method framework

As explained in Chapter Three this thesis describes a mixed methods research study. The researcher has chosen to adopt the suggestions of Teddlie and Tashakkori (2009) who advocated that each part of a mixed methods study follow the criteria of validity appropriate for that particular approach, either qualitative or quantitative. This

researcher has therefore used the validity criteria set out by original GT as a mark of this work's validity, together with the respondent validation, methodological congruence (Design fidelity according to Teddlie and Tashakkori 2009) and reflexivity to establish the rigour and validity of the qualitative aspect this body of work.

Summary

An adapted form of GT, which fits with the researcher's objectivistic epistemological position, was used as the qualitative method to collect and analyse the data used to answer the research question. The aspects of GT which have and have not been utilised in this study have been discussed within this chapter. The specific procedures used in this study for collecting and analysing data are detailed in the next chapter below.

Chapter Six: The use of Grounded Theory in Phase One

6.0 Introduction

This chapter details how phase one of this research study was conducted. It records the sociodemographic information about the patient population interviewed and describes the grounded theory method used for collecting and analysing the data collected from the participants. The chapter ends by describing the core category and substantive grounded theory developed from this research study.

6.1 Study Design

As stated in chapter 4 section 1, phase one describes the qualitative part of this research. This is a cross-sectional qualitative interview study using an adapted grounded theory approach. The study aims to use this method to ask the research question;

What do people with Chronic Obstructive Pulmonary Disease (COPD) and prescribed ambulatory oxygen (AO) perceive as the advantages and disadvantages of their system and how do those perceptions affect their use of the AO system?

6.2. Ethical and Research governance considerations

As described in chapter one of this thesis, this qualitative phase was an individual work package for the parent HTD study. The process of the original submission to the Department of Health covered issues such as the peer review of this study and Intellectual Property rights to the research developed, including data protection and storage.

Ethical approval for this study was sought from the relevant LREC (Local Research Ethics Committee), in this case from the Isle of Wight, Portsmouth and South East Hampshire Research Ethics committee. Approval was initially sought on the 30 May 2006 and after amendments to the patient's information letter, final approval was granted on the 19th July 2006 (LREC: 06/Q1701/61) (Appendix 1).

The project was registered and approved by the Research and Development office at Portsmouth Hospital Trust as patients were being recruited from Portsmouth Hospital Trust (appendix 2). The University of Southampton acted as the Sponsor and the Insurer for this study (appendix 3 and 4). The researcher used the Lone Working protocol in place at Portsmouth City Primary Care Trust to ensure safe working alone whilst visiting patients in their home. This involved ensuring someone knew the researcher's whereabouts whilst visiting patients, and phoning in after finishing an interview.

In the original version of the study permission was sought to interview 30 participants in their own home and 15 participants in 3 focus groups. Focus groups were seen as being able to provide qualitative data from a larger number of people through systematic questioning (Lawal 2009). The researcher intended to use the focus groups in a broad brush approach to identify issues and then use the individual interviews to explore those in more depth. However, when invitations were sent to participants inviting them to attend the focus groups some of the people who received the invitation telephoned to say they would be happy to take part in the study but were not able to travel to a venue. Other patients who were approached to form a focus group did not reply at all and it became obvious that having a focus group was not going to be possible. Potential participants who had originally been invited to the focus groups were resent invitations to be interviewed at home and all replied positively to the change of venue. The few potential participants who did reply to the focus group invitation explained that travelling was difficult for them, others did not give a specific reason for not wanting to take part in a focus group, but it could be speculated that travel was hard for all or they did not wish to be part of an unknown group talking about a sensitive subject.

6.3. Access to Participants

As described in chapter 5 (5.4.3.), a combination of convenience, purposeful and theoretical sampling was used to select patients with COPD who had been prescribed Ambulatory Oxygen systems (AO). The details of potential participants who had been prescription AO were held by the respiratory nurse at the respiratory centre at Queen Alexandra Hospital. The nurse accessed this database to identify potential candidates. The inclusion criteria were kept as open as possible in order to recruit as wide a range of participants as possible.

6.3.1 Inclusion criteria

All these criteria needed to be met:

- Patients who had been prescribed Ambulatory oxygen, either in conjunction with LTOT or by itself
- Patients who knew their diagnosis: COPD
- Patients prescribed Ambulatory oxygen systems who lived in the area covered by the relevant LREC committee
- Patients able to give informed consent

This study concerned COPD patients who had been prescribed AO. Morse (2007) suggested that within GT initially recruiting as wide a variety of patients with experience of the phenomena under study is important to enable the researcher to fully investigate different aspects of the phenomenon. The inclusion criteria above were designed to give as varied a cohort of participants as possible by not excluding by age or gender or severity of condition.

6.3.2 Exclusion Criteria

Meeting any one of these criteria meant exclusion from the study:

- Any patient who had a recent hospital admission (within 6 weeks of data collection) as they may not be clinically stable.
- Any patient whose primary diagnosis was not COPD e.g. cardiac conditions, other lung conditions such as lung fibrosis, cystic fibrosis.
- Any patient with a communication problem which would make taking part in an interview impossible.
- Any patient with co-existing illnesses such as lung cancer as this may alter their need for supplementary oxygen and influence their perception of oxygen delivery systems.

6.3.3 Recruitment

The respiratory nurse from the local oxygen assessment centre accessed the oxygen patient database for potential participants meeting the inclusion criteria. She sent an introductory letter (appendix 5) and Information Sheet (appendix 6) to patients eligible for inclusion in the study, asking them if they would like to participate in the study. Patients,

who wished to participate, i.e. opt into the study, or have more information, were invited to return the attached slip in the stamped addressed letter provided. The researcher then contacted the patient by telephone to answer any questions about the study. If the patient wished to opt into the study, a convenient date was set for a home interview.

Patients, who did not reply to the first invitation letter, were sent a second letter. If there was no response by the patient to the second letter, no further approaches were made, and the patient was excluded from the study. Patients were recruited in a tiered way. The first participant was used as a pilot to test the semi-structured interview schedules and revise it according to the data collected.

6.3.4 Sampling

At the start of the qualitative phase patients were recruited by convenience sampling within the cohort defined by the inclusion/exclusion criteria. As the study continued and in line with GT, The researcher would conduct an interview which was analysed before interviewing any further participants. Areas of research which were thought to need more exploration were highlighted and the recruiting nurse would send letters to those specific patients in an effort to theoretically sample participants during the study. For example, people who lived alone and therefore had no carer. If a potential participant identified through theoretical sampling, failed to respond or did not want to take part in the study, the researcher relied on convenience sampling to recruit other participants. Patients continued to be recruited until the no new codes or categories were being revealed from data analysis. In this study 27 participants were recruited to in-depth interviews at home.

6.4. Sociodemographic data

Table 6 below summarises the sociodemographic details of the 27 participants in this study. Just over half the participants were men (14 of 27) and three of the participants were under 60 years of age (8%). The average age of all the participants was 68 years, with a range from 54 – 85 years. Most of the participants (92%) were married and their spouse was the primary carer. Three (8% of participants), lived alone and relied on relatives who lived some distance away for any support. Eleven of the 27 participants (41%) had given up driving and were reliant on electric buggies to take them to the local shops or to appointments. All the participants in this study had been diagnosed with

COPD. The average time since diagnosis was 10 years and 5 months (with a range from 18 months to 40 years). The average time the participants had been prescribed long-term oxygen therapy at home (LTOT) was 2 years 4 months (a range of 3 months to 10 years), and/or Ambulatory oxygen (AO) was 1 year 3 months (a range of 3 months to 4 years). The time delay in being prescribed AO in addition to LTOT probably reflects the change in the prescription of AO. Before February 2006 AO was not widely available for prescription, and few patients had an AO system. The time delay between diagnosis of COPD and the prescription of supplementary oxygen suggests that most participants had not needed supplementary oxygen therapy until the disease had become quite severe. This mirrors the accepted course of this slowly progressing incurable disease which causes increasing lung damage, over a period of time (Cornwell et al 2010). Table 14 below details the sociodemographic data collected from the participants.

Table 14: Participants' Sociodemographic data

Participant	Age	Gender	Carer	Transport
1	66	Male	Wife	Buggy
2	70	Female	Husband	Car
3	74	Female	Husband	Car
4	59	Female	Husband	Car
5	54	Female	Husband	Car
6	56	Male	Wife	Motorbike
7	58	Female	Husband	Car
8	69	Female	Husband	Car
9	72	Male	Wife	Buggy
10	83	Male	Wife	None
11	63	Female	Husband	Car
12	69	Male	Wife	Buggy
13	73	Female	None	Buggy
14	74	Female	Husband	Car
15	85	Male	None	None
16	72	Male	Wife	Buggy
17	76	Male	Wife	Car
18	81	Female	Husband	None
19	71	Female	Husband	Car
20	77	Female	None	Buggy
21	85	Male	Wife	Buggy
22	86	Male	Wife	Car
23	66	Male	Wife	Car
24	76	Male	Wife	Car
25	83	Male	Wife	Car
26	75	Male	None	None
27	62	Female	Husband	Car

Buggy= electric scooter as the main mode of transport

In this study 24 of the 27 patients interviewed were going out on a regular basis, although all said this was much less than they used to go out. Three participants went out very rarely as detailed in Table 15 below:

Table 15: How many times participants reported they went out

Number of days leaving the house per week	Number of participants
Every/most days	9 (33%)
3-4 days per week	11 (40%)
1-2 days per week	4 (14%)
Less than weekly	3 (11%)

6.4.1. Consent

Initial consent was sought from the potential participant from a respiratory nurse at the respiratory centre at Queen Alexandra Hospital (QAH). She sent a letter explaining exactly the reasons for doing the study and the procedures involved. The letter asked for the patient to contact the researcher if they wished to be involved but stressed that this was not obligatory and that no detrimental effects would be incurred if the patient decided not to become involved. Once the patient had agreed to be involved in the study, he/she was contacted by the researcher to organise an interview. The participants were asked to sign a consent form, at the interview, but were assured that they could stop the interview at any time if they wished and withdraw with no repercussions.

6.4.2. Confidentiality

Once a patient agreed to be involved in the study they gave the researcher his/her name, phone number and address. Each participant was given a study number which corresponded to the tape and the transcript. The master copy of the participant demographic information and its corresponding study number was kept on a secured computer within the University of Southampton until all the data collection was complete and then any indentifying data were destroyed. No participant was referred to by name within the data analysis or in conversation with any other interested party.

6.4.3. Care of participants

Every effort was made to ensure participant autonomy through this study. The approach of asking patients to contact the researcher by letter if they wished to be considered for the study allowed them time to consider if they wished to be involved without the pressure of a researcher seeking face to face permission. Patients were assured they could withdraw from the study at any time; and this meant that the interview would be stopped and the researcher would leave. They were shown copies of the question schedule so they could pre-empt any questions which they may have found offensive. They were repeatedly assured that there was no right or wrong answer to any questions and they were speaking in complete confidentiality. Within the data analysis the autonomy of the participant was represented by using their words to form the categories and themes which emerged from this study. Participants were asked if they would like a copy of the findings of the study, although none were requested.

6.5. Development of semi-structured schedule of questions

Before the first interview a schedule of semi-structured questions was prepared (appendix 7). This schedule of questions was originally devised by the researcher through her own observations of patients with AO. The interview schedule was then piloted on a COPD patient with an AO system, who was sitting as a patient representative on the steering committee for the whole HTD programme. Any suggestions he made concerning why he used his ambulatory oxygen as he did, were incorporated into the final schedule. This basic schedule served as a springboard for the initial interviews and was then moulded by the data received from patients as the study continued. Certain questions e.g. around carrying the equipment were retained in the questioning throughout the study, as they appeared to act as incentives for participants to talk about their experiences.

6.6. Interviews

6.6.1 Preparation for interviews

Each participant was contacted at home and a convenient time for the researcher to call was arranged. They were greeted and the consent form was explained to them (appendix 8). They were reassured that they could withdraw from the study at any time, with no adverse consequences at all i.e. the tape would be turned off and no further questions asked. If they agreed to sign the consent form (they were given a copy to keep for their

own records) the interview continued. A Sony TCM-20DV tape recorder was used for all interviews, and this was positioned by the researcher and tested. The participant was assured the tape could be stopped at any time. Although the participant was the principle contributor of the data recorded by the researcher, in some interviews the carer was also present, at the participant request, and in these cases the tape recorder was placed to pick up the contributions from the carer as well.

6.6.2. The interview

Each participant was asked some basic introductory questions about their COPD to get them used to talking to the researcher and into the tape recorder. During the interview non-verbal gestures from the participant were recorded as much as was possible on paper by the researcher and memoed with the data analysis for that interview. If the interview was interrupted the tape was turned off until the disruption had passed. This happened in several interviews where the participant would answer the telephone or a carer would enter the room. Carers would often contribute to the discussion and although the researcher had not specifically consented them (they were not included in the ethics submission) the researcher allowed them to speak freely. The researcher felt that as a guest in their homes it would be very difficult to not allow carers to speak. Additionally the comments made by carers were invaluable in understanding some of the participant's experiences. Participants were encouraged as much as possible to talk as freely as they could to allow rich and deep text to be produced. The researcher endeavoured to take the role of 'separate' listener as dictated by the theoretical perspective of this study, and encouraged the participant to express themselves freely without expressing her own personal opinions or comments, but support them with smiles and encouraging nods.

In order to ensure reliability the researcher would from time to time, repeat to the patient what had been said. For example if the patient said they found the cylinder too heavy, to carry the researcher would repeat that back to them for confirmation. The researcher did this to confirm that a statement was true. At the end of the interview the researcher summarised some of the main concerns and opinions expressed, and sought confirmation that she had understood correctly. At the end of the interview the patient was invited to add anything they liked on the subject of AO systems. The recording then ceased and the patient was thanked for their help. The researcher explained that the tape would be

transcribed and anonymised and the results of the whole study would be considered by a larger longer project looking at the development of AO systems.

6.6.3. Transcription

Each interview was transcribed as quickly as possible after the recording was made to allow adequate study of each transcript before the next interview. The interview was played in its entirety twice by the researcher before transcription of the recording occurred. The researcher transcribed each tape into a password protected Microsoft Word document, anonymising any reference to the patient or any other person mentioned in the text. Once the whole interview had been transcribed the tape was listened to again and compared with the transcript to ensure the accuracy of the resulting text. Each transcription was then titled by participant study number and line numbering applied to the text. Each anonymised transcript was printed out as a document to facilitate analysis. Any name mentioned in the text is a pseudonym used to increase readability but protect the identity of the participant.

6.6.4. The second interview

In addition to recapping what the participant said in the interviews, the researcher felt a second method of verification may be useful to the validity of this study. Ten months after the initial interview after further ethics permission had been sought and granted (appendix 9), seven patients (33% of the study patients who were still alive) were sent a second interview letter asking if the researcher could interview them again. All agreed to a second interview. This interview was also conducted in the participant's home. Each participant was given a written list of the collective topics which had emerged from the round of initial interviews. This interview was not recorded and participants were asked their opinion of the list and if they felt it represented what they had said at the initial interview. The participant's responses were written down by the interviewer. The participants all agreed that the list they were given was representative of their views. Some participants had additionally comments which were incorporated within the findings and discussion chapter.

6.7. Analysis of the data

The process of analysing the text in GT has been outlined earlier in Chapter Four. Within this study Glaser and Strauss's method constant comparative analysis was applied to the text, in terms of open/substantive/theoretical or advanced coding (Hall and Callery 2006).

6.7.1 Analysis

- *Open coding:*

All interviews were transcribed as quickly as possible after interview to facilitate the interviewer's memory of the interview which may help with transcription. Each transcript was read and re-read. The researcher identified pieces of data, either sentences or paragraphs which seemed important to the research question. Each piece of data was named or coded in the margin until the whole transcript had been coded. As explained in Chapter four section 4.5.5.1, this type of coding uses mainly inductive reasoning as the researcher uncovers perceptions and experiences from the data, and deductive reasoning by comparing these emerging codes with the data from other participants. The comparison with other participants allows the researcher to collect similarities and differences about the same processes. Examples of open coding from this study are documented in Appendix 10. Memos from and of the data were continually written in parallel with all the coding phases, as a way of allowing the researcher to ask questions of the data itself. Examples of Memoing from this work are documented in appendix 11.

- *Substantive coding;*

These codes were themselves transcribed to another booklet, together with the corresponding text. For example, any code (and its corresponding text) that had anything to do with the weight of the cylinder were transcribed onto separate sheets. This process was continued with all the coding categories derived from the original transcripts. The collected codes for e.g. weight, from all the participants were then studied for similarities and differences. As the selective coding continued the researcher uses not only inductive and deductive reasoning but uses abductive reasoning (Chapter Four section 4.5.5.1) to look for links between the codes and categories emerging from the data. In this way the researcher begins to form a core category which helps to explain the phenomena under study. These linkages were continuously memoed by the researcher on separate cards. Questions such as how and why? What is happening here? Examples of selective coding used in this study are demonstrated in appendix 12.

- *Advanced/theoretical coding;*

Here emerging categories continue to be examined for their components and how they fit with the developing core category. The researcher uses abductive reasoning to conceptualise connections between the data and the core category. Here the researcher looked for commonsense links between categories that could explain the process under study and refine the core category. From the core category, substantive theory could emerge. Within this study further literature searches took place at this point to look for similar theoretical knowledge. Examples of advanced coding are documented in appendix 13. Again memoing was used extensively to allow the researcher to question any social processes that appeared to be emerging from the coded data.

As described in chapter five (5.3.7) the coding procedure was an iterative process where analysis moved backwards and forwards throughout the text.

6.7.2. Theoretical sensitivity

As described in chapter four sections 5.6, the researcher used common-sense as a guide to look for links between codes and categories, developing substantive codes to theoretical codes. For example the common sense link between reporting not being able to carry AO but still using AO outside the house, was due to the intervention of carers. The researcher's own clinical knowledge enabled her to understand patient's use of other medical interventions and their need to relieve breathlessness as a symptom.

6.7.3. Theoretical saturation

As described in chapter four sections 5.7, collection of data continued until the researcher considered the data had become saturated, that is that no new data or codes were being derived from the participants. Some aspects of the interview framework continued to be used throughout the study. Questions around for example; carrying the equipment and use of AO outside the house, were continually used. This was done to try and capture different experiences even if the data was considered to be saturated.

6.7.4. Memoing

Throughout the entire procedure of data analysis the researcher wrote memos. As described in Chapter four section 5.8, memo writing as used to allow the researcher to question what was happening in the data and detail decisions within the research process. Examples of memoing are used in this study as detailed in the appendices used in the coding procedure cited above.

6.7.5. Formulation of a core category

As the findings developed in this study it was possible to produce a core category to explain what the researcher believed was happening in the analysed data. From the constant comparative method and substantive and theoretical coding procedures, it was possible to build up a common-sense picture of how participants used their AO. Different viewpoints could be taken on the core category that was developed within this study. For example, carers were influential in how the participants used their AO, and therefore might have acted as the core category, but not all carers were present during the interview and not all participants had carers. Therefore carers could not be used to explain the processes under study. Available transport was another area which could have been explored further to establish if that could have acted as the core category. However, from the data collected, a clear overall category emerged quickly from the analysis and formed the connecting category which helped to explain the processes under study. Although no participants used these actual words, it was possible to conceptualise that participants used AO according to the advantages and disadvantages that they perceived. The core category was therefore labelled as 'advantages versus disadvantages'.

6.7.6. Formulation of theory

As explained in Chapter four, substantive GT (SGT) theory arises from the core category to explain the social process under study in a defined group of participants and should encapsulate what is happening, from the data collected. Within this study the core category emerged during the analysis and was used to connect and explain the emerging categories from the data collected. The SGT which was developed was:

'Patients with use their AO system according to the perceived advantages or disadvantages they associate with the system'

This SGT/core category is used to explain the model of the findings in chapter six.

6.7.7. Literature searches

As discussed in chapter 4 section 4.6, an initial literature search in COPD pathology and medical adherence was conducted for ethics submission. As the data analysis continued more literature searches were undertaken to explore areas around adherence, and patient behaviour in other similar areas of chronic conditions. These findings are woven into the findings in chapter six.

6.8. Validity and reliability in this GT study

As reported in chapter four, within this GT study, the tenets of validity and reliability are based on four criteria which Glaser advocated in 1978. These are that the theory produced must 'fit' with the area under study, that it must 'work' to explain the social processes uncovered, that the theory must have 'relevance' to the area under study and lastly that any theory must be 'modifiable' in that it may be changed by subsequent research. This researcher would argue that this GT study has produced theory which explains the processes uncovered from the data analysis.

- Core category: 'advantages v disadvantages'
- SGT: 'Patients with use their AO system according to the perceived advantages or disadvantages they associate with the system'

Subsequent discussions between the researcher and clinical peers reinforced the fit and workability of this theory for the researcher. Clinicians recognised many of the behaviours as familiar and agreed that the theory explained patients' behaviour towards AO.

6.8.1. Methodological congruence

The researcher has articulated her philosophical position and maintained that methodological continuity throughout the study by remaining detached from the research subject and treating the data objectively. The researcher has used the coding procedures and memoing procedures dictated by an original GT approach. Another more experienced researcher was able to assess the suitability of the codes devised by this researcher and advise accordingly. The researcher has produced a core category and a substantial GT from the analysis of the data. The researcher believes that logical, common-sense connections are made between categories, and the data and abstractions.

6.8.2. Reflexivity

As discussed in chapter four sections 8.1, the researcher has included other aspects of study validity which are pertinent to qualitative work in a modern setting. These are areas which the researcher acknowledges may have affected the rigour of this study.

- Expertise

The researcher is not an expert in GT technique and acknowledges that this may have affected the results of this study. Aspects of the study which may have been affected by the researcher's expertise are cited below;

- Previous experience

As a clinical physiotherapist working with COPD patients the researcher thought initially it would be difficult to not to have pre-conceived ideas, but actually she discovered on the first interview that she knew absolutely nothing about why patients make any decisions about ambulatory oxygen. So as far as not introducing her own bias into the study, it was much easier than she thought, but something she was very careful to consider during all the interviews. The researcher thought the hardest part of interviewing these participants was maintaining distance as far as their illness was concerned. These participants were all very unwell with limited lives ahead of them, and not introducing bias and sympathy as a removed on-looker was much harder than any theoretical or clinical bias as a physiotherapist with some knowledge of COPD generally.

- Knowing the participant

Although the researcher introduced herself only as a researcher, she knew about a third of the participants from previous pulmonary rehabilitation programmes, and thought that this contact may make the participants more difficult to interview. But actually knowing the participants as patients enabled her to ask them more difficult questions and explore different possibilities more because she knew them better. Having said that, as the study the researcher developed her ability to ask more in-depth questions increased even with participants that she had not met before.

- Semi-structured interview schedule

The researcher was conscious that the semi-structured interview questions reflected the needs of the greater HTD study and thought this limited her ability to explore what the participants said to some degree. However, what also became clear was that the issue with weight reported by the participants enabled data saturation on that particular concept to occur half-way through the cohort of interviews and this enabled her to develop more questions about feelings and responses to different aspects of COPD later in the study. However this may have influenced the early part of the study and the responses from those participants who were interviewed first. To correct this she used respondent validation to go back and see those early participants and explore their feelings, about for example stigma, more deeply.

- Power issues within the interview

As the study continued, the researcher began to realise the importance of stressing at the beginning of the interviews that there was no right or wrong answer and no ramifications from what the participant wanted to tell the researcher. She probably did not stress this enough in the early interviews which may have affected how rich the data was from those participants. Not including the carers in the original ethics consideration may have denied the researcher a rich vein of data on how participants perceive their AO in light of their home situation.

- Data analysis

In analysing the data the researcher attempted to ignore all previous knowledge, and work entirely on the data received from the patient. She felt that she was able to do that successfully but the codes she developed were not extensively questioned by my supervisors as they were going through problems related to a strategic review within their department, although one supervisor did see some coding. The researcher is unsure if this was a problem for this study because most of the core themes which evolved were

extensively reported by most of the participants and negative cases were included in the study. However that lack of independent checking may be a weakness of this study. In the original Ethics submission the researcher envisaged that she could use focus groups as a means of triangulating the data. However it did not prove possible to recruit to these groups so she used respondent validation as a means of member checking the results of the study. The researcher managed to recruit 7 patients (33% of those still alive) and they agreed generally with the study result, which adds to the validity this study.

- Theoretical sensitivity

Having some clinical knowledge enabled the researcher to develop a theoretical sensitivity to the data and helped with data collection and analysis. Whether that sensitivity was good enough to collect all relevant data is unclear. Not having any theoretical sensitivity to psychological issues may have been a drawback to this study, as many such issues were raised. The researcher did not feel that any previous clinical knowledge interfered with any codes or category development, as she had no experience of COPD patients using AO in their own home. However she could be sensitive to issues around the use of other medication and problems with breathlessness.

- Negative Cases

Negative cases were incorporated into the theory model presented in chapter seven. These cases were used to explain differences in the findings and fully explore the research question.

- Memoing

The researcher used extensive Memoing throughout this study and this enabled her to develop an audit trail around theoretical sensitivity. The researcher was able to question what was important to answering the research question and look for interconnections by using memos extensively.

6.9. Summary

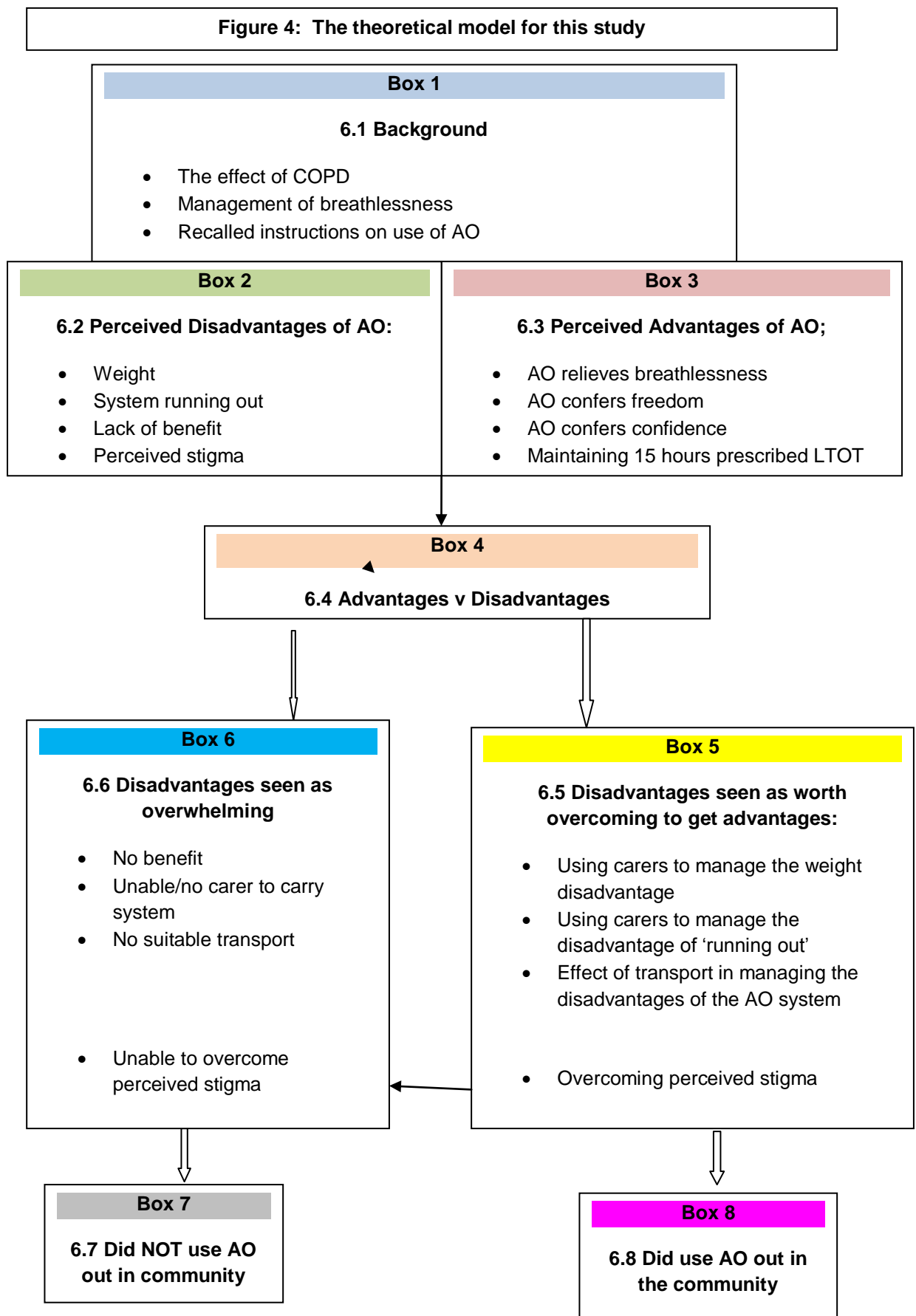
An adapted GT approach was used in this study to produce theory about the area under study and answer the research question. The core category is used in the next chapter, chapter seven, to present the findings from this study.

Chapter Seven: Findings from phase one

7.0 Introduction

This chapter outlines the findings which have been derived from the analysis of the data provided by the participants. These findings aim to answer the research question by presenting a grounded theory of the use of AO in patients with COPD. The chapter introduces a theoretical model that has been used to outline the findings in this chapter and has been organised around the devised core category of 'advantages/disadvantages' of AO and how that influenced the participant's use of the system. The terms 'advantages' and 'disadvantages' were used by the researcher when uncovering common-sense links in the collected participant data. The model is set out as a series of boxes, which represent a category of findings associated with the research question. The model begins with Box 1 containing a background section which aims to set the scene of how COPD participants were managing their COPD generally, as this may influence their AO usage. Linking the boxes is a directional arrow, which depicts how the participant appeared to act on the perceptions outlined in the box before. The results of the action are outlined in the subsequent box. The model continues in numerical order outlining the participants' perceptions of their AO and then moves on (numerically) to outline how the participant managed their AO before finally detailing actual use of AO in the community.

Within the findings the actual words of the participants are printed in *italics*, followed by the participant number and then the page number and line number of the quotation from the participant's individual transcript. All names are pseudonyms.



7.1. Life with COPD - Box 1

Box 1
<p>Life with COPD</p> <ul style="list-style-type: none">• The effect of COPD• Management of breathlessness• Recalled instructions on use of AO

Box 1 describes the background of this study, in terms of how participants perceived the impact of living with COPD and how they managed the condition on a day to day basis. The research question explicitly concerns AO, but how the participants perceived they were managing their lives in terms of any restrictions they felt about leaving the house because of their breathlessness, and how they usually controlled their breathlessness, may contribute to answering the research question. The instructions the participants recalled receiving about using AO impinges specifically on their use of AO and is an important consideration affecting how participants may have decided to use their AO systems.

7.1.1 Effect of COPD

Participants were asked to describe the effect of COPD on their lives, as a background to their use of AO and to obtain a perspective of where AO fitted into their daily routines. All participants described the challenging and disruptive effects of COPD on their lives. All spoke in terms of the things they could no longer do due to the effect of breathlessness. One participant described how her life had changed;

*“I use to swim, I use to ride horses and look after my friends horses
when she was away, I use to walk my dogs, I use to do all my shopping
and now I can’t do any of I because I’m just so breathless, even just
standing up makes me puff” (27, 4, 132)*

One participant who had been working until recently described how the breathlessness associated with COPD, impacted on his life;

“For seventeen years I ran an off-licence and I could stack cases of beer fifteen high by, just by sort of virtually throwing them up into position. I was never a big man but I was always very very fit and able and willing, and I first noticed the effects of breathlessness after I had finished in that job and took up engineering with my son-in-law, and it was just a matter of simple things like can you walk up to the front office Jim and see if there’s any mail, or that new material is over there Jim and gradually it became harder and harder to do anything physical and my breathing would just go and go and go. Then it became difficult to drive because of the er physical effort of changing gear and stuff like that” (21, 1, 6)

Breathlessness as the most pervasive feature of COPD has been highlighted by other research (Eek et al 2011; Seamark et al 2004; O’Neill 2002) and a narrative study by Bailey (2004) described how all the participants thought fear of breathlessness impinged on every aspect of their lives.

This participant described how frightening being breathless was;

“Panic, that’s probably the worse effect, I just, although deep in my head I know I’m going to recover from it, my initial reaction is that I’m not going to errr fear that’s it, that the link directly with that is fear that I’m never going to recover from it, helplessness, yeah those three words panic fear and helplessness are probably the best

descriptive” (1, 2, 63)

7.1.2 Management of Breathlessness

All the participants in this study explained they had experienced breathlessness and all had developed individual strategies to try to manage this crippling symptom. These strategies included avoiding the activities that may cause breathlessness, or by using tried and tested methods to control it, including using medications. This may have influenced their view of AO, because they were already using non-oxygen strategies to help them cope with this distressing symptom. Using tried and tested strategies for managing breathlessness is described in other research in COPD (Frazer 2006). Participants described how they coped with breathlessness using techniques which they found helpful in the past and this involved either using their inhaler or self-talking, for example two participants described using inhaler medication when breathless;

“if I do get really out of breath very often the wife will say do you want your oxygen? Sometimes I say no, I try and delay it by using my puffer and see if that works first, often it’s enough to get my breath back” (17, 2, 46)

And;

“I have inhalers that I use and I find that you know, fairly often that clears it you know, or go sit quietly, I must admit sit quiet and that sort of clears it, if not then I put the gas, the oxygen on” (13, 2, 47)

Whereas two others described self-talking and using learnt breathing exercises as useful;

“If I feel really rough then I get a bit panicky and I can’t control the panic,

*it's like I said I'm all uptight, but if it's just breathlessness then I thinks
right calm down and then I just sits down anyway and take it easy”(5, 1, 26)*

and

*“I get breathless moving from here (chair) to there (sink) but I just
do me breathing exercises, (xx physiotherapist) taught me and they're
fine, I lean on the sink and get my breathe back and then I can carry
on” ’ (7, 6, 182)*

These patients had COPD for many years before they received oxygen therapy, and it may be that their tried and tested techniques for coping with breathlessness had become well established before they received AO, so oxygen was seen as the last resort rather than an established part of the coping routine. The use of tried and tested strategies to control breathlessness may give the participants the feeling of more control over oxygen use which in turn could help them feel empowered to control the treatment they feel they need (Aujoulat 2007). This could be an important factor in their use of AO. But equally they may be used to, and accept, that going out of the house involves being breathless and utilise strategies they used before being prescribed AO.

7.1.3. Recalled instructions on using an AO system

Participants were asked what, if any, instructions they could recall being given on why they had been prescribed AO and how to use the system. Unexpectedly none of these participants said they had received, or could recall receiving, any specific detailed instructions on using AO, particularly if the AO system was delivered to the house as part of an LTOT package on discharge from hospital or as a prescription from the General Practitioner (GP). One participant reported for example;

“just got that (AO) didn't we, never told me about taking it or

what to do with it” (3, 5, 168)

and another participant reported a similar experience

“it was just delivered” (16, 6, 262)

Other participants had received AO from their GP’s, and had used it for several years, but they could not recall getting any specific instructions for using AO systems;

“not particularly, I mean just use it when I felt like it...when I felt like I needed it basically and that was on an ad hoc basis”

(1, 3, 71, man who received his AO from his GP)

Two participants did recall receiving some information from the nurses at the respiratory centre when the participant was assessed for AO;

“No instructions, not really no, just that it only lasted for two hours and that’s it” (4, 3, 76 received AO after an oxygen assessment)

and

“I think the only thing they told us was when you go out it will help you to go out” (Carer 9, 6, 188)

Understanding how and when to use a medication is recognised as an important part of helping patients to self-manage their own condition, including their use of medications (Veazie and Cal 2007). The lack of specific guidelines on the use of AO is

reflected in the lack of comprehensive information patients appear to receive. Petty and Bliss (2000) state that patients must use AO when walking, but this is the only found paper which specifically states functional usage.

All participants reported that they had some instructions from the man (working for the oxygen provider service) who delivered the AO systems to the participant's house,

*“the guy who bought it told me how to switch it on to two litres
per minute and he said just turn it to that”*

(Carer, 4, 4, 145 whose spouse had received LTOT on hospital discharge)

And another participant who lived alone and received her LTOT after a respiratory assessment reported who showed her how to use her AO system and when to use it;

P *“yes, the gentleman who bought the one the last time he showed
me how to use it”*

Q what did he say?

P *“to use it when I needed it and nobody can tell me when to use it
other than me knowing, you know, when I need it” (13, 8, 262)*

The lack of specific usage instructions to the patient is reflected in the instructions to 'use it when you are out' rather than use it when you are walking or doing activities. The fact that these participants could not recall any specific information on how to use their AO systems must have affected their actual use of the system, possibly detrimentally. The apparent lack of instructions would have affected how participants perceive their AO system. One example of this may be that 50% of the participants in this study expressed a fear of becoming dependant on oxygen.

Two participants explained how they felt;

“This is the fear I have, once you start using oxygen, you tend to need, need it more” (4, 3, 145)

And

“the doctor told me once you can’t get addicted to it but it does worry me that you can get addicted to it, you seem to, well you seem to get addicted to most things” (22, 3, 115)

Fear of dependency has been recorded in other studies looking at oxygen usage, for example in the Ernest (2002) study the author found that patients who verbalised a fear of becoming dependant on oxygen did not use it. Comprehensive information given to the participant when AO is prescribed may have alleviated these fears and allowed increased use of the AO systems prescribed.

7.1.4. Box 1 Background Summary

In this study carers and participants seemed totally involved with the daily management of COPD so they could continue as normal a life as possible. The participants complained that breathlessness was the most intrusive symptom they had to deal with, but described trusted techniques to help them overcome it. These strategies may not involve the use of AO. The apparent lack of information given to the participants was an unexpected finding.

7.1.5. Perceived Disadvantages and Advantages of the AO system

As data collection continued the core category emerged around perceived advantages and disadvantages in using the AO system. Here the disadvantages are described

first in order to allow the reader more clarity in understanding why some participants had decided to overcome any perceived disadvantages to utilise the personally perceived advantages.

7. 2. Perceived Disadvantages (Box 2)

Box 2 describes the response of participants when asked what they perceived the disadvantages of the AO system to be.

Box 2

Perceived Disadvantages:

- Weight,
- Running out
- Lack of benefit
- Perceived stigma

7.2.1. The Weight of the AO system

Twenty-one of the 27 participants (88%) described the weight of the system as their main problem with using AO, because they could not carry it:

“I mean how on earth are you supposed to lug a great weight like that around and walk very far, this is my problem I can walk in here (home) but I can’t walk very far when I’m out because I’m lugging that” (27, 3, 96)

And;

“well its heavy its 7 pounds in weight and even Desert Orchid when he ran the Grand National wasn’t handicapped with an extra 7lbs, I

feel it's far too heavy, what the authorities can do about it, I don't know.
If they could get it down to something like the size of a little inhaler that
asthma people use that would be it, I feel at the moment it's very
impractical" (25, 2, 43)

Participants believed that the weight of the cylinder would negatively affect their breathing and increased their perception of breathlessness. Another study looking at adherence in AO found that weight was cited as the most common reason for not using AO (Ringbaek et al 1999). Participants justified not carrying the AO system because the weight would negate any help it delivered:

"for me the exertion of carrying it would take away any help I was
getting from the oxygen" (4, 3, 113),

Evidence from other studies in COPD support the fact that COPD patients experience more significant muscle weakness compared to a non-COPD sedentary population of the same age (Vogiatiz et al 2007), and therapeutic interventions such as long-term steroids may contribute to this muscle weakness (Berton et al 2001). All the participants in this study were over 50 years of age and some were on long-term steroid medication so this may have contributed to their problems with carrying the cylinder.

In this study only one participant was carrying his own AO system,

"I just slings it on my shoulder and then I walk along, if I feel I wants
it I've got it there and I've got it all rigged up" (23, 4, 108)

This man had a carer with a disability and was used to going out of the house on a regular basis, he had been diagnosed with COPD only recently so may have had less muscle weakness than the other participants.

Weight was seen as a concrete practical problem for the majority of participants in this study, and their physical inability to carry the AO system had far reaching effects on how they utilised AO outside the house, in that some did not even consider taking AO when they went out because of the problem with weight. However many participants still took their AO out of the house despite saying they could not carry the system, how and why they did that is explored further when participants talked about the advantages of the system.

7.2.2. The system would 'run out' of oxygen

Each cylinder is equipped with a small clock-face dial which indicates the amount of oxygen in the cylinder in a traffic lights system; green for full (to a half), orange (for one half-to one quarter full) and red for only a quarter full. Practically the dial is obscured by the jacket covering the cylinder, so the patient has to lift the cylinder out of the jacket to look at the meter.

Six participants expressed a fear of the cylinder running out of oxygen when they were away from home:

"I'm frightened it's going to run out" (3, 8, 241).

One relatively young (63) participant who went out on a daily basis with her AO system explained her experience of the AO system running out when she said:

"they told me it would last for three hours, it didn't it lasted a lot less than that, if the point of portable oxygen is that you can get on with your life you shouldn't have to worry if the damn thing is empty or not" (11, 6, 181)

One woman who lived alone had become so frightened of the AO cylinder running out that she preferred to stay with at home with her concentrator which could not run out: When talking about a visit to her daughter she said:

P *"I go over and I know if I use it (AO system) then I want to come home again"*

Q Why is that?

P *"well I can see by the dial you know it's going down and she knows you know if I want to come home again because this is the one I'm safe with (points to concentrator)" (13, 4, 135)*

Although only a minority of participants said they were worried by the system running out, it seemed that if the participant had actual experienced the system being empty then they had been affected by it. There appears to be little comparable research evidence on problems with AO equipment but a study of diabetic patients, the authors report that lack of trust in the equipment compromised adherence (Pfutzner and Somavilla 2010). Participants who had not experienced the oxygen running out first hand, maintained a trust in the equipment and the oxygen levels shown on the gauge;

"well you can see on the gauge how much oxygen is left and then you can order another one, or take another cylinder out with you. It's not a problem and I don't think I'm not very technical, it's just there for you to see. Picking it up (the cylinder) out of the case to look at the gauge is madness, but you can see it very well when it is out" (24, 5, 247)

7.2.3. Lack of benefit

Some participants felt that the AO system was not useful for them because it was not beneficial, in terms of relieving breathlessness when walking outside the home;

“it doesn’t help me as much as I thought it would, my doctor seems to think that if I had it when I was out I’d be able to walk much further but I don’t think it does and now I have to have someone with me to carry it as well but it doesn’t really help” (2, 2, 61).

A man who had his AO system for 6 months responded when asked if he found his AO system useful:

“Getting no benefit out of it at all, I don’t know that they (AO cylinders) are making any difference to my breathing, because I’m still out of breath, even when I use it straight away I still can’t get my breath” (9, 5, 150)

No perceived benefit from an intervention has been identified in other research looking at medicinal non-adherence (Resptrepo et al 2008) as well as in specific oxygen studies (Ernest 2002). Where participants got their expectations of AO benefit is hard to establish exactly, but lack of information on what to expect AO to help with, may also be a factor.

Participants who were using an electric buggy to get out of the house, similarly described how AO was of no benefit to them, but for different reasons;

“I just got out for an hour or so everyday so I top myself up (With LTOT)

before I go and use the oxygen here (LTOT) again if I need when I come home. I don't get off the buggy so I'm not too breathless, so I never need to use my cylinder because I don't get breathless" (20, 4, 131)

And

R: do you take your oxygen with you on the buggy?

P: *no, as I say when I'm sitting down I'm fine, very rarely do I get out of breath, well if I do I use my inhaler (13, 4, 120)*

This group of participants felt that there was no benefit to them in taking AO out because they did not experience breathlessness when sitting on their electric buggies. Therefore they did not take AO out with them.

7.2.4. Perceived Stigma

Participants vocalised that they did not want to be seen in public carrying the AO system which perceived as embarrassing. None had actually experienced any stigma, but said that they felt they would be stigmatised by the community if they used AO out of the house.

Stigma itself has been defined as any attribute or disorder that marks a person as being unacceptably different from the "normal" people with whom he or she regularly interacts, and that elicits some form of community sanction (Berger et al 2011). Research suggests that stigmatising diseases can be further divided by their visibility; if the problem is visible and cannot be hidden, the stigma may be more acutely perceived by the individual (perceived stigma), and there is a higher risk that the 'normal' population might act negatively towards the person with the disorder (enacted stigma) . Whereas if it problem is not visible and there is an opportunity to hide the disorder than the individual may feel more in control and more socially normal, but may

also be continually fearful of the disorder being discovered by others (Earnshaw et al 2012).

Apart from any disruption having COPD may have on a participant, there may also have a more public image if the patient coughs, or has to carry medical equipment with them. This may present the participant with a very public face of illness that may be stigmatising (Bury 1982).

One woman who was on oxygen for 24 hours a day, (except when she went out) explained;

*"I wouldn't like people looking at me, I just feel embarrassed about it
...I think it's probably me, I have always been very independent and
I don't like being ill...and I don't want other people to know I'm ill"*
(2, 3, 89)

In their qualitative study on individuals with COPD, Williams et al (2007) also found that patients complained of feelings of embarrassment because of the visibility of their oxygen equipment. In this study participants seemed to equate how they looked with an external representation of health.

One woman who had used oxygen for 3 years described how her embarrassment at using AO was changing her life;

*"I was on the governors of my old school and I haven't been to a meeting
for the last year so I should resign because I haven't got the confidence
now to just go in there without my oxygen in case I do need it in front of
everybody ...I just feel I don't want to be different from everyone else,*

I feel embarrassed, they probably wouldn't take any notice but I would..

I would feel not a fit person and I don't like itI don't want to be

different" (22, 2, 78)

This participant describes the disruption that her need for oxygen has caused in her life and here she describes withdrawing from a social role because of not wanting to be seen as different. Withdrawal from social events was also documented in a study on Osteoarthritis patients, where the pain and deformity suffered by those patients disrupted their lives and caused them to withdraw socially (Sanders et al 2002).

Earnest (2002) in his study on using long-term oxygen also found patients who used oxygen described their embarrassment and self-consciousness when using AO in the same terms as the participants in this study. In the study presented here, men and women were equally affected by feelings of embarrassment and neither of the two men who had been specifically prescribed only an AO system (but not LTOT), were using their AO system outside;

"I think it would be very embarrassing in a shop if you had to start

rigging this up you know.....yes, normally I'm sitting in the car and

I put it on I'll get a paper or pull something over it so no-one can

see it" (10, 5, 136)

Only one wheelchair user felt embarrassment when using her AO system,

"I think it is a bit embarrassing people do tend to do a double take

now and then and you're conscious of people sort of trying

to have a look see" (2, 7, 254)

In this study embarrassment was the most frequently cited reason for not using AO out of the house, even if the participant thought AO was important enough to devise strategies to overcome the weight disadvantage they appeared not to be able to overcome the problem of perceived stigma. A study into another chronic condition by Hall et al (2007) suggested that patients weigh up the perceived importance of any medication against any other concern. Here it seemed that participants felt that not being seen as different was more important than having AO with them in public. Two of the participants, who were re-interviewed twelve months later as part of the respondent validation, were beginning to use their oxygen outside more. They explained that they now felt they needed AO more. So it seems that feeling more benefit from the intervention may make the intervention more worthwhile and important over other concerns.

7.2.5. Summary Box 2

The disadvantages which participants ascribed to their AO systems fell into the specific categories cited above. Most participants suggested they felt AO had more than one disadvantage, and mainly these were disadvantages that had been personalised experienced by the participant. Perceived stigma was the only disadvantage that participants said they suspected they would experience if they used AO in public but none reported experiencing real stigma in the community. Only one participant did not cite a least any disadvantages to the AO system they had been prescribed.

7.3 Perceived advantages to an AO system (Box 3)

Box 3 describes the participant's perceptions of the advantages that they derived from using the AO system.

<p style="text-align: center;">Box 3</p> <p style="text-align: center;">Perceived Advantages;</p> <ul style="list-style-type: none"> • AO relieved breathlessness • AO confers freedom • AO confers confidence, • Maintaining the 15 hours prescribed LTOT
--

Participants often related more than one benefit. Some appeared not to actually use their AO systems when out of the house; but just having the system with them appeared to be perceived as advantageous.

7.3.1. AO Relieved breathlessness outside the house

Many participants suggested that the AO system relieved breathless for them if they were out of the house;

"I use it 100% of the time. If my husband pushed me in the wheelchair by the time I stand up I'm breathless so I've got to have my oxygen and then I'm fine and then I'll use it when I need it... I use it when I'm out like for 2 to 3 minutes until it settles me down and then I'm fine and off I go again". (7, 4, 106 and 7, 7, 224,)

Participants had used the oxygen they had at home to relieve breathlessness according to the individual participant's perception of oxygen, and they used the AO system in the same way.

"if everything's tickety boo I won't use it at all or another day anything

*up to 4 times I would say when I'm breathless and then we carry on
and I'm fine" (1, 6, 171)*

Having oxygen available to them enabled participants to use this medication to help them overcome the symptoms of breathlessness, when they were out of the house. Participants went on to describe other benefits of the having their AO system with them.

7.3.2. Freedom

Some participants explained that having an AO system gave them the freedom to go outside the house:

*'f I didn't have one (an AO system) I wouldn't be able to go anywhere,
so in that respect I can get out'(7, 8, 252)*

and

*"as I walk along if I feels I want it I've got it there, I've got it all rigged
up so I just like stick it in and turn it on, it gives you more freedom, gives
you more freedom "(23, 4, 110).*

Mr Smith, a 66 year old man who had used AO for 18 months explained how he had asked his GP for an AO system:

*"it allows me to do more, allows me more freedom because ...I was in
hospital...when I came home I was institutionalised, I was frightened to*

come out of my room...so that's why I asked for portable oxygen because I knew how well it (oxygen) it helped me indoors and er.. the world's my oyster now, I mean I can do what I like within reason obviously but, yes it's given me much more freedom, freedom is the word" (1, 4, 122)

Research published on the use of AO systems suggests that AO does improve quality of life in COPD patients by allowing them to get out of the house (Eaton et al 2002). It is the cornerstone on which the prescription of AO is based (Duck 2006), allowing a patient to continue participating in his or her community.

7.3.3. Confidence

Participants also explained that just knowing the AO system was there gave them more confidence when they left the house:

'it just gives me confidence knowing that it's there' (5, 6, 178)

And

'having the confidence that they're (AO cylinders) there, I think that gives you a bit of freedom (14, 5, 149)

And

'they (AO cylinders) has increased my confidence in going out so it's helped me mentally yeah, I think it's given me more confidence in going out and I know it's available to me at all times' (21, 6, 185)

This increase in confidence was not confined to the oxygen users themselves. Mr Wright, who had an AO system for 2 years, and his wife both expressed their confidence in having the system with them when they left the house:

Mr Wright commented that:

'I'm all right because it's there (AO system), whatever I do it's just there (12, 7, 236)

The importance of having confidence in a system or intervention has been well documented in research literature on the use of oxygen in COPD patients (Earnest 2002). Knowing that they had an AO system with them appeared to give these participants a feeling of control and power over the management of their symptoms, specifically breathlessness. This enabled the participant and carer to feel confident enough to leave the house. None of these participants appeared to have experienced the cylinder running out so, for them, that was not a problem. Other research has shown that AO can increase a patient's quality of life (Eaton et al 2002). In this study participants did express the feeling that the AO system enabled them to go out into the community even if they did not actually use it.

7.3.4. Maintaining a prescription of 15 hours of oxygen per day

Only one participant explained that she used her AO to ensure that she adhered to the 15 hours of oxygen per day, as she had been instructed by the Respiratory Centre:

Q Just describe to me how you use it.

P *"well I would take it with me tomorrow for example, I'm visiting my mother and she lives in Swindon so it's a two hour trip, two hours there and two hours back and to spend time with my mother, it doesn't fit in with my oxygen times so we take the portable oxygen with us, and then we I*

can use it on the journey, to make sure I get my fifteen hours”

(11, 3, 99)

Ringbaek, et al (1999) suggested that one very important aspect of using AO was that it allowed patients to ensure they received 15 hours of oxygen per day, irrespective of any other advantage, which meant they were more likely to be able to fulfil their LTOT prescription of 15 hours of oxygen per day. This highlights the problem of the lack of instructions for patients using oxygen for 15 hours per day, in that there is no evidence to show how a patient should actually use their oxygen over a 24 hour period; should they use it for 15 hours only and then have no oxygen for 9 hours, or should they use it throughout the day including when exercising. This participant was told to use oxygen for 15 hours per day and so had developed a regime to allow her to achieve this, which involved using AO when away from her LTOT. It was not clear why this participant had specifically received or remembered this instruction compared to the rest of the study cohort.

7.3.5. Summary of Box 3

Participants related the positive benefits of AO if they had personally experienced them, either for themselves or for their carer. Confidence when leaving the house was the mostly commonly cited advantage of having an AO system, even if the participant did not use the AO when out.

7.4 Advantages v Disadvantages (Box 4)

Box 4
Advantages V Disadvantages

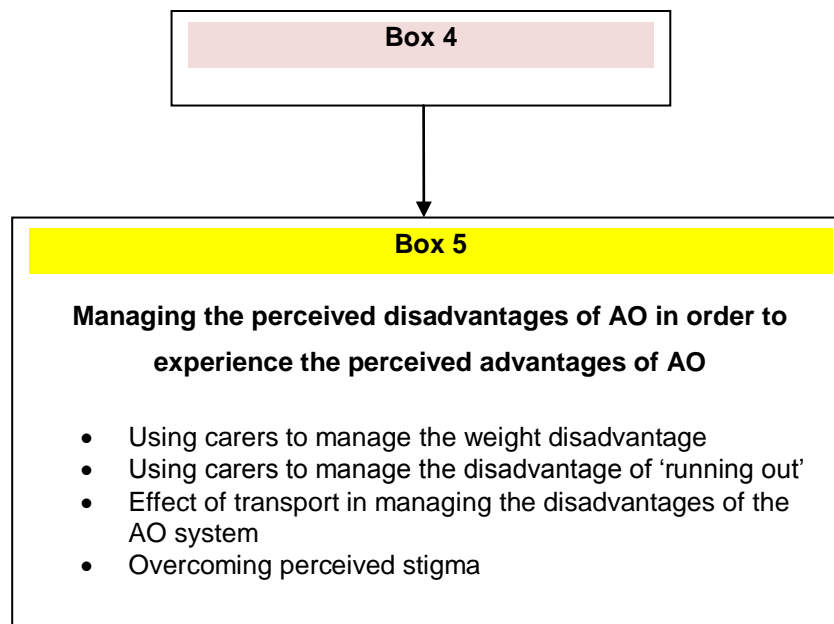
All the participants appeared to weigh up the pros and cons of using an AO system in the light of their own perceived experiences and circumstances. This concurs with other studies looking at adherence within chronic conditions which suggest that

patients decide according to their own criteria, if they will use the intervention or not (Hall et al 2007). Participants who mentioned 'weight' or 'running-out' as a disadvantage were still attempting to take their AO systems out of the house because they said they wanted to use it to combat breathlessness when out. They used support from others or transport to help them achieve their aim of using the system outside the house. Other research cites the importance of social support in making decision about adherence to medication (Chan et al 2008; Luczczyńska et al 2007). Here the use of social support was important in that someone was willing and able to carry the equipment, relieving the participant of an extra burden. Other participants did not have social support, or an unwell carer, so appeared unable to utilise the system. Schildermann et al (2008) argue that to adhere to a medication, patients have to take some responsibility and control. It may be that these participants, who had not explored any alternatives to taking their AO outside, had low willingness to self-manage. Further explanations could go back to the importance of education and that these participants did not understand why they should use AO, or they did not perceive AO to be useful enough to overcome the management problems. A further group chose not to use any social support available to them, so chose not to attempt to overcome the disadvantages because they did not perceive the advantages were beneficial to them personally. Here participants cited lack of benefit, or perceived stigma as insurmountable problems. Perceived stigma was the one overwhelming disadvantage which affected many of the participant's use of AO.

If participants decided to overcome the disadvantages to use AO outside they appeared to do this in a tiered response. They would use carers and transport to allow them to take AO out of the house and put it in the car or on a buggy, so they could have the benefits of using AO away from the house. But most could not then overcome the disadvantage of perceived stigma and would not use the AO in public. This is discussed further in section 6.6 below. In this study only three participants were actually using AO in public and only one of those was carrying his own AO system. The participants who attempted to overcome the disadvantages to use the AO system outside the house are considered below in section 7.5. The participants who perceive the system had too many disadvantages to overcome are discussed further below in section 7.6.

7.4.1. Managing the disadvantages in order to experience the perceived advantages of AO

Box 5 describes the advantages that participants said they perceived from the AO system. If they suggested that the system had advantages they were attempting to take the AO system out with them. The directional arrow between boxes 4 and 5 describes this link, and how participants went about managing the disadvantages in order to enjoy the perceived advantages is described in Box 5.



Participants, who perceived benefits in using AO, were taking the system out of the house. They used strategies to help them do this which consisted almost entirely of getting help from carers. For example participants who were worried about the cylinder running out asked their carer to check the cylinder for them. These participants had devolved responsibility for the cylinder to their partners and that may be because they were physically unable to lift the cylinder and check the gauges. But this behaviour may also reflect a way of including the partner in their daily care.

7.5 Managing the disadvantages of the AO system (Box 5)

Box 5 records how participants suggested they managed the perceived disadvantages which they had encountered with their AO system.

Box 5
<p>Managing the perceived disadvantages of AO in order to experience perceived advantages of AO</p> <ul style="list-style-type: none"> • Using carers to manage the weight disadvantage • Using carers to manage the disadvantage of 'running out' • Effect of transport in managing the disadvantages of the AO system • Overcoming perceived stigma

7.5.1. Using carers to manage the weight disadvantage

Of the 24 participants using their AO out of the house, most reported being reliant on their carers to lift the AO system either onto the buggy or into the car:

"my husband carries it" (19, 3, 70)

One carer suggested that the only way the participant could go anywhere with the AO system was because:

"The only reason she can get out is because I'm there to do it, if I wasn't there she would not be able to do it, I mean carry it anywhere or sort it all out, it's so impractical and not made for people with breathing problems, and it's a good thing I'm alright" (carer, 2, 6, 196)

The apparent reliance on the carers to move the cylinders and ensure the oxygen cylinder was full seemed to be accepted as a normal part of family life for these COPD participants, and no carer complained about their extended role. On the other hand, according to the carers some participants were less aware of the essential role of the carers:

*“she doesn’t think it weighs too much because she doesn’t have
to hold it - I carry it everywhere for her”* (carer, 3, 5, 121)

One study has suggested that COPD patients may not be aware of their dependency on others to do activities, if the task is made relatively easy (Falter et al 2003). This might be why these participants did not regard carrying the oxygen cylinder as a problem. Other research into family functioning in severe COPD suggested that specific roles for family members may be important in achieving better functioning (Kanervisto, et al 2006). In this study getting the carer to help with AO may have enabled both participant and carer to play a role in achieving something which was important to both, allowing social contact, shopping etc, whilst at the same time ensuring the participant had as much support as possible.

Heijmans (1999) suggested that the beliefs of carers/spouses were crucial to how patients cope with long-term conditions as their view of the illness and their illness representations will influence the patient’s beliefs about their condition. Minimisation of the illness by the carer was found to relate to poorer functioning in rheumatology patients because they felt they were not being taken seriously, whereas maximisation of the condition ‘forced’ patients into more of a sick role. In this study the beliefs of carers were not discussed, but it was very evident (in this study) that the carers not only carried the AO system but also controlled the ordering and monitoring of the ambulatory oxygen systems, even if the participants were able to do this themselves. This may imply that the carers had stronger beliefs about the importance of oxygen than the participants or that it was just a practical solution for the couple. Some carers would not leave the home without oxygen, despite the views of the participants, because they were worried about their partner’s symptoms. One carer explained that;

“I would worry if he didn’t have it, I wouldn’t go out I won’t leave the house without it just in case. I mean we probably won’t need it but if it’s there then I know it’s ok” (carer, 17, 8, 258)

Breathlessness, and the fear of breathlessness, can be as frightening for family members and carers as for the sufferer, so carers may have been motivated by this fear to do their best to try to reduce symptoms and maintain social function as much as possible. The positive effects of social support have been documented extensively in other studies looking at adaptation to other long-term conditions where research has suggested that positive social support can augment the patient’s own coping skills and optimism (Luszczynka et al 2007; Chan 2008), and more research has begun to identify how positive social support mediates good health through actual physiological pathways (Uchino 2006).

7.5.2. Using carers to manage the disadvantage of the cylinder running out

Participants who had mentioned that they perceived the AO cylinder may run out had elicited help from carers in managing this problem. As one participant reported, after saying she thought it was a problem;

Q Does it worry you how long the cylinder lasts?

P *“no, not really, my husband keeps a check on it” (14, 5, 161)*

And another participant agreed;

“Fred always checks that’s it’s going to be long enough” (7, 7, 221)

Having someone to lift the cylinder up and check that it was full, enabled these participants to perceive the benefit of AO out of the house.

7.5.3. Effect of transport in managing AO system

The use of AO outside the house appeared to be linked not only to the carers' ability to manage the weight of the system, but also the mode of transport which was available to each participant. The majority of participants had access to a car or used an electric buggy or wheelchair when they left the house. The buggy and wheelchair users who took AO out of the house, said they were happy to have the AO system on the chair. But even then, a carer had to put the AO system on the buggy

"I have it with me on the buggy when we go out, someone has to lift

it on for me' and I sits with it between my legs" (17, 5, 150)

Participants described how, having decided AO was helpful; their carers managed putting AO on or in the suitable transport so they could use it out of house, as one carer said;

"I put it in the car, usually it's in the front and you (participant) holds it"

(C 17, 3, 94)

and

"it's in the back of the car, John (husband) does all that" (19, 5, 147)

Having carers and suitable transport, allowed the participant to enjoy the perceived advantages of the AO system away from the house.

One man would put the cylinder in his car boot and use it as he needed it;

"I've got a bottle in the boot of my car and a mask and if I've been

shopping by the time I walk back to the car, open the boot and have a crafty, not a drag of a fag or something, but a little snifter of the oxygen bottle” (25, 3, 72)

One participant who had an electric buggy was taking AO out with him, but he was reliant on someone to lift the AO on and off the buggy.

“someone puts it on the bars and for the most part I can turn around and pick up me mask and one thing and another” (1, 5, 139)

But participants also said that even if they used AO in the car, they did not use it out of the car. Even participants who were using LTOT for 24hours a day, said they did not use their AO outside the car

Q how long do you use your oxygen for everyday?

A *“all the time now, apart from when we go shopping I don’t use it then”*
(19, 1, 29)

Another participant who was also on oxygen 24 hours a day had adopted a similar pattern of use although her carer complained that;

“It’s on from the moment she gets in the car until we get back but she won’t wear it in the shops” (Carer, 2, 8, 248)

These participants had overcome all the disadvantages they had previously mentioned in order to have the benefits of AO when they left the house. They were, with the help

of carers, taking AO out with them in order to have oxygen outside the house. But organising the AO to be taken out of the house did not imply use. Only three out of the eighteen participants, who took AO out of the house, reported they used AO in public. The main reason the participants gave for not using the AO system outside in the community appeared to be perceived embarrassment.

7.5.4 Overcoming perceived stigma

Three participants suggested that they were not embarrassed by using AO, or had resolved their embarrassment because they perceived they needed the oxygen to relieve their breathlessness and that priority had over-ridden any feelings of embarrassment. The participants who were using their AO out in community described not being embarrassed, both described how they had been embarrassed initially when they first started using AO.

One participant described what happened to him;

“you don’t see many people walking around with this on their shoulder and they see you and it’s gone, the first time I wore it to football and they were all looking at it, and then the other week I could park the car right next door to the football pitch they were playing and I was watching the football and one of the girls came along, one of the young mums and she said oh you haven’t got your oxygen this week Fred, where is it and I said oh it’s in the car I said it’s there if I want it, I said if I want it X would come and get it for me and then she said oh that’s alright then and that was it, now nobody takes any notice” (23, 5, 153)

And his carer added

“my daughter said to him she said don’t worry dad she said, we all know

you need it you know” (23, 5, 167)

This was the only participant who was carrying and using this AO system outside the home and it seemed that initially he had been embarrassed, but with the support of his family he had been able to overcome those feelings and use his AO system outside. Similarly, one man who had had an AO system for 18 months on his buggy agreed, and described how he used to be embarrassed;

“It used to bother me but not now. I’ve stopped being embarrassed

by anything in life, nothing embarrasses me now, I used to get embarrassed

by using inhalers for goodness sake, but nothing embarrasses me now”

(1, 6, 186)

This participant was always accompanied by his carer so it may be that having her support enabled him to overcome his feelings of embarrassment. Research has suggested that social support may be very important in overcoming stigma (Ablon 2002) but for other study participants this did not appear to hold true.

7.6 The disadvantages were seen as overwhelming (Box 6)

Box 6
<p>Disadvantages seen as overwhelming</p> <ul style="list-style-type: none">• No benefit• No carer to carry system• No suitable transport• Unable to overcome perceived stigma

This box describes the decisions of the participants who appeared to find the disadvantages of using AO unconquerable, and so did not use AO out of the house.

7.6.1 Lack of benefit

Participants who cited lack of benefit (discussed at 6.2.3 above) did not attempt to take AO out of the house with them.

7.6.2 No carer to carry the AO system

The 4 participants who said they were unable to carry the AO themselves and who cited lack of a carer to carry AO, lived alone or had reduced their activities so much they rarely went out. All had given up their cars and were reliant on distant relatives to take them out. As one man who was reliant on his daughter to take him out explained, using AO was more difficult if you were reliant on others and he did not want his daughter to worry about the cylinder as well as himself

“it means her getting the wheelchair out and putting in the car and everything, it’s too much trouble, if I could still drive I’d keep it on the back seat and I could use it that way” (15, 6, 185)

Other participants had carers but did not wish them to carry the system; one participant explained that this was because she preferred to walk on her own

“I can’t carry it at all so it means Philip has to carry it around and I’ve got very thin skin so I don’t want anyone with me at all in case I get bumped” (19, 3, 70)

Having no suitable carer meant that participants did not have the means to carry the AO system out of the house, and therefore they were unable to use it outside the home. It was difficult to assess in this study if this had significantly handicapped the

participant from going out as they appeared to go out very irregularly. Whether they would have gone out more if they had more help and more information on alternate carry systems was not specifically addressed during this study but may be an area for further study in the future.

7.6.3. No suitable transport

Some participants suggested that they did not have the transport to carry AO out with them;

“I still ride my motorbike so I can’t take that with me” (6, 4, 227)

And one participant who had an electric buggy explained why he felt it was not feasible to carry AO:

“because the point is I’ve got one of those electric things and it’s very heavy on that and it will not go on the back of the wheelchair and tips it backwards and if you put it on the front and tries to carry it it puts the weight forward and I don’t think a person could push it” (9, 2, 57).

If the participant did not have access to carers or transport they appeared to be unable to take AO outside the home. No participant suggests that any other carrying method had been suggested to them, e.g. shopping bags with wheels, so it was not possible to explore if these participants would have used AO with other carrying methods.

7.6.4 Unable to overcome perceived stigma

Participants who reported they perceived the disadvantage of being embarrassed by their AO system did not use their AO outside the house. If the participant had a car they continued to use AO in the car, but not out in the community. Many participants

described not seeing AO out usually in the community and so how they would feel different from the rest of the public;

“I don’t think I could bear you know, people looking at me because

I’ve never seen anybody with this equipment in my whole life, I’ve never

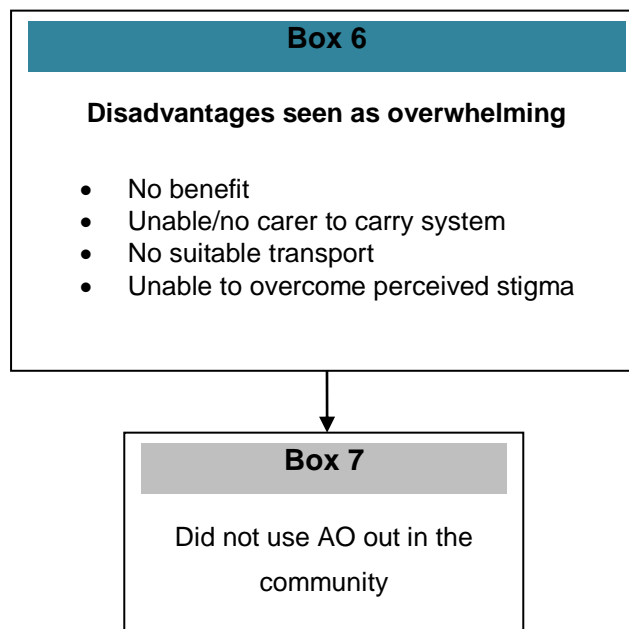
seen anyone walking along with oxygen” (4, 2, 61)

Here the participant felt embarrassed by having a piece of medical equipment with them, either because the equipment itself was unusual or because they felt it labelled them as being unwell. In this study, being embarrassed in public was cited as a problem for all of the participants bar three. Boyles et al (2011) suggest that there is an underlying dilemma in COPD of where to explain/justify the condition or to conceal it. The authors suggest that this is due to fear of exposure at having a lung condition and using oxygen equipment in public may increase the ability of others to recognize and therefore potentially stigmatise an AO user. This may go some way to explaining the perceived embarrassment cited by so many of the participants, and why they ultimately did not use their AO in public.

7.6.5. Summary of Box 6

This box describes the participants who felt so negatively about AO that they had decided not to use it. Not using the system could mean not using it at all for those who described a lack of benefit, or not using it in public for those who felt perceived stigma.

7.7 Not using AO in the community



Participants described the effects of the perceived embarrassment of using an AO system. They described how they did not want to appear to be unusual from others out in the community.

As one participant said;

“well I feel that people would look at you, I look around when I go shopping and everyone has a walking stick so it doesn’t particularly worry me the walking stick, but an oxygen bottle I don’t know, it’s just that I feel that people would stare at you and it would make me feel very uncomfortable” (25, 4, 109)

It may be that participants in this study did not use their AO in public because they wanted to pass as ‘normal’, ensuring no-one knew about their condition (Earnshaw et al 2012), and not taking a piece of oxygen equipment with them, would enable them to pass as an ordinary person. As reported earlier, none of the participants in this study reported having experienced prejudice or ‘enacted stigma’ rather they seem to feel that

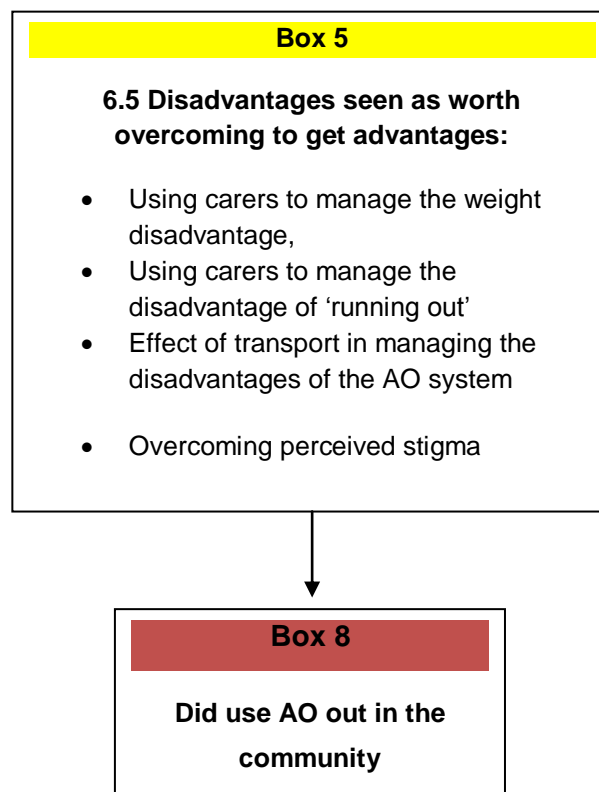
they could or would be stigmatised if other people knew about their COPD, which has been described as 'felt' stigma (Berger et al 2011).

7.7.1. Summary of Box 7

In this study, some participants who perceived a benefit from AO which was enough to make them enlist social support to circumvent the physical barriers to using AO, still did not use it outside the home because they seemed to find it difficult to reconcile their social selves with a social image of a 'sick' individual.

7.8. Using AO in the community (Box 8)

Box 8 describes the participants who felt able to use AO in the community, because they did not feel embarrassed by the system.



The participants who were not embarrassed used their AO and who described a perceived advantage of AO used AO when they went out. One participant said

R: do you always take your portable oxygen with you?

P: *“yes, always, Mary puts it on the back of the wheelchair and I just turn around and pick up my mask and use it” (1, 5, 141)*

This participant was reliant on a carer to lift the AO system onto his wheelchair. The only other participant using his AO system, carried it himself;

“yeah, I get on well mostly, I wear it if I go and see the grandkids play football on a Sunday or if I have to walk, or if I go to the beach and just walk steadily along” (23, 3, 83)

This was the only participant in this study, able to carry and use the AO system by himself out in the community.

These participants appeared to have been able to overcome the disadvantages of weight, fear of running out and embarrassment to use AO in the community.

7.9 Summary of chapter seven

This study was designed to answer the research question;

What do people with Chronic Obstructive Pulmonary Disease (COPD) and prescribed ambulatory oxygen (AO) perceive as the advantages and disadvantages of their system and how do those perceptions affect their use of the AO system?

The theoretical model at the beginning of this chapter aims to help answer the research question and the findings above are cited as supporting evidence for that model. The researcher developed the core category of

‘Advantages v Disadvantages’

using common-sense links during the analysis of the collected patient data. This core category explained the behaviour of the participants in the area under study.

Participants described four main disadvantages of the AO system

1. Embarrassment at having an AO system with them in public
2. Lack of benefit from the AO system
3. The weight of the system
4. The fear of the system running out

If the participant perceived that lack of benefit from AO was for them the disadvantage, they did not then appear to perceive any advantages to the system. They did not use AO out of the house.

Participants described four advantages to the AO system;

1. AO relieved feelings of breathlessness
2. AO gave a feeling of freedom
3. AO gave a feeling of confidence
4. AO enabled them to fulfil a prescription of 15 hours of oxygen per day

Participants attempted to manage the weight and the potentially running-out disadvantages to the AO system if they thought oxygen was beneficial to them and they could perceive advantages to the using the system. Participants managed those disadvantages by

1. using their carers to overcoming the weight problem
2. using carers to overcome the potentially running-out problem
3. using available transport to carry AO out of the house

If the participant had no suitable carer they tended not to use their AO system, even if they had cited the advantages to the system. Carers carried AO systems into cars or onto buggies so the participants could utilise them as they needed. The absence of suitable transport also appeared to prevent the participant using AO out of the house.

Participants, who had overcome all the disadvantages cited above and took AO out in the car, reported a last disadvantage:

1. Being embarrassed by the AO system

Participants managed this disadvantage by avoiding taking AO out in public with them. The three participants who were using AO out in public seemed to perceive that the advantages of AO outweighed even the disadvantage of being embarrassed and did use AO in the community.

Although no participant cited lack of information as a problem, only one participant could recall any information from healthcare professionals on the use of their AO equipment. It is difficult not to conclude that, from the view of a healthcare professional, the lack of instruction/information on the use or importance of AO did not influence use by the participant. This lack of information together with running out of oxygen and the strength of feeling around stigma were unexpected findings.

7.9.2. Production of theory

In this study a Substantive Grounded Theory (SGT) and a core category have been developed. The core category has been presented above.

7.9.3. A Substantive Grounded Theory

In line with GT the SGT proposed encapsulates the theoretical model and findings from this study;

‘Patients with COPD use their AO system according to the perceived advantages or disadvantages they associate with the system’

The next part of this thesis describes the production and development of a questionnaire designed to explore if the perceptions recorded here, were also found in a larger cohort of COPD participants.

Chapter 8 - Phase Two: The background to the development of the quantitative questionnaire

8.0. Introduction

Phase two involved the development and production of a quantitative questionnaire designed for use in future research to explore if the perceptions recorded from the phase one qualitative cohort would be found in other COPD participants using AO. The reasons for using a questionnaire as part of this study were explained in Chapter Four. The questionnaire is used to triangulate the findings from qualitative interviews and increase the generalisability of the whole thesis. This chapter outlines the literature search and theoretical background to phase two of this thesis. It begins with the theoretical development of a questionnaire, and then goes on to describe the theoretical background for pre-testing a questionnaire, using cognitive interviewing techniques and piloting. This pre-testing resulted in a developed questionnaire which has not yet been used to collect information from a large cohort of people who have COPD and AO.

The pre-testing approach used in this thesis has been divided into two distinct *consecutive* stages;

Stage One: A primary cognitive interviewing study which was used to pre-test the participants understanding and response to the questionnaire itself.

Stage Two: A secondary pilot study was used to pre-test the resulting questionnaire to explore how that questionnaire performed when used in a different cohort of participants.

Dividing the pre-testing phase into two stages is supported by Gehlbach and Brinkworth (2011) who argued that a cognitive interview stage followed by a pilot phase enhanced the validity of the final questionnaire. The reasons why these two stages are important are discussed further below.

8.1. Methodological underpinnings

Phase two of this PhD programme involved the deductive part of this mixed methods thesis. The researcher argued in Chapter Four that her approach to the inductive interpretative phase one of this study was objectivistic in nature; using a questionnaire in phase two could be seen as a continuation of that epistemological approach. For the researcher the difference lies in the change from an inductive research *method* to a deductive research *method* by using a questionnaire. By design, questionnaires have set question and answer formats that are laid out ‘*a priori*’ and which dictate the nature of the data collected by the researcher (Rattray and Jones 2007). This resulted in the collection of pre-dominantly coded data which could be numerically analysed from the questionnaire in contrast to the analysis of text data in phase one

8.2. The research question

The research question driving the development of the questionnaire in this second phase of the thesis was;

‘Are the beliefs uncovered in the qualitative phase held by a different population of people with COPD who have been prescribed AO?’

This question is not answered within this thesis. Phase two of this thesis is about the development of the questionnaire that will be used in the future to answer the above question.

8.3. Background to questionnaires

Parflook (2005:1) defines a questionnaire as ‘an instrument consisting of a series of questions and/or attitude opinion statements designed to elicit responses which can be converted into measures of the variable under investigation’. Questionnaires are increasingly employed in health-care research because they enable the collection of information from a large cohort of respondents using what is thought to be a ‘standardised’ format. This assumes that every respondent understands the same question in the same way, and therefore differences in results are due to true

differences in the population, and not the way the questionnaire was understood (Jobe 2003; Boynton et al 2004). However Collins (2003) argued that although researchers promote questionnaires as a standardised tool for collecting data, the reality is that data obtained from questionnaires are often not necessarily standardised at all. The researcher normally assumes the respondent understands the questions and answers on the questionnaire and can recall the required information accurately, whereas in reality this is not always the case (Taviernier et al 2011). Additionally, questionnaires can often contain other types of errors which can fundamentally affect the validity and reliability of the question/answer/coding/analysis process (Forth et al 2010). Groves et al (2009) argued that the only way to expose any weakness in a questionnaire is to pre-test the questionnaire.

8.3.1. Identification of constructs informing the questionnaire

The goal of this questionnaire was to establish to what extent the beliefs uncovered from the cohort involved in the qualitative phase would also be found in different participants from the same population i.e. people with a diagnosis of COPD who have been prescribed AO. This questionnaire was therefore designed to test the responses of the qualitative participants (as opposed to exploratory) and used as a method of triangulation to increase the validity and generalisability of the qualitative interview study findings (Denzin 2010) The questions used in the questionnaire were based on the findings of phase one which were:

1. That participants appeared to receive little information on their AO systems from healthcare professionals.
2. That participants found their portable oxygen system too heavy
3. That participants were reliant on carers to help them with their portable oxygen system
4. That participants were frightened that their portable oxygen would run out whilst they were using it
5. That participants were embarrassed by using their portable oxygen in public
6. That available transport affected AO use

7. Additionally the researcher conceptualised that patients used their AO system by weighing up the personal advantages and disadvantages of the system.

Face or content errors occur when questionnaires do not ask questions pertaining to the area under study (Groves et al 2009). Using naturalistic enquiry to supply the constructs within a questionnaire can be seen as a way of avoiding *face/content error* because the questions are based on the experiences of a similar cohort (rather than what a researcher or expert panel think). This may help to ensure that the participant filling in the questionnaire will have a better understanding of the questions and responses (Barton et al 2011). Because the questionnaire was devised from patient experience, the response set may better reflect the range of those possible experiences and therefore enable the respondent to answer the question. This is particularly pertinent to this questionnaire as the researcher is aiming to confirm or reject the presence of the perceived experiences of the phase one participants.

8.3.2. Formulation of questions

The formulation of the questions used in any questionnaire rests on two basic premises; firstly that the questions relate to the area under study and secondly that they will allow the researcher to collect the information necessary to answer the research question i.e. the question asked will be driven by the goals of the questionnaire (Williams 2003). The questions in this phase were based on the results of the phase one study. How questions are put together and the language used is the subject of copious academic advice and this is discussed further in the next section.

8.3.2.1 Types of question

The importance of the wording used in a questionnaire is fundamental to achieving the recovery of usable data and so all aspects of wording must be considered. Wording of the questions needs to be as clear and understandable as possible and only language that can be understood by the respondent should be used (Boynton et al 2004).

Groves et al (2009) suggested that the ideal question should be designed:

- To evoke the truth

- Not to be ambiguous
- Not to presume an answer
- To avoid bias i.e. be objective

Although this is the ideal, it is difficult to ensure that all questions meet these criteria. A question may be understandable by some respondents but not others, and some may be upset by a sensitive question, whereas others may not (Boynton 2004). Groves et al (2009) argued that pre-testing the questionnaire is the only way of ensuring the wording format is as understandable as possible and will deliver the necessary data for answering the research question.

Within an open/closed format Beaumont (2009) considers that all questions fall into one of four categories. Table 16 below describes those four categories, all of which were used in this study:

Table 16: The four question categories according to Beaumont (2009)

Question category	What the question is used for
Factual /knowledge base	Where the researcher is assuming the respondent has the knowledge to answer the questions
Attitudinal	Where the researcher is asking the respondent about attitude/belief/feeling
Classification/categorical	Where the researcher is asking the respondent to place themselves in a category e.g. age group
Numerical	Where the researcher is asking the respondent a question with a numeric answer; e.g. age

8.3.2.2 Response formatting

Questionnaires use two basic types of response or answer formats; open or closed (Marshall 2007). Open responses are unstructured and invite participants to write their own answer. Open responses may be used more in an exploratory questionnaire where the researcher is actively looking for new data from the respondent, or in questions where the researcher is unsure they have captured all available responses.

Closed questions have a pre-set response format and the respondent answers by choosing which he or she thinks is the right answer (Sporrle at 2007). Providing responses allows the researcher to collect the information required, but if the researcher gives too few responses data may be lost, or if the question has too many alternate responses the respondent may not answer correctly. Basing the response format on the results of a qualitative study helps to ensure, as far as possible, that all potentially relevant responses are included (Barton et al 2011).

Within the closed answer format responses can also offer multi-choice or scaled answers to get more specific information. A table of possible responses is listed in Table 17 below. Scaled responses such as in single-option scales (e.g. Likert scales) which are often used in asking opinion or attitudinal questions, where a range of options may be needed to better describe what a participant may perceive to be true. This is discussed further below.

Single and multiple response options were used in this study. The paired ranking responses were not used as the researcher was not looking to compare a construct's influence but identify the presence of the construct itself (Groves et al 2009).

Table 17: Different response types based on Beaumont 2009 and Rattray and Jones 2004.

Response Type	Description
Single-option variables (closed)	The Respondent is asked to pick one response from several options e.g. Likert scales a uni-directional scaling method which seeks to ask respondent how much they agree/disagree with a statement so may be useful in obtaining attitudes and beliefs
Multiple choice options (closed)	The respondent is asked to pick more than one option if they all apply either in an ordered response or in a multiple choice question.
Paired comparison or Ranking responses (Closed)	The respondent is asked to pick one of two possible response according to their subjective rankings

In addition to selecting an appropriate response to capture data, it is also necessary to determine specific response formats. For example Likert scales are scaled responses often used for questions which ask about attitude or beliefs (Rattray and Jones 2007). Classically a Likert scale goes from 'strongly agree' to 'strongly disagree' using a five to seven point scale with a 'neither agree or disagree / don't know' option in the middle (Groves et al 2009). There is academic discussion around including a middle option which some researchers suggest forces the respondent to make a choice but reduces any response bias because the respondent cannot just opt out (Brown and Maydeu-Olvares 2011). Other researchers suggest that the respondent really might not know or have an opinion on the question and therefore a 'don't know' option is perfectly justified (Saris and Gallofer 2007). In this phase a middle option was given to respondents in responses using a Likert scale because 'don't know' may be a justifiable position. In the qualitative phase not all participants complained of every construct uncovered, so it is to be expected that some participants in this questionnaire phase would not be aware of the problems experienced by other participants.

The researcher decides the type of response used for each question during the initial stages of questionnaire development (Groves et al 2009). In this study where there had been a difference in opinion between participants in the qualitative study the researcher used a Likert scale to capture as many responses as possible, where the response was a simple yes/no the researcher used a dichotomous yes/no response format (appendix 21).

8.3.2.3. Position of questions

There has been much academic debate about how much influence the position of questions has on the response from the respondent (Marshall 2007). Some researchers have suggested that the most difficult questions should go near the beginning of a questionnaire, so that if the respondent gets tired of the questionnaire and returns it before finishing at least it is half answered (Bradburn et al 2004). Others such as Trochim (2006) and Drummond et al (2008) disagreed and argued that difficult questions should be placed towards the back of the questionnaire. These researchers suggested that

- the opening questions on the survey should 'set the scene',
- questions should go from general to more specific
- all questions concerning one topic should be grouped together

Dunn et al (2003) have argued that the position of questions makes no difference to completing the questionnaire. As there is no clear consensus on the design of questionnaires the researcher chose to use the experience gained in phase one study, where the opening questions were general and easily answerable, and designed to put the participant at ease. In order to assess the reliability of the respondents' answers to the questions, questions relating to the same construct (e.g. weight) were spread throughout the questionnaire.

8.3.2.4 Delivery and response rate of questionnaires

Questionnaires can be successfully completed on-line via the internet as well as by post or in an interview (Beaumont 2009). Although mailed questionnaires tend to have a low response rate (Dunn et al 2003), this phase used a posted questionnaire and not

an internet based questionnaire because of the experience of the researcher was that most COPD patients, at this time, were in an older age group and did not have internet access.

8.3.3. Coding Questionnaires

Coding of questionnaires describes the process of translating nonnumeric responses from the questionnaire into numeric data, so that they can be statistically analysed (Groves et al 2009). Coding is usually achieved using a statistical package, where the responses have to be divided into codes/variables for analysis. Forth et al (2010) suggest that wording errors in the coding of questionnaires (how the construct is described and coded) can contribute to coding errors and therefore even in coding the language used by the researcher must be carefully considered. The coding strategies used in this study during both stages of the pre-testing are described further below.

Questionnaires can be 'weighted' by the researcher so areas of importance for the researcher can be identified and stand out (Heesmans 2007) or where there is a known difference between groups who may receive the same questionnaire (Grove et al 2009). Groves et al (2009) argued that 'weighting' was only required in complex surveys and was not adopted in this study. This was because it was a small study but also because the questionnaire responses were determined by the participants in the qualitative study and for them different things were important. Participants completing the questionnaire belong to the same general COPD cohort so may also feel that different items had differing important. Each response was given equal weight and scored with genuine numerical values.

8.4 Validity and reliability in a questionnaire study

How useful and usable a questionnaire is in terms of gathering the data to answer a research question is determined by its validity and reliability (Kember and Leung 2001). The terms validity and reliability are confusingly used interchangeably within survey methodology, with some authors describing the same factors under reliability and some under validity, and some authors using different terms to describe the same concepts (Groves et al 2009). Both terms are used to identify 'errors' within a

questionnaire. Errors are described as anything that can interfere with the collection of data from a questionnaire preventing the researcher from answering the research question fully (Groves et al 2009).

8.4.1. Validity

Groves and his colleagues (2009) suggested that the term 'validity' is used to describe how well a questionnaire accurately reflects the area under study. For Kember and Leung (2001) this equates to errors in face validity and content validity; do the questions accurately represent the purpose of the questionnaire, are the questions and answers understandable, are they answerable, are they biased? Some authors advocate ensuring validity by comparing constructs within the questionnaire with known constructs from other validated questionnaires from the same area of study. However Saris and Gallhofer (2007) point out that if such a questionnaire existed why would there be any point in producing a new one? Rattray and Jones (2007) suggest that validity lies in obtaining an expert opinion to ensure the right scales and concepts have been addressed.

In this quantitative study validity refers to two areas, firstly in errors of face validity; do the questions pertain to the area under study? Secondly, is the question and response wording enough to ensure the ability of the participant complete the questionnaire as the researcher intended. The cognitive interviewing (CI) pre-testing (stage 1) was used to assess validity in this study.

8.4.2. Reliability

Within the academic literature around questionnaires there are several definitions of reliability. For example; Groves et al 2009 argued that reliability relates to the measure of the variability of answers over repeated trials, or across items designed to measure the same construct. An European Union (EU) commissioned paper (Eurostat 2010) argued that reliability (or as they termed estimation errors) concerned the errors in distribution and sampling of the questionnaire.

Another approach to reliability is to use multiple questions to measure the same construct, and is most often used to measure subjective states. Here Cronbach's alpha is used to as an accepted measure of inter-item consistency, to assess multi-item reliability (Groves et al 2009). In this thesis the researcher was not looking to measure subjective states, but to see if the perceptions found in the qualitative phase were also found in the questionnaire phase. One participant of the cognitive interviewing study did complete the questionnaire again six months later. By doing this the researcher has used the test-retest suggestion of Groves et al (2009), albeit in only one participant. The results of the re-test were not included in the pilot study as the participant had helped develop the questionnaire, and was not therefore a different participant.

8.5 Pre-testing a Questionnaire

Pre-testing a questionnaire aims to increase the response to the questionnaire because it ensures that the questions can be answer adequately by the respondent, allowing the collection of data needed to answer the research question (Beatty and Willis 2007). To achieve this questionnaire must be as error-free as possible before it is distributed to the final target participants. Pre-testing is a means of evaluating not only the questionnaire itself but also the data derived from the pre-test pilot group completing the questionnaire (Groves et al 2009). Questionnaires can be pre-tested through different approaches.

8.5.1. Peer reviewing

Peer reviewing, that is the testing the questionnaire on the researcher's peers is often used as a cheap, convenient method to pre-test a questionnaire. Although this was done in the very early development of the first two questionnaires it was not pursued further. This is because the researcher agrees with Boynton (2004) who argued that the most important part of the pre-test process is to involve a sample who represents the cohort to whom the final questionnaire will be delivered. Pre-testing with patient representatives ensures that the researcher understands the responses of the patients themselves, not fellow professionals.

8.5.2. Focus Groups

Focus groups (i.e. groups of 4-6 respondents) who are likely to be representative of the target respondents, are often used to obtain feedback about questionnaires and ensure they are error-free. Jobe (2003) suggested focus groups are a useful and valid means of pre-testing a questionnaire and can give useful insight into the comprehensibility of the questionnaire and the sensitivity of any questions. Alternatively Collins (2003) and Goodwin and Chappell (2009) argued that focus groups do not give enough insight into problems within a questionnaire because they tend to assess the gross features of a questionnaire such as; length, acceptability, gross comprehension and acceptability to respondents, but do not look for problems which relate to how the questions are understood or answered at an individual level. The researcher agreed with the arguments of Collins because additionally this questionnaire is designed to go through the post, so each respondent will receive the questionnaire individually at home, and will complete it at home, not in a focus group setting. For this study the researcher felt she needed to pre-test the questionnaire in circumstances which most closely resembled how the final questionnaire would be received by the respondent.

8.5.3. Cognitive interviewing

Cognitive Interviewing (CI) uses face to face individual interviews to understand how the respondent comprehends and answers the questions. It is defined as:

‘the administration of draft survey questions while collecting additional verbal information about the survey responses, which are used to evaluate the quality of the response and to determine whether the question is generating the information that the author intends’

(Beatty and Willis 2007 p288)

CI can take place in the respondent’s home which mimics how the final cohort will receive a postal questionnaire, and therefore using CI may provide more accurate insights into how the individual respondent would answer the final questionnaire. Additionally CI involves re-testing the same questionnaire with the same respondents over time, actively involving the respondent in the development of the questionnaire.

This has the advantage of using the respondent's knowledge on the subject under study as the questionnaire evolves. CI also employs the use of a panel of 'experts'. After each round of interviews the questionnaire is presented to a group of expert judges who confirm which changes should be made. The presence of this panel with the CI process is thought to ensure that the process of change within the questionnaire is objective, and this improves face validity (Rattray and Jones 2007).

8.5.4. A pilot study

In a pilot study the questionnaire is sent to a small group of participants and the data recovered from the completed questionnaires are analysed to ensure that the coding of the answer formats is error-free, and that the questionnaire delivers the data required to answer the research question. Information on how the questionnaire performed can be collated, such as completion rates, non-response rates, missing data or errors in coverage or bias which may explain why the questionnaire did not give the information required (Willis 2005).

8.6. Pre-testing in this phase

The pre-testing of the questionnaire was divided into two stages in this research because this allowed the researcher to develop the questionnaire with one cohort and ensure that questionnaire could be used in a different cohort. This was done because although CI is a useful way of ensuring a questionnaire is as error-free as possible, it may only be error-free for those participants who took part in the CI study (Willis 2005). Therefore in order to ensure that the developed questionnaire did produce the information required by the researcher a further pilot study was undertaken in a different cohort of participants.

8.6.1 Stage 1 Cognitive interviewing

Historically, cognitive interviewing emerged as a method of pre-testing questionnaires in the 1980's with an amalgamation of two disciplines; survey methodology and cognitive psychology, forming the CASM (Cognitive Aspects of Survey Methodology). The drive behind this new approach was the increased use of questionnaires, the recognition that questionnaires lacked rules which ensured error-free design, and the

explosion of cognitive psychology as a discipline (Willis 2005). Bradburn et al (2004) suggested that survey methodologists and cognitive psychologists focused on different aspects of what makes up a questionnaire and this is summarised below in table 18 below.

Table 18: The approaches of survey methodologists and cognitive psychologists

Survey methodologists focused on:	Cognitive psychologists focused on:
Wording of the question	Encoding strategies or how the question was understood
Structure of response format	Retrieval strategies; how the necessary information was recalled from memory
Context of the questions	How the respondent made a judgement about the answer needed
Questionnaire instructions	How the response was achieved

Collins (2003) argues that survey methodologists have long been aware of some of the formatting errors within questionnaire design, but identifying that a respondent could not answer a specific question did not help identify why they couldn't answer it, so it was difficult to find a solution to that problem. The input from cognitive psychology enabled researches to explore and identify the processes by which a respondent looks at and answers a question (Lapka et al 2008).

Cognitive psychologists suggested that people answer questions according to a question and answer processing model (Jobe 2003) which suggests four areas of cognition which need to be addressed in order to answer a question:

- How respondents understand/comprehend the question,
- How respondents retrieve the information necessary, from memory

- How respondents make a judgement about the information necessary to answer the question
- how respondents decide on the response to the question

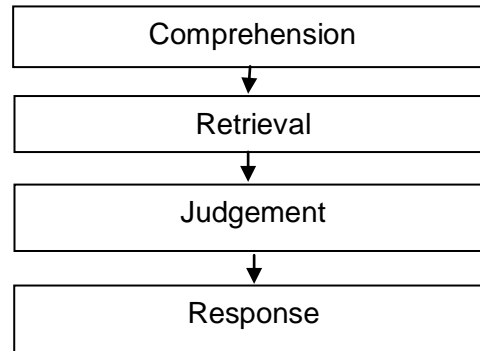
These four areas i.e. comprehension, retrieval, judgement, response have been described by psychologists in much of the seminal theoretical work addressing the cognitive aspects of survey methodology which was produced when the two disciplines conjoined (for example see, *Cognitive Aspects of Survey Methodology; Building a Bridge between Disciplines*, published in 1984). However debate continues as to how these four areas interlink. Table 19 below describes the features of these four areas in more depth.

Table 19: The four areas of cognitive processing thought to be important in answering a question based on Beatty and Willis 2007

Area of cognition	Description
Comprehension	<p>The wording needs to supply the necessary stimulus to memory in order to allow the respondent to retrieve the knowledge necessary to answer the question. The words need to be recognisable and comprehensible to the respondent</p> <p>Does the respondent understand the question in the same way as the researcher?</p> <p>Do the words make sense? Do they make sense within the context they are in?</p> <p>Does the layout of the words in the question alter the comprehension for the respondent?</p>
2. Retrieval from memory	<p>Word recognition is linked to the context in which the word is stored in memory, so recognition of words makes retrieval from memory easier. Less significant events will be forgotten.</p> <p>Does the wording help retrieval of memory?</p> <p>Can the respondent remember details?</p> <p>What wording would help them recall detail?</p>
3. Judgement	<p>The respondent makes a judgement about the answer to a question depending on their knowledge, their comprehension of the words used in the question, and their cognitive ability to retrieve information from their memory. These aspects combine to allow the respondent to make a judgement on the responses</p> <p>Is the wording comprehensible and understandable?</p> <p>Are there enough cues in the wording to help them retrieve the information required?</p> <p>Does the response set cover all possible alternatives?</p>
4. Response	<p>Selecting an answer involves the three steps above, and further comprehension and understanding of the response set and the alternatives they supply. Respondents may see the answers as value-laden and choose because of other considerations e.g. social appearance/belonging or may choose a response by rejecting all other possible answers before choosing the most appropriate.</p> <p>Does the response set give enough alternatives? Does the response set give too many alternatives?</p> <p>Is the wording of the responses clear and comprehensible to the respondent?</p> <p>Does the respondent have the knowledge to make a choice from the responses?</p> <p>Does the respondent have the cognitive ability to retrieve necessary information?</p>

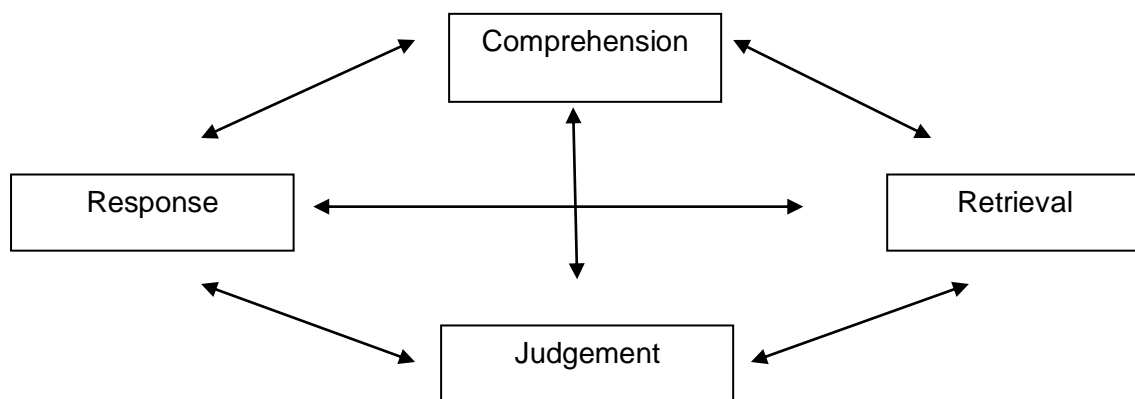
How these four stages of answering a question combine is still an area of discussion. For example Jobe (2003) suggests suggest a sequential processing between each of the four stages as described in Diagram 5 below:

Diagram 5: Representation of a question/answer model based on Jobe (2003)



However, Collins (2003) suggests that the linking between these four areas can better be represented by a simple model, depicting that this process is not a linear process but co-dependent as seen in Diagram 6 below:

Diagram 6: Representation of a question/answer model based on Collins 2003



The Collins (2003) model intuitively seems more likely to reflect reality, where comprehension, retrieval, judgement and response are interlinked as opposed to being a rigid succession of processes as suggested by Jobe (2003). Both models suggest that these four areas are part of the fundamental cognitive process a respondent goes through when confronted with a question. The effect of a cognitive perspective on survey methodology was to enable researchers to explore questionnaires for possible errors from a cognitive perspective. For example the importance of understanding how

the wording of the question can act as a stimulus to achieve the retrieval of a memory necessary to answer a question (Lapka et al 2010).

Beatty and Willis 2007 (p288) concluded there is no common definition of CI but describe it as 'the administration of draft survey questions while collecting additional verbal information on survey responses, which is used to evaluate the quality of the response or to determine whether the question is generating the information that its author intended'.

Groves et al (2009) argued that there is no single universally accepted technique used to do cognitive interviewing and that the researcher may choose one or multiple approaches e.g.:

- Concurrent 'think aloud' –where the respondent verbalises the questionnaire as they read and answer it
- Retrospective 'think loud' –where the respondent verbalises how they arrived at an answer after reaching it
- Confidence rating- where respondents rate their confidence in the answer they have given
- Paraphrasing – where respondents restate the question and answer in their own words
- Definition – where respondents provide definitions for key terms in the questions
- Researcher probing-where the researcher asks specific questions of the respondent about the question and answers as they go through the questionnaire.

There is little general agreement in the literature as to which of these different cognitive techniques generate the most useful results although De Maio and Landreth (2004) argued that similar results are found, whatever technique is employed. However, the most commonly used techniques are 'think-aloud' and 'probing' (Beatty and Willis 2007) and these are the techniques which have been adopted in this study.

8.6.2. Think aloud

Think aloud is the first technique described as a particular cognitive interviewing technique tool (Willis 2005) and relies on the respondent reading aloud through the questionnaire and reporting aloud what they are thinking as they progress through reading and answering the questions.

8.6.3. Probing

Probes are specific questions asked of the respondent as they complete the questionnaire. They can be set before the interview (pre-scripted) or reactive questions i.e. questions that occur to the researcher at the time of the interview (Beatty and Willis 2007). The relative advantages and disadvantages of 'think-aloud' and 'probing' are considered in table 20 below.

Table 20: The advantages and disadvantages of the most commonly used CI techniques based on Beatty and Willis 2007

Technique	Advantages	Disadvantages
Think -aloud	Relatively easy to undertake from the researcher's view point Reduces interviewer bias Interviewer does not need expert knowledge on interviewing	May be poorly performed by respondents May not provide enough information on questions
Verbal Probes	Provides a focus for interviewer and respondent Does not interfere with the process of responding to the question Creates useful additional information on questions/response set	Creates artificiality and may interrupt the respondents flow Collected after the response so may be affected by memory Relies on interviewer judgement – especially if the probes are not pre-scripted

The modern proponents of CI state that both 'think-aloud' (TA) and 'verbal probing' (VP) are entirely complementary and should be applied together so the researcher can gather as much useful information as possible about the questionnaire (Willis and Beatty 2007; Willis 2005). A recent study by Priede and Farrall (2011) concluded that TA was better at examining how the respondent understood the questions and VP uncovers more specific problems and so both techniques are useful together. Beatty and Willis (2007) suggested that the type of interview and the interviewer's style may be deciding factors in using different techniques. For example if the interviewer wishes to be less intrusive they may just use 'think-aloud,' but if they were undertaking an exploratory questionnaire where gathering more information would be useful, then probes may be more beneficial. Experienced interviews may be best suited to reactive unscripted probes asked as the interview progresses, whereas inexperienced CI interviewers would be better suited to pre-scripted probes. Within this study think-aloud was used with some scripted codes, as the researcher was inexperienced in cognitive interviewing techniques. However she did also use unscripted probes if she needed more information from the participant.

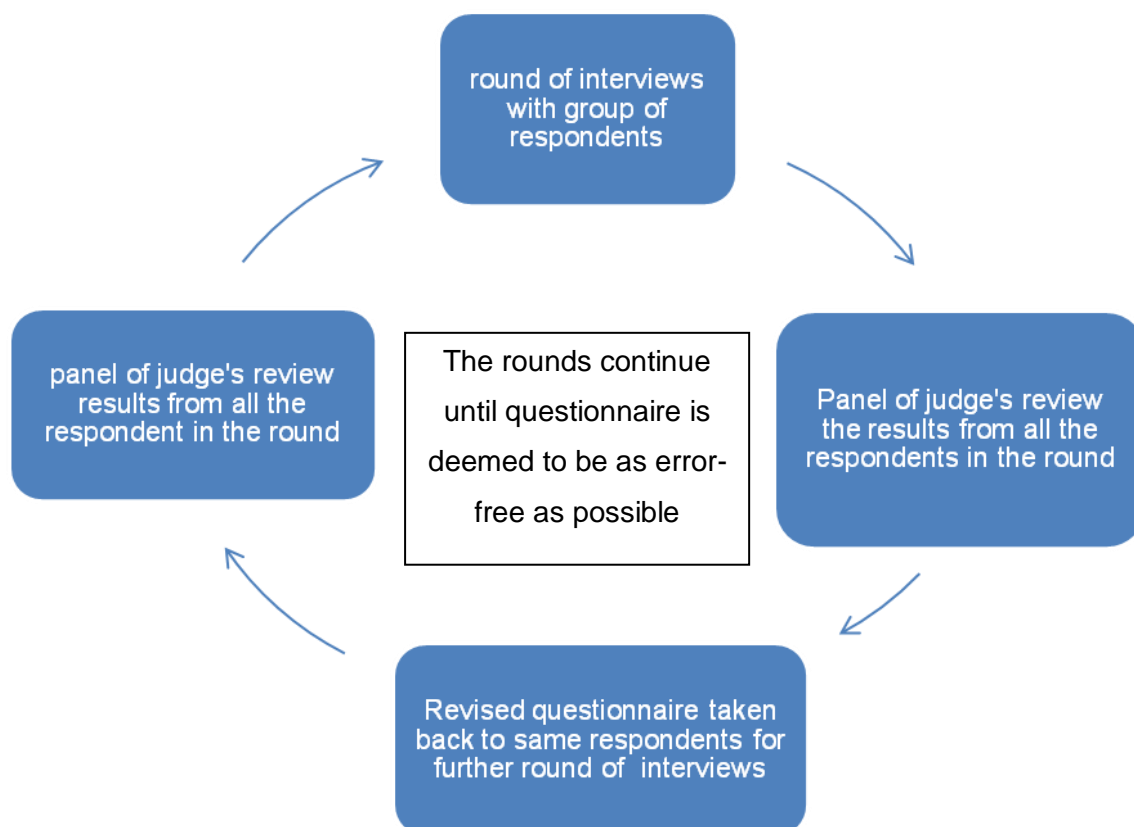
8.6.4. Effectiveness of cognitive interviewing

Beatty and Willis (2007) state that the reason for undertaking a CI phase for questionnaire pre-testing is that it will improve the useable responses in a questionnaire and the response rate. This gives the researcher more useable data to answer the research question and promotes the validity of the questionnaire. Several authors reported they found CI uncovered more apparent problems with a questionnaire than face to face interviewing alone (Murtagh et al 2007; Conrad and Blair 2009). However Groves et al (2009) points out that finding a problem does not indicate how to solve it correctly to suit everyone. Authors argue that different respondents will have different views about the same problem/question and that a single problem may seem more important than it actually is, depending on the reaction of a single respondent (Pressor et al 2004; Conrad and Blair 2004).

To address this potential weakness in CI, the procedure for conducting CI interviews has evolved from one interview to circular rounds of interviews with different respondents concluded with a judges' panel (Holbrook et al 2006). This cycle is depicted as a circular process in diagram 7 below. The interview rounds begin with the

completed questionnaire which the researcher shows to a group of respondents. The researcher records the results from the TA and VP used in the CI interview. The results are taken back to the judges' panel for examination and the panel make the decision to change the questionnaire if necessary. The amended questionnaire then goes back out to the same respondents for another round of CI. This cycle continues until the questionnaire is deemed as error-free as possible.

Diagram 7: The cyclical nature of CI interviews and the judges' panels



The inclusion of a judges' panel allows any problems with the questionnaire to be assessed by more than one researcher.

8.6.5. The Judges' (Expert) Panel

The panel is made up of a group of people who have experience in questionnaire design or the subject matter under research (Willis 2005). The panel can help highlight problem questions/responses which have been identified during the interview rounds

and decide if any changes should be made. This corporate view ensures objective decisions about the question/answer format can be made (Olsen 2010). There is little guidance on how panels decide what questions should be changed, but the process seems to rely on the individual expertise of the panel members to suggest changes which may be useful (Willis 2005). Within this study the judges' panel consisted of two of the researcher's supervisors and the researcher.

8.6.6. Sample size and recruitment in cognitive interviewing

CI is useful in uncovering potential problems with questionnaires. However how a respondent views a questionnaire may be dictated by their individual circumstances. Therefore it is important to use CI with a representative sample of the final target cohort (Willis 2005). There appear to be no fixed guidelines on sample size but Beatty and Willis (2007) suggest that each round should consist of 5-15 interviews, so 5-15 participants. This was the guideline used within this study and 5 participants resulted in 5 interviews per round.

8.6.6.1. Deciding when to stop the interview rounds

Research suggests that the interview rounds should cease when the questionnaire is considered as error free as possible by the researcher and the judges' panel (Lapka et al 2010). Betty and Willis (2007) compare this with category saturation within qualitative research where data is collected until no new data are forthcoming. This was the guideline adopted by this study.

8.6.6.2. Coding of CI interviews

The data from CI can be recorded in several ways and there is no definitive method advocated across CI research (Willis 2005). The results can be coded numerically (as in questionnaire coding) with the codes reflecting specific CI problems likely to be exposed during CI. Additionally the researcher may record separately how the respondent answered each question, or how they approached the questionnaire for example if he looked engaged, if he asked anyone for help. These are written as field notes and collated for each participant/question at the end of the round of interviews. In this way the researcher can build up a picture of how each respondent viewed the

question/answer set and how much of a problem each question caused. The judges' panel can then weigh how difficult a specific question/answer set was for all the respondents and make a decision to change the dataset from the whole round, not just one individual. Deciding whether or not to change a question can depend on several factors. Willis (2005) cites that changing a question may depend on different criteria, for example; how many participants had a problem with it, if the question produces the answer required, or if the question is surplus to information already required. The rounds of interviews and judge's panel continue until the questionnaire is no longer being changed by the participants and the questionnaire is deemed by those participants to be as error-free as possible.

8.7. Stage Two: pre-testing the questionnaire using a pilot study

A second stage of piloting was employed as part of the pre-testing of this questionnaire. In this study further pre-testing took the form of a small pilot study. The researcher is a self-funded student and so undertaking a large pilot study was not possible due to time and financial constraints. Bradburn and his colleagues argued that students with financial restraints should undertake small pilot studies with at least "10-12 of the representatives of the final cohort" (2004:317), and that advice has been adopted here. They maintained that even this small number of pilot participants would help the researcher ensure that the questions were clear, understandable and able to collect the information needed to answer the research question.

8.7.1. The need for a Stage Two pre-test

Although CI can provide an invaluable insight into how a respondent completes the questions and answers, it has limitations in ensuring an error-free questionnaire. Willis (2005) and Gehlbach and Brinkworth (2011) argued that CI only identifies problems with questions or answer formats in the respondents who form the CI study group. Respondents (from outside the CI study cohort) may discover problems in the questionnaire not exposed by the study respondents. Therefore there is a need for a further pre-testing stage. Additionally, Willis (2005) maintains, CI is not designed to deliver statistical information. CI is concerned with the respondent's understanding of the question and answers not the statistical significance of the data from a CI sample which is usually very small (Willis 2005). So pre-testing by piloting in a larger cohort

may be useful for statistical analysis of the questionnaire. Willis (2005) also argued that the results of a CI study may depend on the expertise of the researcher/interviewer, and that inexperienced interviewers may uncover fewer problems than an experienced one.

This researcher is inexperienced which may affect the CI results, but she also agreed with Gehlbach and Brinkworth (2011) that the questionnaire should be tested in a different cohort of participants. Five participants were recruited to this CI stage, which is the smallest acceptable number according to Beatty and Willis (2007), therefore continuing to pre-test in a different cohort was seen to be advantageous to the pre-testing of this questionnaire. The researcher decided there was a need to continue to pre-test the questionnaire by sending it out to another group of participants to gauge their reaction, problems with completion, skipped questions, incorrect responses, and non-responses in the returned questionnaire (Gillham 2007). This entailed piloting the finished questionnaire in a different cohort of participants.

8.7.2. Piloting the questionnaire

Piloting in this study meant sending or giving the questionnaire that was developed from the CI study to different participants. These participants were part of the same general population as the CI participants and the final target participants; that is people with COPD who had been prescribed AO, but different participants from either previous study. Gillham (2007) maintains that within a pilot study the researcher is looking for missed or incomplete responses, crossed out responses or participants responding with not applicable (N/A). The presence of these responses may indicate misunderstanding by the participant or erroneous questions/response formats.

8.7.3. Coding the questionnaire

Capturing the results of the questionnaire in a form which can be statistically analysed is the aim of most questionnaires. The '*a priori*' use of closed answer formats which can be coded allow the information from questionnaires to be analysed. Open answers would need to be coded qualitatively and the results produced in a text form (Groves et al 2009).

In a closed answer format the text response is coded according to a numeric scale for each variable possible within an answer set, so every possible answer has a unique code. Therefore careful consideration of the classification within answers and the data being collected needs to be considered. Groves and colleagues (2009) argued that all codes must have a structure which reflected a unique number for analysis, a text label for that code, both of which should be exclusive to a category. Codes must be able to handle all responses, including the 'do not know' response, a response for respondents who legitimately skip a question that does not apply to them, as well as registering questions that have not been answered. Gillham (2007) maintains that coding answers can be very simply achieved, so that answers can be presented numerically or statistically.

Most coding of questionnaires use a computer programme to enable the researcher to record and subsequently analyse data. Mistakes in inputting information is another source of error in questionnaires, either because the answer set was not definitive enough or the researcher has made actual mistakes in translating the answers into a coded form (Groves et al 2009).

8.7.4 Coding in this study

All the responses from the returned questionnaires were examined and coded. The codes were developed to be as simple as possible according to the advice of Gillham (2007). A database was developed in Excel to manage the returned data. Part of piloting this questionnaire was to ensure that the questions/answers could be simply coded to allow statistical analysis of the answers. The coding system employed was a simple numeric coding of 0/1 for single choice questions, each option on multiple choice questions were given 0/1 for every available option to establish if the construct was present. There were no skip questions designed, and Likert-type scale questions were coded with individual numbers with a 0-5 scale. Any answers which included open-responses were coded in a qualitative manner.

No weighting of responses took place in this pilot study as it was clear from the qualitative study that what was important for one participant was not necessarily important for another. Therefore all responses were given equal weight.

Missing data was coded with MD so that it was obvious within the coding activity. Incorrect answers were coded with IC. Any N/A answers were coded with N/A. Using these codes distinguished them from the codes being used to code correct responses.

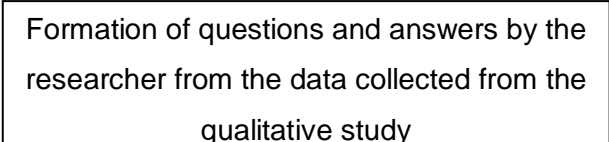
8.7.5 Statistical analysis

The statistical analysis of any questionnaire is driven by the demands of the research question (Groves et al 2009), this can be delivered in terms of descriptive and inferential statistical analysis of the collected data. Descriptive statistics being used to describe the results within the cohort and inferential statistics used to infer results to a further population (Crossman 2012). In this pilot study the researcher was looking to confirm the questions were usable and the responses would give answers which could be statistically coded. The developed questionnaire would be looking to confirm the presence of the perceptions and experiences of participants in the qualitative study. The researcher would use descriptive statistics to explore this, so the questionnaire must be able to give responses which could be coded for descriptive statistical analysis, in terms of numbers and percentages.

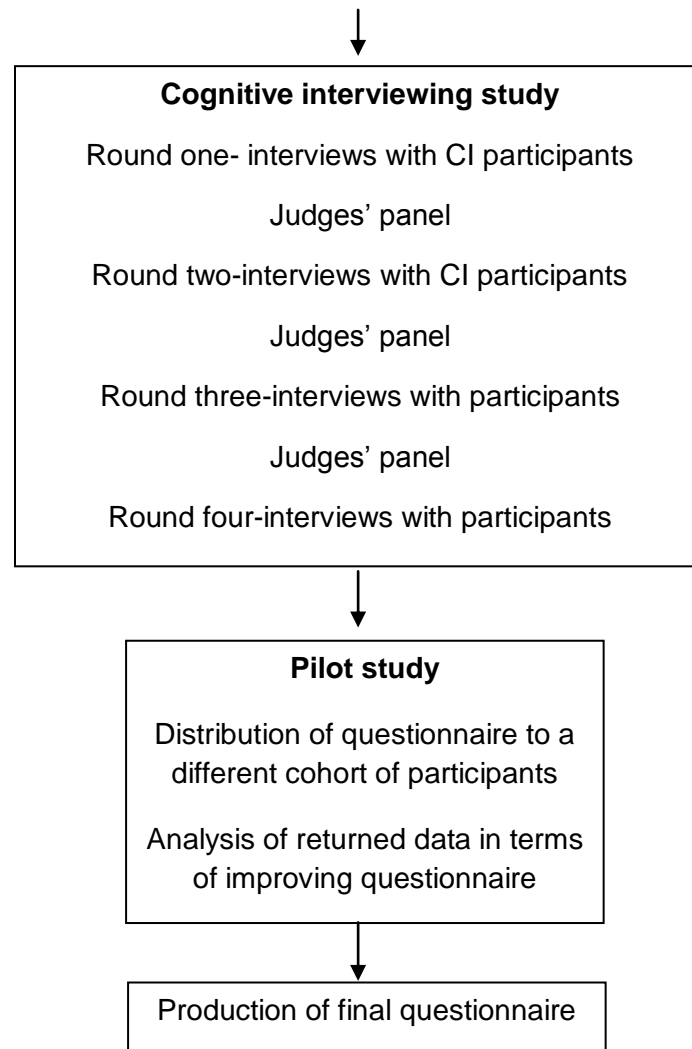
8.8. Summary

This chapter has described the academic background to pre-testing and developing a questionnaire. It describes the background to cognitive interviewing and piloting of a questionnaire. Figure 8 visually represents the two stages of questionnaire pre-testing employed in this study.

Figure 8: The development of the questionnaire in this research phase



Formation of questions and answers by the researcher from the data collected from the qualitative study



The following chapter describes the method by which the pre-testing of the questionnaire was conducted

Chapter 9: Phase 2 – developing the questionnaire

9.0. Introduction

This chapter describes the process used in developing a questionnaire based on the findings from the phase one study. The chapter is divided into three parts. The first part describes the use of cognitive interview techniques to pre-test the questionnaire and is called first stage pre-test. The second part goes on to describe the method and procedure used in the pilot study and is called second stage pre-test. The final part of this chapter draws on the results of both stages of pre-testing to describe the development of the questions for the final questionnaire.

9.1. Using two different approaches to developing the questionnaire

In the development of this questionnaire the constructs used to form the questions were based on the findings uncovered from the qualitative study. The initial stages of the questionnaire were developed by the researcher, the cognitive interviewing study was then employed to ensure the question and answer format was understandable to participants. The pilot study was employed to discover if the questionnaire was working to return useful information from different participants and change the questionnaire if it was found that it did not. Figure Eight was presented at the end of chapter Eight (8.8) and describes the stages of development used in producing the questionnaire.

9.2. First stage Pre-test – the Cognitive interviewing Study

9.2.1. Study design

This was a prospective cross-sectional research study using cognitive interviewing techniques to aid the development of a questionnaire.

9.2.2. Ethical and research governance considerations

Ethical approval was sought and granted through the Faculty of Health Science's internal ethics committee. Full permission was granted (FoHS-ETHICS-2010-02; appendix 14). Recruitment began after confirmation of insurance and university sponsorship was received (Appendix 19).

9.2.3. Access to Participants

Breathe Easy is a social support network for people with COPD in the UK. Members meet regularly once per month, in venues local to them. The researcher approached the chairmen of two local Breathe Easy groups (consecutively) and asked for permission to talk to the group at their next meeting. At that meeting the researcher presented the study to the group and asked if anyone with COPD and AO might be interested in taking part in the research. Anyone who expressed an interest was given an information pack to take home and read.

9.2.4. Inclusion criteria

All these criteria needed to be met:

Anyone with COPD as a diagnosis

Anyone with an ambulatory oxygen system at home

Anyone able to give informed consent

9.2.5. Exclusion criteria

Meeting any one of these criteria meant exemption from the study:

Anyone not having a diagnosis of COPD

Anyone who did not have a prescribed ambulatory oxygen system

Anyone unable to give informed consent

9.2.6. Recruitment

The researcher attended two successive sessions of the local Breathe Easy group to talk about the research project and distribute research study packs. This pack contained the patient information sheet (appendix 15) and invitation letter (appendix 16). Anyone who wished to be considered for the study was asked to contact the researcher directly by phone. The packs were given out in non-addressed envelopes so anyone not interested could just discard the invitation. People who attended the local Breathe Easy session or were local Breathe Easy members and wished to be involved in the study, were asked to reply to the invitation/study pack they received. The researcher's details were contained in the study pack and so volunteers telephoned the researcher if they were interested in taking part in this study. The packs were anonymous so the researcher only had access to those participants who replied to the invitation.

The majority of people attending Breathe Easy are people with COPD, and the greatest majority of portable oxygen user have COPD (from local service information) so the likelihood is that most portable oxygen users have COPD. Within the researcher's area the local Breathe Easy groups have emerged from the locally run pulmonary rehabilitation groups who also have a majority of COPD attendees. Therefore the person most likely to be recruited had COPD. The researcher was able to ask all volunteers when they contacted her for inclusion in the study if they had COPD or not.

9.2.7. Sample

This study recruited a convenience sample of five participants with COPD and prescribed AO from the local Breathe Easy group.

9.2.8. Sociodemographic data

The table below summarises the Sociodemographic details of the 5 participants who took part in the cognitive interviewing cycles.

Table 21: Sociodemographic data for CI study

Participant	1	2	3	4	5
Gender	Female	Male	Male	Male	Male
Type of AO	Liquid Oxygen	Cylinder Oxygen	Cylinder Oxygen	Cylinder Oxygen	Liquid Oxygen
Carer	Husband	Daughter	None	Wife	None
Transport	Car	Car/buggy	Car/buggy	Car/buggy	Car
Going out	X4 weekly	X3 weekly	X3 weekly	Everyday	Everyday
LTOT	Yes	Yes	Yes	Yes	Yes
Age Range	70-89	70-89	70-89	70-89	50-69

9.2.9. Initial development of the questionnaire

Following the analysis of the interviews from Phase One the researcher collated the experiences of the group which most seemed to affect how they used their AO. This represented those experiences that were reported by many of the participants so, in qualitative terms, were topics which were saturated more quickly. This was described in Chapter Seven at 7.9. The formation of questions in the questionnaire began with those reported experiences and trying to write a question which asked what the researcher wished to know from the respondent. The questions were developed (version 1) through discussions with academic and clinical peers and supervisors. Reviewing the literature on questionnaire design (as discussed in the Chapter Eight section 8.3 onwards) highlighted the importance of ensuring the questions were readable and unambiguous. Questions were altered through this initial development if one of the readers felt that the question or answer format was problematic in terms of the language used or comprehension. Table 22 describes the area of interest highlighted in the qualitative study and the questions devised by the researcher to form the constructs in the version 1 of the questionnaire (appendix 17).

Table 22: The areas of interest produced by the qualitative study and the questions devised

Reported experience or perception	Question devised by researcher
Remembered information around use of AO	<ul style="list-style-type: none"> • What information did you receive about using AO? • Who prescribed AO for you? • Were the controls/equipment explained to you? • Were you given any other information on usefulness of oxygen/addiction?
Weight of the equipment	<ul style="list-style-type: none"> • What do you think about the weight of the AO system? • Does the weight prevent you taking the equipment out?
How do you use AO	<ul style="list-style-type: none"> • How many times do you leave the house per week? • Do you take AO with you? • Do you use it when you are out?
Fear of running out	<ul style="list-style-type: none"> • Are you worried your AO will run out when you are away from home? • Does that prevent you taking it out?
Embarrassment	<ul style="list-style-type: none"> • Are you embarrassed to be seen in public with AO? • Does that prevent you using AO outside?
Transport available	<ul style="list-style-type: none"> • Do you keep AO in the car/buggy? • Do you take it on public transport?
Carers	<ul style="list-style-type: none"> • Who carries the AO when you are out? • Who maintains/re-orders the equipment?
Advantages v Disadvantages	<ul style="list-style-type: none"> • Do you think your AO has more advantages? • Do you think your AO has more disadvantages? • Do you think your AO is helpful to you?

The researcher based the type of response used for each question on the findings from the qualitative study. Where there had been a difference in opinion between participants in the qualitative study the researcher used a Likert scale to capture as many responses as possible, where the response was a simple yes/no the researcher used a dichotomous yes/no response format (appendix 21). Version 1 of the questionnaire was discussed with peer groups, supervisors and other healthcare professionals working in COPD. Once the questionnaire was thought to be as complete as possible (version 6), it was then used with participants in the cognitive interviewing study (appendix 18).

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The researcher pre-prepared any specific probes or questions to be asked during the interview (appendix 19) as discussed in Chapter Eight.

9.3. Other considerations within this process

9.3.1. Consent

Initial consent was sought on an opt-in basis. The participants who received information packs and wished to be involved in the study contacted the researcher by phone. The researcher stressed that the research was purely voluntary and no detrimental effects would be incurred if the potential participant decided not to be involved. Written consent was obtained from the participant in their own home (see appendix 20) before the interview commenced. Again it was stressed that even if they signed the consent form they could withdraw from the study at any time, and that meant that the interview would stop and the researcher would leave.

9.3.2. Confidentiality

Once the participant had agreed to be involved in the study, the researcher noted their address and phone number and they were assigned a study number. The contact details were held separately from their study details, on a secure computer at the University of Southampton and were destroyed when they were no longer required. No

participant was referred to by name in the data analysis, judges' panel or during conversations with any other party.

9.3.3. Care of Participants

Every effort was made to ensure the care of the participants was properly considered. They were asked to telephone the researcher if they wished to opt-in to the research so they had time to consider the impact of participating in this research and discussing it with others. They were given the researcher's telephone number so if they wished to cancel or re-arrange an appointment or withdraw from the research they could do so promptly. Withdrawing meant that any interview would be stopped and the researcher would leave or not visit them. The researcher is an experienced respiratory practitioner and aware of the symptoms associated with COPD and so instructed participants to cancel or postpone appointments if they were unwell. They were assured that they were completely free to access any medication or oxygen they may need during the interview. It was not envisaged that the questionnaire would upset any of the participants, however if this did happen the researcher would stay with them until they felt better or a carer arrived. They were repeatedly assured that their opinions were paramount in formulating the questionnaire and so whatever their views they were very useful, even if they felt they were being negative.

Recruitment began June 2010 and finished when the 5 participants had been recruited. This CI study began in June 2010 and ended in January 2011.

9.4. Preparation for the 1st round interviews

Each participant was interviewed at home at a time convenient to them. They were asked to say whatever they liked during the interview even if they thought it might be perceived as negative, as their views were essential in ensuring the questionnaire was as useful as possible. They were asked to imagine that the questionnaire had come through the post to them and what they would do and think about the questions and answers in that situation. Three of the participants had their carers with them and they wished their carers to be involved. The carers' contributions were noted by the

researcher. The participant agreed to the interview being taped recorded and that was set up and tested.

9.4.1. The 1st round Interviews

The participants were given version 6 of the questionnaire and asked to read the questionnaire aloud as they went through it. It was explained to them that this was part of helping the researcher to understand which questions and answers had been badly written or were not clear. They were instructed to read through the questionnaire aloud including the introduction and all the instructions as well as the question and answer format. They were told the researcher may have specific questions to ask them, but that they should ask for any clarification which they felt was needed throughout the reading task. As the participant read through the questionnaire the researcher took notes documenting:

- The number of times they repeated an instruction/question/answer,
- Whether they asked for clarification of the instruction/question/answer
- Any suggestions made about the format of the questionnaire
- Any suggestions about the questions/answers themselves
- The contribution of the carers
- Any skipped questions and answers
- Any incidences of not knowing the answer
- Any incidences of reading the question but not answering
- The general demeanour of the participant-if they were engaged or not in answering the questionnaire and if that interest waned as they continued

The researcher also asked specific probes, for example; 'what do you think that question is asking?' or 'do you think the meaning of that question is clear?', if she needed further clarification of how the participant understood the question or used the

response format. The participant was encouraged to suggest changes to the questionnaire, for example if the participant repeated the available answers several times as if they were searching for a more appropriate answer but were unable to find it, they were encouraged to suggest a response which they thought would be more appropriate.

9.4.2. Coding of the interviews

The tape recording of the interview was transcribed and compared with the researcher's written notes for every part of the questionnaire as it was read aloud. Some of the interviews could be coded during the interview itself for example, how many times the participant repeated the question or answer or specific questions of clarification. Additionally the researcher specifically recorded the participant's approach to the questionnaire. Did the participant include the carer to answer the questions and select answers all the time or just if they could not find an answer response they felt adequately answered the question? The researcher also recorded if the participant was engaged with the questionnaire or if they appeared to lose interest as they continued through the questionnaire and if that made any difference to how they read and answered the questions. Any suggestions on improving the questionnaire were also recorded.

The results of each 1st round interview were individually collated onto an Excel sheet and a Word document. The Excel sheet was used to give an overall pattern of the questions which had caused the most problems (appendix 21) and the Word document (appendix 22) was used to document the response of each participant to specific probes used by the researcher during the interview, for example: Were the instructions clear? Did the participant understand the question/answer? Additional information was recorded if the participant made any comment about the formatting of the whole questionnaire for example: Did the questions flow? Were they in the right order? Was the page layout clear? Table 23 describes an example of the coding and recording, in Excel and Word, for the same question from one participant.

Table 23: The Excel/ Word coding sheet (1a,b,c, and 3a,b from questionnaire version 6) used with **one** participant.

Q1=repeated question, Q2=Asked for clarification, Q3=no problem with question

R1=repeated responses, R2=asked for clarification of responses, R3=correctly completed, R4=incorrectly completed, R5=did not have the knowledge to answer the question

Question 1a: Do you have liquid oxygen? 1b: do have cylinder oxygen? 1c: if you have cylinder oxygen how much does it weigh? Question 2: Can you write down the capacity of the cylinder from the bottle? Question 3: How long have you had portable oxygen? 3b: Do you use a conserver?

Question	Question				Response				
	Q1	Q2	Q3		R1	R2	R3	R4	R5
1a	√	√			√				√
1b	√	√							√
1c	√	√							√
3			√		√		√		
3b		√							√

Table to show an example of the worded results from the notes taken by the researcher through the **same** cognitive interview with the **same** participant over the **same** two questions (NB no question 2 on version 6 of the questionnaire).

<p>Pt 2 -Question 1</p> <p>Thought parts a,b,c confusing and asked for clarification Unsure if has a cylinder or liquid oxygen –never been told so <i>cannot answer question</i> Does not know where to find the weight of the cylinder and said would not look if asked, -tried with carer to find weight on cylinder but unable to do so- <i>cannot answer part b and c of the question</i></p>	<p>Pt 2- Question 3</p> <p>No problem with how long has had cylinder answered immediately Does not know what a conserver is so could <i>not answer question</i></p>
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Additionally the researcher wrote notes on every interview to include the approach of the participant, the effect and influence of the carer, if present, and whether the participant remained engaged with the questionnaire throughout the whole process.

The collated results from all the participants in the Round 1 interviews were collated in terms of a Word document that could be discussed at the Judges' panel. Each question was described individually and the response of the each participant recorded. Table 24 below describes an example of the collated responses of each participant to each question.

Table 24: An example of the collated responses of participants to the question 1 in questionnaire version 6; used in the Round 1 interviews

Question	Perceived problem from participants 1-5	Description
Introduction	1-no problem 2- no problem 3-no problem 4-no problem 5- identifies words perceived as 'bad English'	All participants read through introduction only one comment about use of English. All said they understood
1a "What kind of oxygen do you take with you outside the house"?	1- no problem 2-unable to give answer- does not know 3- unable to give answer- does not know 4-unable to give answer- does not know 5-no problem	3 participants unable to recognise type of oxygen system they have. 2 of the 3 thought they were on liquid oxygen despite having cylinders-just never been told. Liquid oxygen users had been told they were on liquid oxygen so they had no problem identifying system
1b "If you have a cylinder oxygen how much does the cylinder weigh"?	1-asks for clarification of question, Unable to answer question as does not know 2-asks for clarification of question Unable to answer-does not know 3-asks for clarification of question Unable to answer as does not know 4-asks for clarification of question Unable to answer as does not know 5-did not know the answer	None of the participants could answer the questions-they just did not know. Two of the participants tried to look for the weight but it meant lifting the cylinder up and that was hard and then they could not find the right number because of all the other identification markers on the cylinder.

9.4.3. The 1st Judge's Panel

The judge's panel consisted of the researcher and two supervisors. They were arranged as quickly as possible after each round of 5 interviews had taken place and had been collated. The judges considered all the responses recorded to every question and answer format and each response was discussed individually. They also discussed the researcher's impressions of how the participants had managed the questionnaire. Any potential change to the questions or answers or instructions was considered if more than one participant identified a problem understanding the question words or the answer words or the instructions words:

- If the question format had been identified as difficult to understand
- If the question had resulted in an incorrect response
- If the instructions or question words had resulted in the answer being skipped
- If the answer response was reported as difficult to understand
- if the participant did not know where to put the answer response
- If the participant had added an additionally answer
- If the format of the questionnaire itself had been problematic
- If the participant had suggested changes
- If the researcher thought that any question or question layout was problematic

Changes were more likely to be made if more than one participant had found a question/answer difficult. Table 25 below gives an example of how the information about questions/responses was dealt with during the Judges' panel and what, if any, decision was made to change the question/answer format.

Table 25: The decisions made at the Judges' panel with the introduction and question 1a and 1b of version 6.

Question	Perceived problem from participants 1-5	Decision at judge's panel	Change implemented
Introduction	1-no problem 2- no problem 3-no problem 4-no problem 5- identifies words perceived as 'bad English'	Change one word	Word changed from 'little knowledge' to 'little known'
1a	1- no problem 2-unable to give answer- does not know 3- unable to give answer- does not know 4-unable to give answer- does not know 5-no problem	Add pictures to aid identification of oxygen	Change format of question to include pictures add 'do not know response'
1b	1-asks for clarification of question, Unable to answer question as does not know 2-asks for clarification of question Unable to answer-does not know 3-asks for clarification of question Unable to answer as does not know 4-asks for clarification of question Unable to answer as does not know 5-did not know the answer	Remove question	Question removed

All the question/answer formats, and the questionnaire generally were discussed with the panel and the researcher altered the questionnaire to reflect the decisions made by the panel. The researcher then returned to the participants for a further round of interviews with questionnaire version 7.

9.4.4. 2nd round of interviews

The researcher returned to the participant with the new questionnaire (version 7; appendix 23). Care was taken to explain the whole process to each participant to ensure that they would not be upset if their suggestions had not been included in the new questionnaire. In fact this did not happen. The participant read through the questionnaire as before and the researcher recorded their responses in a written format as before, however the second interviews were not recorded by tape. Tape recording had proven to be of no benefit on the first round interviews as although the participants read the whole questionnaire allowed they did not read the number of the questions, so the researcher had to interrupt them and this disrupted the interview. The same carers were present as during 1st round of interviews. The responses of the participants were recorded.

9.4.5. Coding in subsequent rounds of interviews

Coding for the second and subsequent rounds of interviews changed. The researcher found that the Excel sheet of coded responses became unusable once either the order of the questions or the question wording were changed on the questionnaire. So the Excel method of coding was dropped in favour of Word recording for each question at each interview. As the rounds of interviews progressed it emerged that participants had problems answering questions which had Likert-scale responses. The reason for this is unclear but may reflect the changeable nature of the condition or patient's educational status. The researcher changed the responses to yes/no dichotomised responses where the scales were problematic and this improved the response. This is discussed further below.

9.4.6. 2nd Judges' panel

The Judges' panel met again after the 2nd round of interviews had taken place and the results had been collated. The panel followed the same format as before but particular attention was paid to any questions, answers or instructions that had been highlighted

in the first round as a possible problem was still found to be a problem in the 2nd round. For example, some of the questions which had a Likert scale answer response caused problems to three of the five participants in the 1st round of interviews. The researcher changed these responses to dichotomous yes/no answers which improved completion of the questionnaire. In the 2nd round, despite changing the wording of the question, two of the five participants still reported having difficulties with the question so the wording was preserved but the formatting of the question was altered to see if that resolved the participant difficulties. One participant had no problems completing the questionnaire.

9.4.7. Further rounds of interviews and Judges' panels

As the rounds of interviews and panels continued it was possible to build up a profile for each question and clearly identify problem questions and whether any changes to the question suggested by the judges had resolved those problems. Table 26 below demonstrates how the question/answer profile could be produced for each question/response format.

Table 26: to demonstrate how problem questions/answers profiles were built up during the study
Question 1 (version 6 and subsequent versions) asked ‘What kind of portable oxygen do you take with you when you leave the house?’

Response to Question 1	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
Round 1 (version 6)	No problem	Could not answer does not know	Could not answer does not know	Could not answer does not know	No problem
Round 2 Addition of two pictures 2 parts of question removed (version 7)	No problem	Answered correctly	Could not answer- Does not know, did not recognise picture	Could not answer- does not know, did not recognise picture	No problem
Round 3 Addition of more pictures and increase in instructions plus pictures on front page (version 8)	No problem	Answered correctly	Answered correctly- Thought pictures were hard to see	Answered incorrectly	No problem
Round 4 Bigger pictures included (version 9)	No problem	Answered correctly	Answered correctly	Answered correctly	No problem

The rounds of interviews and judges' panel continued until the participants reported less or no problems with the questionnaire. This consisted of 4 rounds of participant interviews and 3 meetings of the judges' panel. The last round of interviews after the last judges' panel was to confirm with the participants that no further changes were needed in the questionnaire (version 9; appendix 24). Once the questionnaire was thought by the panel to be as near 'no-alterations' as possible the cognitive interviewing stage was deemed to have finished.

9.4.8. Summary of the results for the CI stage

- Version 6 of the questionnaire was used to start the CI stage
- 5 participants were interviewed in rounds
- Between each round any changes in the questionnaire were reviewed by a judges' panel
- There were four rounds of participant interviews and three judges' panels
- The rounds of interview continued until the questionnaire was deemed as correct as possible, that is no further changes were deemed necessary by participants

This final version of the questionnaire (version 9) (appendix 24) was used in the pilot research stage described below.

9.5. Second stage pre-test – Pilot Study

The version 9 (appendix 24) of the questionnaire from the CI stage was used in the next stage of pre-testing in a pilot study with a different set of participants. The reasons for performing a second pilot study are discussed in Chapter Eight.

9.5.1. Study Design

This was a prospective cross-sectional pilot questionnaire study.

9.5.2. Ethical and research governance considerations

Ethical approval was sought and granted through the Faculty of Health Science's internal ethics committee. Full permission was granted on June 1st 2011 (FoHS-ETHICS-2011-044) (appendix 25). Recruitment began after confirmation of insurance and sponsorship was received (appendix 26).

9.5.3. Access to participants

The researcher approached the two Breathe Easy (BE) groups in her local area, to recruit different participants. The researcher explained this research study at a meeting of BE and individually to the chairman of both groups and asked them to give/send stamped sealed un-addressed envelopes to members who had ambulatory oxygen, but had not been present at the meeting. Each envelope contained the questionnaire, an invitation letter (appendix 27) a patient information letter (appendix 28) and stamped addressed envelope for returning the questionnaire to the researcher. The invitation letter invited the participant to write any comments they thought helpful on the questionnaire before returning it to the researcher. This was done to enable the researcher to collect any further useful comments from a different cohort of participants. The five people who had volunteered for the CI study were asked not to complete the questionnaire if it was sent to them. One was given the questionnaire to repeat, to allow the researcher some insight into the reliability of the questionnaire. These results were not included in the results presented here.

9.5.4. Sample

This study recruited a convenience sample of 13 participants from the local Breathe Easy groups.

9.5.5. Recruitment

Recruitment began in June 2011 and ended in August 2011. The study received thirteen completed questionnaires. No further questionnaires were received during the study period.

9.5.6. Response rate

Twenty questionnaire packages were given out during meetings and to the Breathe Easy chairperson to distribute to members with AO. Thirteen completed questionnaires were returned to the researcher. This represents a return rate of 65%. The questionnaire was given to the Breathe Easy chairperson to hand out or send on to absent members. The researcher is unaware of how successfully this process was completed.

9.5.7. Results

The returned questionnaires were coded by the researcher as they were received from the participant. Data was collated onto an Excel spreadsheet (appendix 29). Once the data had been encoded onto the database it was checked against the returned questionnaire to ensure accuracy. As discussed in Chapter Eight, MD was used to code missing data, IC was used for incorrect data and N/A was used for coding where participants had responded with not applicable. In addition to those codes any comments by pilot participants were also noted down during the coding process. Additional comments may suggest that the response format is not sufficient so could affect the ability of the questionnaire to collect data. Table 27 below summarises the sociodemographic data returned from the pilot questionnaire.

Table 27: Summary of the sociodemographic data from Stage two pilot study

Sociodemographic marker	Number of participants (n=13)
Age Group 50-69	7 (54%)
Age Group 70-89	6 (46%)
Living with a partner or carer	10 (76%)
Living alone	3 (23%)

Table 28: Summary of oxygen usage by participants

Using cylinder oxygen	8 (62%)
Using Liquid Oxygen	5 (38%)
Using oxygen for 2 + years	4 (31%)
Using oxygen for 1-2 years	3 (23%)
Using oxygen for 12-6 months	3 (23%)
Using oxygen for 6 months	3 (23%)
AO prescribed by Respiratory Centre	5 (38%)
AO prescribed on hospital discharge	3 (23%)
AO prescribed by GP	4 (31%)
AO prescribed by Other	1 (physiotherapist) (8%)

The results of this Stage Two pilot study are presented in terms of questions that appeared to fulfil the needs of the researcher in answering the research question, and those that were not answered correctly (missing data, added responses).

9.5.7.1 Correctly completed

Questions that recorded a range of answers, or were deemed to be congruent with either the qualitative results or CI study results were thought to be completed adequately. For example; (the question numbers are marked as on the pilot questionnaire)

Table 29: To show how many participants had AO explained to them

5: Did anyone explain to you WHY you needed Portable Oxygen	No. of Participants
Yes	5 (38%)
No	8 (62%)

This question recorded a range of responses which generally agreed with the findings in the qualitative and CI studies, in fact relatively more people said they had been told why they needed AO. The participants who answered 'NO' were predominantly those discharged from hospital with AO or who had received AO from their GP. For healthcare professionals (HCP's) identifying who did not receive instruction or information could enable specific targeting of those medical services to improve the information delivered to the patient on prescription of AO. It would also highlight the need to ensure information had been delivered to that patient.

The follow-on question was designed to find out what the participant had been told and this also recorded a range of answers, suggesting the response set was adequate to capture all the responses necessary. No additional options were supplied by the pilot participants. It would be useful for HCP's to be able to identify specific instructions as this may directly affect use of the AO system.

Table 30: To show how many participants had received AO instructions

6: What instructions did you get for using Portable Oxygen?	No. of participants
I was told to use it when I went out	4 (30%)
I was told it would help me when I was out	1 (8%)
I was told to use it when walking outside	1 (8%)
I was told to use it when exercising (pulmonary rehabilitation)	4 (30%)
I was told to use it whenever I was breathless at home	3 (23%)

The question was answered by all participants and records a range of answers which gives a useful insight for clinicians. For example only one participant was specifically

told to use AO whilst walking. At least eight (62%) of the 13 participants were not specifically instructed to use AO when exercising outside the home in the community. The participants using AO for pulmonary rehabilitation recorded that option only and nothing else, so they may only be using it for pulmonary rehab. This would suggest that 12 (92%) participants had not been instructed to use AO specifically when walking outside the house. This appears to support the findings from the qualitative study that specific instructions in using AO when walking may not be supplied to users. Here again this highlights the need for more specific AO user information.

Table 31: Who showed the participants how to use the AO controls

7. Who showed you how to use the controls on your Portable Oxygen?	Participant
The respiratory centre showed me	0
The hospital staff showed me	0
The oxygen delivery person showed me	12 (92%)
The oxygen delivery person showed my family/carer and they showed me	1 (8%)
No one showed me	0
Other, please state who	0

This result is entirely consistent with the qualitative study findings that the delivery man is the person who is showing the participant how to use the AO equipment. This is a requirement of the oxygen supplier so is not a surprising finding in itself. All 13 participants (100%) reported they understood the instructions given to them (Question 8). But four (30%) of the participants said they did not feel confident to use AO when they first received it (Question 9). This highlights an area where HCP's may be able to improve the use of AO, by ensuring patients felt confident with AO when starting to use it. Additionally whether the information given by the delivery man is sufficient and correct may be crucial to using AO effectively. The next question gave some insight into the need for more information.

Table 32: To show if participants would like more information on AO

10a. Do you think that more information would be useful to you?	7 (54%) replied YES
10b. Do you think more information would be useful to your family?	8 (62%) replied YES

The participants who did not want more information were the ones who had been using AO for the longest time, which suggests that they had formulated individual methods of coping with their condition and AO, so may not feel further information would be necessary. The need for further information on AO is an area where HCP's can and should intervene to ensure the patient had enough information to feel confident to use AO. The need to involve carers in this education is also highlighted, so the family can devise coping strategies together to use AO effectively.

Table 33: To show how participants said they would like to receive any extra information

11. If you were to receive some more information on using Portable Oxygen how would you like to receive it?	Participants
Written information	6 (46%)
Face to face at home	5 (38%)
Face to face in the respiratory clinic	2 (15%)

The findings suggest participants wanted to have either some kind of written material to keep as instructions on AO use. The third option has been removed in the final questionnaire as some areas have respiratory clinics which no longer perform AO assessments.

Participants were asked how much they used AO at home. Using AO at home is not part of the AO prescription process and may be an important indicator for HCP's working with patients; patients may not have the correct instructions about AO usage, or they may be clinically deteriorating and needs further medical intervention. Or they may have been instructed to use AO whenever they feel breathless which would include breathlessness due to household activities.

Table 34: To show how many participants used AO inside the house

12. Do you ever use your Portable Oxygen system inside the house?	Participants
Always	1 (8%)
Sometimes	2 (15%)
Never	5 (38%)
Only if I'm unwell	5 (38%)

Question 15 was designed to ask how often participants went out:

Table 35: To show how often participants went further afield

15. How often do you go further afield for example to the supermarket?	Participants
Everyday	4 (30%)
4-6 times per week	3 (23%)
2-3 times per week	1 (8%)
Once a week	4 (30%)
Once a month	1 (8%)
I do not go out of the house	0

Again this question shows range of answers, which would be expected. No participant recorded not going out of the house, which is consistent with having AO prescribed only for patients who are leaving the house.

Table 36: To show how participants used their AO out of the house

17. When you go out..... <i>Please tick all the boxes that apply</i>	Participants
I keep my Portable Oxygen in the car in case I need it	6 (46%)
I use my Portable Oxygen in the car AND in public	2 (15%)
I use my buggy when I am out so do not need to use my portable oxygen	1 (8%)
I keep my portable oxygen on my buggy in case I need it	3 (23%)
I keep my portable oxygen on my buggy AND use it when I go out	1 (8%)
There is no room on my buggy for my portable oxygen	0
I cannot use my portable oxygen out as I use public transport/Taxi	0
I use public transport AND take my portable oxygen with me	1 (8%)
I don't use my portable oxygen	3 (23%)

This question provides an insight into how participants use their AO when out. Only three participants (23%) reported using their AO out in the community. Three (23%) reported not using AO outside at all. Again this would help healthcare professionals identify patients who keep their AO in the car as a safety measure, but do not use it whilst out. It would enable HCP's to identify patients who may need more help with transporting AO so they can use it in the community. The next question asked about how the participants manage their AO when out of the house, and how much help they might need to use it.

Table 37: To show how participants carry their AO

Who carries the PORTABLE OXYGEN when you are out of the house? (not in the car/on the buggy)	Participants
I always carry my own portable oxygen	7 (54%)
I can carry it but I need help to put the bag on my shoulders	0
I can carry it but someone else has to use the controls	1 (8%)
My wife/husband/carers carries the portable oxygen	3 (23%)
I use a trolley to carry my portable oxygen	0
I put the portable oxygen system on my buggy/wheelchair	1 (8%)
I don't take my portable oxygen out in the car	1 (8%)
I don't use my portable oxygen	2 (15%)

Again the responses show the range of different ways participants have adopted to take their AO out of the house. Finding that the majority of participants carried their own AO differs from the qualitative study, but may not be surprising. This cohort of participants was out and attending a local support group, so may be expected to be more physically able than some of the participants in the qualitative study.

The next question asked in what was AO carried?

Table 38: To show what participants carried their AO in

19. What do you carry your PORTABLE OXYGEN in?	Participants
Shoulder bag (supplied by the oxygen company)	10 (77%)
Back Pack (supplied by the oxygen company)	3 (23%)
Waist Bag (supplied by the company)	0
Your own bag	0
Trolley	0
Electronic buggy	2 (15%)

The shoulder bag is the bag most commonly supplied by the oxygen providers and this is reflected in the results. This question was altered slightly; the choices which were not used i.e. 'your own bag' and 'trolley' were removed, in an attempt to shorten the

questionnaire. 'Electronic buggy' was also removed as this may be confusing to participants, and a 'something else' option was added for participants to complete.

Questions 22 and 26 asked about how the participants found the controls on their AO system.

Table 39: To show who checks the controls on their AO

22. Do you always check the on/off control yourself or does someone else check it for you?	Participants
I always check my own	8 (62%)
Someone else always checks the controls for me	2 (15%)
Sometimes I check the controls, sometimes someone else checks it	3 (23%)
26. Who checks the oxygen levels in your PORTABLE OXYGEN	
I always check the oxygen levels myself	7 (54%)
Someone else checks the oxygen levels	5 (38%)
Sometimes I check the levels and sometimes someone else checks them for me	1 (8%)

These responses support the range of answers found in the qualitative study, and demonstrates the importance of carers in allowing and helping participants to manage their AO systems. The results may also suggest that participants do not have enough information to enable them to manage their own equipment, or as found in the qualitative study, that looking after the equipment was a task often managed by carers as part of a family coping strategy. In a series of questions about their AO, participants were asked to respond to;

‘I think my portable oxygen weighs too much’

Table 40: To show what participants think about the weight of their AO

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
4 (30%)	7 (54%)	1 (8%)	1 (8%)	0

Since this was strongly found in the qualitative and CI studies the question was re-asked later in the questionnaire with a slightly different phrasing;

‘I think the weight of my portable oxygen is OK’

Table 41: To show what participants think about the weight of their AO

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
0	3 (23%)	1(8%)	8(62%)	1 (8%)

Here it seems that participants did feel their AO systems weighed too much, irrespective of the way the question was posed. Both responses suggest participants had concerns about the weight of their oxygen equipment.

Additionally in the pilot questionnaire the participants were asked

Table 42: To show what participants reported about their AO

Question	Participants responding 'YES'
21. Does the weight of the PORTABLE OXYGEN stop YOU taking it out of the house	7 (54%)
22. Do you ever worry that the PORTABLE OXYGEN may run out whilst you are using it outside the house?	3 (23%)
23. Do you trust the full/empty gauge accurately tells you how much oxygen you have in the cylinder?	10 (77%)

These questions were all correctly completed. As recorded above, seven of the participants found the AO system too heavy to carry out of the house unaided. This concurs with the findings from the qualitative study. Three participants said they did worry about their oxygen running out whilst away from home, and this is reflected in question 23, where the same three participants said they did not trust the full/empty gauge on the cylinder. As found in the qualitative study, running out of oxygen was not a problem unless actually experienced by the participant.

Question 27 asked participants how helpful they felt AO was to them

27. I think my portable oxygen is helpful to me

Table 43: To show how participants responded to question 27

Always helpful	Sometimes helpful	Occasionally helpful	Rarely helpful	Never helpful
4(15%)	3(11%)	3(11%)	3(11%)	0

Interestingly even though three participants said that they did not use AO when they went out, no participant recorded that AO was unhelpful. This may suggest that even though they did not use AO, it was helpful to know it was available if needed.

Participants were asked if they could identify what it was about their portable oxygen system, which they found helpful. These results are recorded below.

Table 44: To show how respondents felt about their AO

28. How do you feel about your PORTABLE OXYGEN System? Please tick all the appropriate answers	Participants
I feel more confident to go out of the house	5 (38%)
I feel I have more freedom to go out	3 (23%)
I feel safer when I'm outside the house	3 (23%)
Portable oxygen relieves my breathlessness when I'm out	1 (8%)
My carer feels more confident if we have portable oxygen with us	2 (15%)
Portable oxygen does not relieve my breathlessness when I use it	0
The system is too heavy to carry	4 (30%)
The system is too embarrassing to use in public	2 (15%)
I do not feel I need portable oxygen	3 (23%)

Although these responses are similar to those found in the qualitative study, no participant recorded that AO did not help relieve their breathlessness when out of the house. This contradicts the findings from the qualitative Phase One study, so there is a discrepancy here. The researcher believes this may be due to the position of the question in a larger question/response set. The researcher has taken this response out of the list and placed it as a separate question. Three participants recorded they did not use their AO, this may be due to lack of benefit but the participant may have thought that since they do not use it they did not have to mark both responses.

Within the qualitative study, some participants found some participants were worried about becoming dependant on oxygen. The same question was asked in this questionnaire, with the results as below:

Table 45: To show how participants responded to questions 29 and 30

29. Do you worry that if you start using PORTABLE OXYGEN more you may become more dependent on it?	10 (77%)
30. Do you worry that PORTABLE OXYGEN may have side-effects which may be harmful to you?	2 (15%)

This indicated that a high proportion of participants were concerned about becoming dependant on oxygen if they used it more. This suggests a distinct lack of comprehensive information for participants, on the use of oxygen as a drug in COPD. It may also suggest that participants are afraid that using more oxygen may be a sign of deterioration. HCP's need to assess if their patients have a fear of addiction to AO, and provide the information and encouragement to ensure patients use their AO effectively. They also need to provide an honest view of the progress of COPD and how patients could be helped to live as full a life as possible with this condition.

9.5.7.2. Question/responses with missing data

There were 21 missing responses across the whole of the pilot questionnaire and four participants were responsible for 18 of those i.e. 85% of the missing data. Some of the missing responses may be due to participants not completing responses which they felt did not apply to them i.e. skipping the response set. One participant returned the pilot questionnaire with an additional 'Don't know' for question two, and that was added to the final version of the questionnaire. The questions which produced the missing data are reproduced below, together with an explanation of how they have been changed to try and correct any errors and improve the response rate.

Question 13 had five missing responses:

Table 46: To show how participants said they went outside

13. How often do you go outside the house into the garden, shed, courtyard or the front gate? So not off the property	Participants
Everyday	5 (18%)
4-6 times per week	1 (0.3%)
2-3 times per week	0
Once per week	1 (0.3%)
Less than once per week	0
Less than once per month	0
Never	1 (0.3%)

The question was originally inserted following discussions in the CI study where two participants felt there was a difference between taking oxygen into the garden and further afield to the supermarket. Participants who did not answer this question may not have a garden and so considered it a skip question. The researcher reduced the number of response options, to shorten the length of the questionnaire and added 'I don't have a garden' as an option in the final questionnaire.

The subsequent question was a follow-up to question 13, recorded three pieces of missing data. Two of the missing data responses came from the two participants who had recorded 'never', in question 13, and therefore could not answer question 14.

Table 47: To show if participants took their AO with them outside

14. When you go outside in the garden, shed, courtyard, or front gate, do you take your PORTABLE OXYGEN with you?	Participant
Always	0
Sometimes	0
Never	8 (62%)
Only if I'm unwell	2 (15%)

The responses suggest that this question adds little to the knowledge required answering the research question and so the researcher removed it from the final version of the questionnaire.

The next question that produced missing data may also have been viewed as a skip question by some participants. The question asked if participants felt their AO had more disadvantages than advantages?

Question 31: **Do you feel that on balance your PORTABLE OXYGEN system has more advantages or disadvantages**

Table 48: To show how many participants thought AO had advantages

31.I feel that portable oxygen has more advantages	Participants
Yes	7(54%)
No	4 (30%)
Don't Know	2 (15%)

This part of the question was answered correctly but the following part (question **32**) had four pieces of missing data;

Table 49: To show how many participants thought AO had disadvantages

32.I feel my portable oxygen has more disadvantages	Participants
Yes	2 (15%)
No	4 (30%)
Don't Know	3 (23%)

Both parts of the question immediately followed one another may have been confusing to the pilot participants. Participants who felt AO had only advantages may have skipped the question asking about disadvantages. The researcher re-worded the questions to give examples, and moved the two questions apart so they would be less confusing.

The last group of questions which produced missing data were the group of questions around being embarrassed by using AO in public.

Table 50: To show how participants felt about using AO in public

34. How do you feel about being seen in public with a portable oxygen system?	Yes	No	Sometimes
I am so embarrassed about being seen in public with Portable oxygen that <u>I do not use it in public</u>	4 (30%)		
I am embarrassed about being seen in public with Portable oxygen <u>but I still use it in public</u>	5 (38%)		
I am not embarrassed about being seen in public with Portable Oxygen	0		

There were four pieces of missing data from this response set. This may be because these four participants do not feel embarrassed about being seen in public with AO and therefore did not feel this question applied to them, especially as the question about not being embarrassed is at the end of the response set. Alternatively the four participants may have felt this was too sensitive a question to answer. However nine participants (69%) did record a result. The subsequent question was a follow-up to this question and asked

Table 51: To show why participants said they would be embarrassed by AO

35. If you do feel embarrassed is it because	Yes	No	Sometimes
I am worried people would stare at me	8(62%)		
I do not want anyone to know I need oxygen	1(23%)		
I do not want anyone to know I have a lung condition	1(8%)		

There were three pieces of missing data from this question. Three of the four participants who did not respond to question 34 did not respond to question 35. This may again imply that they were not embarrassed by using AO in public and so saw this as a skip question which did not require a response. The researcher changed question 34 to ask a yes or no response to the question are you embarrassed by being seen in public with AO. Question 35 was retained, so participants could skip it if they did not feel embarrassed by using AO in public.

There were two sets of missing data from question 38, which asked;

38. Do you have oxygen for use only at home (LTOT)?

Please tick the appropriate answer

1. A concentrator
2. Cylinder oxygen for using for when I am breathlessness
3. No nothing

The question was formatted differently from the rest so may have confused the participants, and also was placed at the end of the questionnaire so the respondent may have been tired or bored by then. The question/response format was changed to follow that of the other questions in the questionnaire. The response set was changed to give one option with a yes/no response set to the question; have you got LTOT at home? A summary of the missing data and changes made by the researcher are detailed in table 28 below.

Table 52: Changes in the questionnaire as a result of the pilot study

As a result of the piloting study the researcher changed some parts of the questionnaire. For example she added a 'Don't Know' response to question 2. How the questionnaire was changed is tabulated below. The final questionnaire, version 10, is recorded in appendix 30.

Table to describe the changes made in questions because of the results of the pilot study

Question	Code and possible problem with question/answer format	Change made to questionnaire
2	Added additional response to answer format – so participant appears to find response set inadequate	Add 'don't know' response to question 2
13	<i>MD from 5 participants</i> - this question was included by the CI study participants; it may be that the pilot study participants do not view going out as two different activities, or question has too many choices	Reduce question to garden only, as going into the garden may be important to some participants, reduce responses and add 'don't have a garden'
14	<i>MD from 3 participants</i> . Probably linked to question 13 above, as same participants as above, did not respond to 13 or 14 despite the 'never' option included.	Remove from questionnaire
32	<i>MD from 4 participants</i> . This is the second question in a line about advantages/disadvantages of AO. Participants may feel they have already said advantages so no disadvantages i.e. skipped	Move question
34	<i>MD from 4 participants</i> . May be an emotive question/skipped question, question may have too many parts, which may be confusing	Change question to yes/no response
35	<i>MD from 3 participants</i> . Part of question 34. Again may be an emotive subject to some participants. May have been seen as a skip question if participants not embarrassed in question 34	Keep question, improve directions for answering
38	<i>MD from 2 participants</i> , may have been viewed as skip or missed because different format	Change response set to yes/no to LTOT only

9.5.7.3. Summary of using a pilot stage

The pilot study was used to test if the developed questionnaire could deliver the responses necessary to answer the research question developed for the quantitative phase of this thesis:

'Are the beliefs uncovered in the phase one qualitative study held by a different population of people with COPD who have been prescribed AO?'

The researcher acknowledges that this was a small pilot study, but it was conducted in a different cohort of participants which enabled some inferences to be drawn. It seems that the participants in the pilot study did recognise and respond to the perceptions uncovered in the qualitative GT study. The pilot revealed some errors in the questionnaire which had not been detected during the CI study and so proved to be a useful part of the questionnaire pre-testing. The questionnaire developed by these two processes is documented in appendix 30.

In developing the questionnaire the researcher used two separate pre-test stages; a cognitive interviewing stage, and a questionnaire pilot study stage. The researcher has considered the advantages and disadvantages of using two separate pre-test stages in the section below.

9.6. The advantages of both questionnaire testing approaches

Using cognitive interviewing to develop the questionnaire had advantages and disadvantages. These different aspects are discussed further below.

9.6.1. The advantages of using CI

For this researcher there were several definitive advantages of using CI in the development of this questionnaire. Using CI allowed the researcher to:

1. Appreciate areas that participants did not understand. Without using CI the researcher would not have been aware that participants did not know what kind of oxygen they were using. If this had remained undetected, then it would have fundamentally affected the questionnaire, since LOX or liquid oxygen is thought by prescribing healthcare professionals to be lighter and easier to carry.

2. Identify misunderstood questions. Asking participants directly if the question was understandable and what they thought it meant, enabled the researcher to identify problem questions. Re-visiting the participant within the cyclical structure of the CI process was useful in ensuring the changed wording of the question was understandable.

3. Identify misunderstanding responses. As above, identifying misunderstood or unclear responses enabled the researcher to change the response set and then check at subsequent visits that the response set was clear and appropriate.

4. Include responses or questions suggested by the participants. During the CI process the participants were encouraged to make suggestions to improve the question/response sets. Any of these were included in the questionnaire.

5. Identify sensitive questions. The researcher found she was unaware that any of the questions were sensitive. During the CI process it became clear that some of the questions were sensitive, and the researcher was able to remove or change these questions to make them acceptable.

6. Identify questions which the participants could not answer because of lack of information. Initially the researcher believed participants would know how long their cylinder would last and how heavy it may be. In fact this proved to be untrue, and these questions had to be removed as participants did not have the knowledge to answer the questions.

7. Identify the use of carers to answers. Because the researcher was present in the participant's home when they answered the questions she was able to view how the participants approached and completed the questionnaire. She was able to see how three of the participants were dependant on their carers/family to help them answer the questionnaire. These three participants discussed most questions with their carers and in one case the carer was the person who filled in the questionnaire. This happened with every version of the questionnaire. The use of carers reflects how embedded the care of the condition is within a supportive family and was found in the qualitative study. The researcher decided to include, in the questionnaire instructions, an invitation to the respondent to complete the questionnaire with a carer if desired.

8. Identify the effect of education on the wording in the questionnaire. The questionnaire was written by a middle class healthcare professional. Two of the participants were professionals and three were not. How participants viewed the question/answer formats was completely different. Participant with higher literacy levels could successfully negotiate skip questions whereas others could not and this resulted in questions with large response sets. The importance of catering for lower literacy levels cannot be overestimated, as the questionnaire has to be completed by anyone, irrespective of educational background. Using CI enabled the researcher to change the words in the questionnaire to more understandable phrases. The addition of pictures also helped in this respect, by allowing identification of equipment visually.

9. Identify that the original questionnaire was too long. Participants complained that the questionnaire was too long, particularly if they had had problems with the wording of the question/answer formats. The problem with length was not found in participants who had no problem answering the questionnaire as they were able to complete it more quickly. The researcher was able to cut down the number of questions during the CI process. In the last version no participant complained of length, but that may be because they were used to completing the questionnaire.

10. Use a judges' panel to help examine the question/answer format. This allowed the researcher to use expert opinion in designing the questionnaire. Expert opinion is

another recognised way of exploring the question/answer formats in a questionnaire. Including the panel as part of the CI process was a valuable addition in assessing the participant's response to the questionnaire.

11. Increase the validity of questionnaire by addressing the face validity of the questionnaire. This was done by ensuring that the question/answer format was understandable and completable during the rounds of CI. The researcher was able to improve the face validity of the questionnaire by changing question or response sets which were unclear to the participants. This increases the probability that the questionnaire can be correctly completed and returned with the information required by the researcher.

12. Gain an insight into the reliability of the questionnaire. As discussed in chapter 7, the reliability of a questionnaire can be gauged as Groves et al (2009) suggested, by asking participants to complete the same questionnaire again and assessing their responses. Within the last round of CI the questionnaire participants were completing a questionnaire, version 9, which was almost the same as the previous questionnaire, version 8. This allowed insight into the reliability of the questionnaire. This is discussed further below.

13. The use of Likert-scales to answer questions emerged as problematic for some participants. The researcher changed these answers to dichotomised yes/no answers. Using CI allowed the researcher to uncover this problem, but changing to yes/no answers may have reduced the depth of response and analysis possible with the questionnaire.

9.6.2. The disadvantages of using CI

Using CI also had disadvantages for the researcher and assessing the questionnaire.

1. CI was a complicated process and involved collecting and collating a large amount of information. The researcher began recording interviews with an Excel sheet of

scores, using the method suggested by the literature (as documented above). This proved un-useable when the questions were changed and so the researcher used word descriptions of the interviews to record results. This was much more satisfactory as it allowed the researcher to describe the problems rather than using abstract codes to categorise the interview results. However it may also be the researcher's lack of experience with CI which made using codes difficult.

2. Visiting participants on a regular basis was time consuming, and the participants themselves, although very helpful, also found the process quite demanding. This was particularly true for the two participants who had had little difficulty with the first questionnaire presented to them. From their perspective the changes in the questionnaires were unnecessary and they therefore found the cyclical process boring.

3. It was sometimes difficult to have an over-view of the questionnaire aims, and not just change the questions/answers to suit the participants in the study. Participants had lots of differing opinions which they thought should be included in the questionnaire. This mostly reflected the different strategies the individual had adopted to help them cope with AO, so was very important for that individual. For example, one of the participants was insistent that there was a difference between going to the garden/courtyard was different from going to the shops as far as the use of AO was concerned. An additional question was added to the questionnaire. Other participants were less sure of the difference, because they did not have gardens/courtyards. The question was modified after the pilot study, because only the garden option was used. If the researcher had been more experienced this question may have been modified earlier. Lack of experience may have contributed to having the researcher having difficulty in deciding which of the participant's additional views were useful and which were not.

4. Five participants took part in this CI process. Each participant was seen four times, it may be that the process would have been more efficient if more participants had been seen less often. The changes in the questionnaire took place within the visit one and two to the participants with one judges' panel. The last two visits were, in

retrospect, small tweaks to the questionnaire. Again lack of experience with the CI process may be responsible here.

Although the researcher acknowledges the drawbacks and problems with using CI as part of questionnaire development, she feels that overall the advantages of using CI to identify problems within the questionnaire, outweigh the disadvantages.

9.6.3. The advantages of using a separate pilot study stage

The pilot study was used to test if the questionnaire which emerged from the cognitive interviewing study, delivered the responses necessary to answer the research question in a larger cohort of different participants.

1. The pilot study gave an insight into how the questionnaire would be answered in a larger cohort of different participants. This offered an opportunity to correct any aspects of the questionnaire which may have been problematic. As said above, using a CI study to increase face validity means that face validity is increased in that group of participants. Using the questionnaire with another, different group, helps ensure that face validity is optimised, improving the completion rate and the data to answer the research question.

2. The return response was good (Gillham 2007) at 65%; where 13 completed questionnaires were received from 20 sent out.

3. The returns showed 21 pieces of missing data, but 4 participants were responsible for 85% of the missing data, suggesting that only 4 of the 13 respondents had difficulty with the questionnaire.

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9.6.4. The disadvantages of using a separate pilot study

The researcher acknowledges that this was a small pilot study, so interpretations of the results from the collected data were limited. However they did show that participants in the pilot study were able to complete the questionnaire successfully.

9.7. Summary of pre-testing the questionnaire

The use of cognitive interviewing techniques to pre-test the questionnaire enabled the researcher to ensure that the questionnaire was as error-free as possible. Using an additional pilot phase enabled the researcher to ensure that the questionnaire could return the responses necessary to answer the research question. Without the two pre-testing phases the developed questionnaire would not be so robust.

9.7. Validity and Reliability

Within this mixed methods study the approach to reliability and validity in each stage has been set out in chapter three. Each phase of the study uses the validity and reliability criteria employed in that type of research (either qualitative or quantitative), with an overview of the study as a mixed method study being considered later.

9.7.1 Validity

The CI study allowed the researcher to assess the face validity of the questionnaire, and improve it through rounds of interviews with participants and an expert judges' panel. The pilot study allowed that face validity to be tested in a different cohort of participants and improved as necessary.

9.7.2. Reliability

The reliability of the questionnaire was harder to establish. The aim of the questionnaire was to explore if certain beliefs were held by the people completing the survey. So there were no constructs to compare. The last phases of the CI process allowed the researcher to assess the response of the participants to two questionnaires which were almost identical. This gave some insight into the reliability of the questionnaire using a test-retest basis. One person who had participated in the CI study also re-completed the questionnaire some six months later, as the pilot study was being conducted. This person completed both questionnaires exactly the same, with 100% of the answers matching. However this is only a tiny snap-shot of the reliability of this questionnaire. These results are documented in Appendix 31.

9.8. Conclusion

Although it was a small pilot the questionnaire did enable the researcher to collect the participant data necessary to establish that some of the perceptions and experiences of the qualitative cohort were found in a different cohort of participants. Both stages of pre-testing therefore helped to develop a questionnaire that could supply the responses to answer the research question for the quantitative phase of this thesis and to triangulate the findings from the qualitative phase, so to improve the generalisability of the whole study. This piloted questionnaire could act as useful tool to help potential users of AO and prescribing healthcare professionals explore potential problems which could affect AO usage.

9.9 Further pilot work

This questionnaire was devised to triangulate the results from the qualitative phase one. Further interesting pilots studies could be to develop the questionnaires in a way where it which could be used to predict potential barriers for new patients prescribed AO. In this way the questionnaire could prove an invaluable platform for healthcare professionals to pick up potential problems with AO use before prescribing the intervention. These potential issues could be explored with the patient prior to prescription, potentially improving the basis for prescription and allowing the both healthcare professional and patient to openly discuss and confront problems in a more patient-centred way.

Chapter 10 Discussion

10.0 Introduction

This thesis set out to explore why people with COPD who had been prescribed AO decided to use it or not use it. This chapter provides an overview of both phases of this thesis and, in line with a mixed methods approach, discusses the findings of both phases together. It goes on to document the strengths, limitations and the contribution of this body of work. This thesis ends with the development of the questionnaire and the researcher will go on to use that questionnaire to establish if the findings of the qualitative phase are present in a larger population of COPD patients. So this mixed methods study will be more extensive than the research described here.

10.1 Overview of this thesis

This research was undertaken from the point of view of a clinician working with people with COPD who have been prescribed AO. As a clinician the researcher was interested in why some people with COPD used their prescribed AO, whilst others did not. AO prescription aims to allow patients to continue to access their interests, pursuits and activities outside the home, whilst being able to access the oxygen they need (Tham and Anantham 2011). Increasing breathlessness has been shown to constrict a patient's freedom to the point where they no longer leave the house (Kanervisto et al 2010, Williams et al 2007). Once this happens the reduction in exercise tolerance has been shown to predispose these patients to deterioration and potentially hospital admission (Garcia-Aylmerich et al 2006). An intervention that can enable patients to improve their control over their breathlessness (including feeling more confident out of the house) may enable patients to continue to enjoy as good a standard of health and living as possible, for as long as possible. So understanding why some patients chose to use the intervention whilst others did not was unclear.

The existing empirical evidence on the use of AO has been predominately quantitative in nature and focused on adherence in AO. This thesis offers a unique insight into the

participant's perspective. This body of work is divided into two separate phases. An initial qualitative phase, which set out to explore the participants' experiences and beliefs about AO, and a secondary quantitative phase which utilised CI and piloting to develop a questionnaire based on the inductive qualitative findings. This questionnaire was developed to explore if other people with COPD who had been prescribed AO, had similar perceptions to those in the initial qualitative study. This is the first questionnaire produced within AO that offers both the patient and the healthcare professional a chance to explore the patient's beliefs about AO and identify potential barriers which may affect their use of this intervention.

10.1.1. The qualitative phase

This phase employed an adapted GT method to inductively collect and analyse the participant data. Twenty-seven participants were interviewed at home using a semi-structured interview approach and the findings are presented in Chapter seven. In line with this GT method, a core category of advantages versus disadvantages was identified, and a substantive grounded theory was developed using common-sense linkage between the emerging categories:

'Patients with COPD use their AO system according to the perceived advantages or disadvantages they associate with the system'

This substantive grounded theory was abducted from the patient data by the researcher but other researchers have found similar underlying reasons for using medicinal interventions in COPD (George et al 2005).

10.1.2. The quantitative phase

The second phase of this thesis was the development of a questionnaire to explore if the perceptions held by the participants in the qualitative phase were found in a cohort of different participants. The questionnaire was developed using rounds of four cognitive interviews with five participants and three judges' panel. A further pilot study was then undertaken with 13 different participants. The pilot study was done to

determine if the developed questionnaire could provide the responses required by the researcher to answer the research question, but in a different cohort of participants. Although the pilot study was small, responses suggested that the perceptions held by the qualitative study participants were also found in this different cohort of participants with COPD and prescribed AO.

10.1.3. Combining qualitative and quantitative research

This thesis uses both qualitative and quantitative research methodologies in a mixed-method approach. Qualitative research is suited to exploring people's insights and perceptions and generating theory around those findings. Quantitative research is suited to testing and generalising theory. As discussed in Chapter Four (4.5), using a mixed methods approach can be seen as controversial (Denzin 2010) but here it is used to complement each approach and increase the researcher's ability to answer the research question in as wide a cohort as possible (Teddle and Tashakkori 2009).

To gain an overview of the whole thesis, and in line with a mixed methods study, this discussion encompasses the findings from both the qualitative and quantitative/questionnaire phases together (the qualitative phase is findings from the GT study and the quantitative/questionnaire phase is the findings from the pilot study). The researcher acknowledges that the pilot study had only 13 participants, but the results still suggest that these participants were able to complete the questionnaire, i.e. that they did recognise and understand the perceptions and use of AO which emerged from the participants in the qualitative phase.

10.2 Summary

This thesis describes a body of work undertaken by a clinician with an interest in COPD patients using AO. Different research approaches are used to explore the patients' perception of AO and to develop the questionnaire to the point it is presented here. The questionnaire could be used now by clinicians to explore how patients feel about their AO and provide a focus for discussions around identifying any potential barriers to AO use. The mixed methods research study will be completed when the questionnaire is used to collect more data from COPD patients.

10.3. Discussion of findings

The findings from both the qualitative and quantitative phases are discussed in further detail below.

10.3.1. The weight of the equipment

Previous empirical research has already identified that the weight of AO equipment may be a reason why patients do not use their AO (Eaton et al 2002, Moore et al 2011). However this thesis uncovered aspects of equipment weight which have not been previously reported, such as the of carrying liquid oxygen which had not previously been reported as problematic.

10.3.2. Problems with carrying liquid oxygen

Within the qualitative phase all but one of the 27 participants were using cylinder oxygen which was known to be heavy (4.8Kgs). One of the overwhelming complaints of these participants was the weight of the cylinder. In the quantitative phase five of the 13 total participants (39%) were using liquid oxygen (LOX), which is lighter (2.8Kgs). However 11 participants (85%) reported that they thought that their AO system was too heavy. This included four of the five participants who had been prescribed LOX. Casaburi et al (2012) found that, in an experimental study of 22 COPD patients, supplying lightweight oxygen cylinders (weighing 3.6kg) made no difference to use or activity in their participants compared with normal heavier cylinders.

This is very important for healthcare professionals who prescribe LOX because it is thought to be a light-weight system which is easy to carry, conferring greater freedom of movement on the patient. The referral guidelines suggest prescribing LOX for patients who are more active, partially because of the reduced weight. These results would seem to suggest that for these participants, LOX was perceived as being too heavy. So prescribing LOX does not automatically confer an easier carrying system from the patients' perspective.

10.3.3. The importance of carers

Other research in chronic conditions has highlighted the importance of carers in a role that positively supports the patient in self-managing their condition (Stephens et al 2010). A recurring finding through this thesis is the importance of carers in helping to physically manage the AO system, which is a unique finding in AO research.

10.3.3.1. The importance of carers in carrying AO equipment

Within the qualitative phase the use of carers to help carry the AO equipment made the difference between being able to use the oxygen outside or not. If participants thought the AO had advantages, then they organised a way of taking oxygen out with them. The majority used their carer to carry the AO. Within the quantitative phase seven of the 13 (54%) participants reported that the weight of the AO system stopped them carrying the system out of the house by themselves. Four (30%) of the pilot study participants reported that someone else carries their oxygen for them when out. This was surprising considering that the cohort in the quantitative phase were probably more active than the qualitative cohort, as they were still going/known to the local breathe easy group, and all reported going out of the house regularly. The importance of the carer in carrying AO was highlighted in the qualitative phase where the lack of a carer meant the participant was not leaving the house with AO at all.

Healthcare professionals need to be aware of the importance of carers carrying the AO system. They need to include the carer in the assessment for AO by asking; is the carer willing to carry it, can they physically manage it or are they disabled themselves? Other research in chronic conditions highlights the importance of carers helping to self-manage, for example in diabetes (Stephens et al 2010). The roles described by Stephens et al appear to be emotionally and physiologically supportive as opposed to the physical supporting role of actually carrying equipment, which was found in this research. Having a carer who can carry the equipment may be the difference between being able to take AO out of the house and not. The present prescription guidelines only ask how active the patient is as a marker of prescriptive need, but if they or their carer cannot carry the AO equipment then it may not be used. Involving the carer in the assessment may be useful to explore this problem further. More information on

possible aids to help the patient carry their own AO would also be invaluable, particularly for those patients with no carer e.g. carrying trolleys.

10.3.3.2. The importance of carers in managing AO equipment

Carers were also identified in the qualitative phase as being important in the re-ordering of equipment, ensuring the cylinder was turned on correctly and that it was full of oxygen. The quantitative phase cohort reported this experience as well. Five (38%) of the pilot participants confirmed that someone else checked their oxygen controls for them, and six (46%) had someone else check always or sometimes check that the oxygen cylinder was full. Carers appear to be an important part of the management of AO in COPD, and yet all the education and support is primarily directed at the patient. Again, involving the carer at assessment may enable the healthcare professional to ensure that the carer is themselves happy with managing the equipment. Healthcare professionals need to ensure that patients without immediate carers receive as much help as possible in managing their equipment, perhaps altering the type of equipment selected to ensure ease of use or involving occupational therapists to review the patient's ability to use dials and valves.

10.3.3.3. Carers influencing the use of AO

Carers also influenced how AO was used by the participant. In the qualitative phase two participants reported that their carers insisted on taking AO when they went out because they were worried that the patient may become breathless when out. No participant reported this as a negative effect. The same experience was recorded in the quantitative phase where two participants reported that their carer felt more confident if they had AO with them. In the qualitative phase, carers seemed dedicated to helping to manage breathlessness both because they themselves found breathlessness distressing and because of its effect on the participant (Bailey 2004). Monin and Schutz (2010) emphasised the positive experience carers themselves receive when they can help relieve suffering, and it may be that being able to give oxygen to a breathless loved-one is beneficial for both parties.

The importance of carers in providing positive support has been found in other studies looking at COPD. One study by Seamark et al (2004: 235) reported carers being 'enmeshed' in the management of the condition. This has been found in other chronic conditions. A recent study in HIV suggested that positive social support could improve medication adherence and slow disease progression (Mosack and Wendorf 2011). Including carers in self-management decisions has been shown to improve the patient's ability to control symptoms (Silveira et al 2011). The research in this thesis uniquely highlights the importance of carers in the management of AO. Including the carer, if permissible, in discussions around the use of AO and the management of breathlessness should become a normal part of the whole AO assessment process. At the moment self-management plans are all directed at the patient themselves, and the carer is not involved unless they happen to be present. However care must be exercised as some research has also suggested that social support can have a negative effect on patients. Carers can become over enthusiastic in making patients use interventions so this possibility has to be considered when including carers in discussions (Stephens et al 2010).

Another related finding from the qualitative phase was that participants with no social support were not able to utilise AO even if they so wanted. They were physically unable to manage their equipment and were less likely to leave the house. The vulnerability and social isolation of this subgroup of COPD patients has been highlighted in other research into COPD (Oliver 2001). In the qualitative phase, participants living alone appeared to have received no information on aids such as trolleys in which to carry AO, so it is unknown if they had received more information, would they have gone out more. Patients, who have no carer to help them, need extra support to enable them to use AO. More research is required to identify exactly what would be most helpful to enable them to use AO in the community.

10.3.4. Embarrassment

Embarrassment or perceived stigma has been recorded in many chronic conditions such as epilepsy, multiple sclerosis and mental health conditions (Michalak et al 2011), and in the use of AO (Ringbaek 1999; Eaton et al 2002). Research suggests that patients with chronic conditions may expect others in the community to devalue them because they have a medical condition. Feeling that you may be stigmatised by others in the community has been shown to undermine the physical and mental health of

patients (Earnshaw et al 2012). Using equipment out in the community has also been shown to increase perceived stigma, Wallhagen (2009) found that people with hearing aids felt stigmatised. Boyles et al (2011) suggested that COPD is a condition which could be seen as a dilemma for patients; to use the oxygen equipment you need outside the house is a visible sign that you have a problem with your lungs, but do you want to reveal you have a lung condition? Using oxygen equipment may force you to reveal you have a lung problem, and you may then feel you may be stigmatised because of the public's connection between lung problems and smoking, perceived as a self-inflicted disease (Lindqvist and Hallberg 2010). Research suggests that stigmatisation of smokers is increasing (Stuber et al 2008), with public anti-smoking campaigns. This may have increased the participants' fear of being actually stigmatised if they use AO out in the community.

In the qualitative phase participants described how if they believed AO to be useful, they organised help in transporting AO, but then would not use it in public because of embarrassment. Only three participants reported that they were tolerant of being seen in public with their AO equipment. This represents only 8% of the total participants in this phase. Within the quantitative phase nine (69%) participants reported feeling embarrassed at being seen in public with AO. Four of those nine (45%) said they were so embarrassed that they would not use AO in public. More participants in the quantitative phase reported that they would use AO out in public despite being embarrassed and there may be several reasons for this. First, they may be aware that gradually more people are out in public with AO. AO only became available on prescription in 2006, and secondly the qualitative phase was undertaken around that time, so it would have been less likely that AO users were about in the community. As AO becomes more visible in the community, then users may be less likely to feel stigmatised. Particularly as the quantitative phase participants who said they were worried (62%) said they were concerned about being stared at with AO. In the quantitative phase four (30%) participants reported they did not want people to know they had a lung condition.

There is some evidence that social support can help overcome the feelings of embarrassment, and in the qualitative phase it was help from his family that enabled one participant to use AO outside. Again carer support may be important to support patients in their use of AO outside. Egan et al (2011) suggested that people who adjust

positively to physical differences may have more social support, have more ability to manage their condition or do not believe general personal appearance is extremely important. Increasing information on why AO is important to each patient may also be crucial. If a patient and their carers fully understand why they are using something then they may be more likely to use it. Personalising information may be a key to enabling patients to use AO effectively outside.

Being embarrassed by AO is something which most healthcare professionals are aware causes some patients distress. However there is currently no intervention or specific help for this problem. It seems illogical to prescribe an intervention which you believe is beneficial and then not help the patient to overcome any specific difficulties which they encounter. At the moment patients are more likely to have their AO removed because of non-use, than to get help with overcoming the embarrassment which is preventing use of AO outside the home.

More research is needed to explore how COPD patients could be helped to overcome any embarrassment using AO may cause. A study of catheter wearers suggested that participants who reported embarrassment felt by using this equipment also reported non-acceptance and lack of adjustment to the condition (Wilde 2003). A similar underlying lack of adjustment to the condition was reported in a study of depressed women who felt perceived stigma (Oakley et al 2012). These authors suggested that learning strategies to help cope with the embarrassment could be useful, and this could be beneficial for patients prescribed AO, but as said above, more research is needed.

10.3.5. AO as a 'security blanket'

Findings from the qualitative phase demonstrate that participants individualised their use of AO, either by not using it at all, taking it with them in the car/buggy only, or using it out in the community. Similarly in the quantitative phase six of the 13 (46%) reported keeping AO in the car and three (23%) reported keeping it on their buggies, only using it if needed. It is well documented that patients who perceive a benefit from their medication are more likely to use it (Saratsiotou et al 2010), but here the perception of benefit appears to cover not just the actual use of any oxygen but the

fact that AO is available to the participant should they need to use it. Within the qualitative phase AO was reported by participants as conferring confidence and freedom to go out. Similar results were found in the quantitative phase where eight (62%) participants reported that AO gave them confidence and freedom, three (23%) participants said they felt safer.

The decision to use AO seems to be broader than just for the relief of the symptom of breathlessness alone. The fear of breathlessness is something described in other research in COPD (Janssens et al 2011) and may be more prevalent in anxious patients, but this was not raised as an issue within the interviews and not explored in this thesis. Outside the house AO appeared to be used not only as an intervention but also as a safety blanket. The devastating impact of breathlessness and how frightening it can be should not be underestimated, not only for the patient but also for their carers (Boyles et al 2011). COPD research looking specifically at perceptive dyspnoea suggests carers are as frightened as patients when they experience breathlessness and feel much more secure if they perceive something helps (Bailey 2004). The fact that participants felt the need to have AO with them irrespective of whether they actually used it or not, may suggest that participants and carers were self-managing for the potential of being breathless or unwell when away from home. This needs to be considered in the context that participants in the qualitative phase reported using AO only after their other strategies (for example, resting and using inhalers) for recovering from breathlessness had failed. All the participants in this research had experienced breathlessness when out before being prescribed AO. Developing their own coping strategies was an important part of continuing to be able to go out, so it is not surprising that AO was used, in some participants, only when these other strategies failed particularly if the participant received no specific information on AO use. Lindqvist and Hallberg (2010) found that a similar pattern in a qualitative study of 23 COPD patients where a feature of COPD daily management was that patients and carers plan outings very carefully. The authors reported that this was because carers and patients said they were constantly afraid of the patient becoming ill when away from home and managed for that scenario.

Encouraging patients to self-manage their long-term condition is a cornerstone of the NHS approach to management of COPD (NICE 2010). For the participants in these

studies self-managing appears to mean taking the oxygen with you in case you feel breathless, but not necessarily using it. This could be seen as sensible pro-active planning. However under the commissioned services for oxygen prescription, the patients who take their oxygen with them just as a safety blanket are at risk of having their AO removed because of “non-use”. Healthcare professionals and service commissioners have to ask themselves if using AO as a safety blanket is any less appropriate than using the actual oxygen itself. When considered in terms of the high rate of anxiety in this group of patients, it should be permissible to allow patients this safety blanket, instead of risking possible emergency admission because of breathlessness. Services within the NHS are commissioned separately so saving money by withdrawing apparently unused AO may not be connected with an increase in an individual's use of emergency services. Removing AO because of apparent non-use may not be connected with restricting patients to their home where they may have an oxygen supply and feel safer. This would result in a decrease in exercise tolerance if the patient stops going out, leading to an increase in GP visits or COPD admissions (Garcia-Aymerich et al 2006). This removal of AO due for perceived “non-use” may be the very definition of false economy.

Healthcare professionals need to understand why patients use AO or do not use AO and that adherence in terms of oxygen usage may NOT reflect the importance of the intervention to the patient. Patient requirements change in the face of an ever-changing chronic condition and what initiates use of an intervention at one moment, may not be the same all the time (Griffiths et al 2010). Comprehensive information about the use of AO may help patients, but healthcare professionals also have to achieve a better understanding of self-managing a chronic condition where fear of breathlessness can be overwhelming. Patients are provided with an intervention they are told they need, but no detailed instructions are given on use. This sets up an expectation that the intervention will be beneficial but they are not told what the actual mechanism of the benefit might be or how to maximise that benefit. This results in patients devising their own strategies for the intervention based on individual need or experience. But clinicians then potentially remove the intervention because it is not being used according to clinician/providers concept of adherence, in terms of cylinder usage outside the home.

10.3.6. The apparent lack of patient information

Giving adequate appropriate information to patients is a fundamental part of enabling them to self-manage their condition (Reach 2011). The lack of information which the participants in both phases of this research could recall being given on AO was a surprising and worrying finding. It is also a finding unique to this thesis.

10.3.6.1. Information on why AO is necessary

Understanding why AO is necessary for a patient would seem to be a crucial part of any assessment and prescription process. However in the qualitative phase participants suggested not knowing (or recalling) why they had been given AO. In the quantitative phase eight (62%) participants reported they had not been told why they needed AO. It is an unexpected finding that participants appear not to have been given this information, or at least not in a memorable format.

AO is prescribed on the basis of flowrate (to maintain oxygen levels) and hours per day (hours outside the home), so a typical prescription would be 2 hours per day at 2l/m. The prescriber estimates likely AO hours based on information from the patient and the level of desaturation when walking (the idea being to titrate the supplementary oxygen to prevent desaturation). No participant in the qualitative phase could recall being told their prescribed hours of AO per day, in fact they followed the advice of the delivery man. Participants in the quantitative phase also reported not knowing their prescription hours (in fact the question was removed because no-one could answer it). The prescriber has to know the hours and flowrate in order to prescribe AO, but it appeared that these participants could not remember being informed. This lack of knowledge over how long AO was prescribed for, or what flow, was another unexpected finding. If patients do not know how long or at what rate their AO is prescribed for each day then they are unlikely to get the maximum benefit from this intervention. If they do not know this information then it is very difficult to see how they could possibly adhere to any prescription.

10.3.6.2. Information on the use of AO

Only one participant in the qualitative phase was able to recall any specific instructions on using AO and that was to enable her to fulfil her daily oxygen requirements. Within the quantitative phase participants reported a variety of instructions but only one (8%) participant reported being told to use AO when walking outside. There are no instructions in the AO prescription guidelines (NICE 2010) as to how participants should be told to use AO and it seems that any instructions are down to the prescriber.

These instructions stand in stark contrast to the instructions patients receive if they are prescribed LTOT at home. Although not part of this study, all the qualitative phase recalled specific instructions on the time they were required to use the LTOT during the day/night and the precise flow rate they were allowed to use. In contrast these leaflets probably represent the lack of knowledge of AO held by healthcare professionals, which in turn relates to the poor evidence base for AO.

One of the original concepts behind the development of AO was that it could be used to ensure the patient got their full time of oxygen everyday but were not tied to being at home. Instructing patients to have their full 15+ hours per day, and then go out, undermines an important part of the aim of an AO prescription. Telling patients that AO will definitely improve their breathlessness is setting up an expectation that cannot be fulfilled. It is known that breathlessness is due to many different causes, including anxiety, air pollution and lack of exercise fitness. Telling patients that AO can relieve dyspnoea indicates a lack of understanding about the aetiology of breathlessness. Not using medications because they do not appear to work has been recorded in other work in COPD (George et al 2005). In the qualitative phase participants complained that the AO did not relieve their breathlessness as they expected. In the quantitative phase this was not expressed, but the researcher believes that was due to the position of the question in a larger set. Three participants in the quantitative phase were not using their AO and lack of benefit may have been a problem. The leaflets sum up the vague instructions received by patients, which suggests that AO is seen as an add-on and not as important as LTOT. It is not surprising that AO patients develop their own self-management strategies given this level of instruction and information.

From the view of adherence it is difficult to see how patients receiving the instructions in the leaflets above could possibly fulfil any expectation of adherence. Without being aware of specific usage in terms of daily hours and flowrate no measure of adherence can be fairly applied to AO, as patients seem unaware of the specific prescription. As clinicians we encourage patients to self-manage (as described in the instructions “use when you are breathless”), but then penalise patients who may not use AO according to their actual prescription.

Although it was not asked as a specific question, no patient in the qualitative study discussed information they had received as to the safety of their AO equipment (for example, the dangers of smoking and the possibility of explosion or fire). They had received information from the delivery man about the safety of their LTOT and its use, but not necessarily about their AO. No participant suggested that they had any concerns about safety but this may be an area which requires further exploration in future research.

10.3.6.3. Wanting more information

All the participants in the quantitative phase responded yes to the question asking if they wanted more information for themselves and their families. They did not specify what kind of further information they needed just a general demand for more. Those on LTOT had all received comprehensive booklets on the uses and dangers of the machine, so perhaps they realised the stark contrast between the receiving specific information for one type of oxygen but not for another. Patient information which is understandable, comprehensive and informative to patients and their families would therefore probably be beneficial as it would fulfil this need and serve as a dialogue between the healthcare professional, the patient and the carer to enable individualising self-management strategies for AO in their COPD with full knowledge of the clinician's expectations around use.

Patients also need information on the potential disadvantages to using AO. There is limited evidence supporting the benefit of AO in exercise (Bradley and O'Neill 2005), and evidence that the weight of the cylinder (Sandland et al 2008) may reduce any benefit the patient may actually derive from using supplementary oxygen.

Including the carers in information giving may be helpful to some patients and help the healthcare professional furnish appropriate information about the use and usefulness of AO. Involving carers in the care of cancer patients has been shown to improve patient management (Silvera et al 2011). Specific information about use of both AO and LTOT to maintain a daily oxygen requirement, but not be at home, needs to be emphasised. Patients need more information of other causes of breathlessness and why AO may not relieve that subjective feeling. They also need information on potential benefits and side-effects and dependency. On the other hand HCPs need to understand how frightening breathlessness is for the patient and the carer, so they have more insight of patients and carers potentially using AO as a safety blanket. Given the reported importance of activities and exercise in preventing deterioration in COPD, enabling the patient to continue to access those activities even if they do not use AO, may be a trade off which is worthwhile if it prevents increasing use of other medical resources.

Shared information on the disease process itself and the proposed intervention including alternatives, benefits, harmful effects and the effective of non-adherence was deemed important by Rosewilliam et al (2011). Participants in the qualitative phase talked about the worry of dependency if they used oxygen more and appeared to have received no information on whether this was a reasonable concern or not. The same concern was identified in the quantitative phase where 10 (77%) of the participants reported being worried about becoming dependant on oxygen. Redman (2005) argued, reasonably in this researcher's opinion, that it is the ethical responsibility of the prescribing healthcare professional to give the patient enough information about an intervention that they can make informed decisions about self-management, and this information appears to be lacking in AO prescription. The reasons why this might be the case are discussed further below.

10.3.7. Running out of oxygen

Another finding from both phases of this research was the lack of information around the use of the oxygen equipment and what to do if a malfunction occurred was also lacking. Two participants in the qualitative phase and three in the quantitative phase reported being worried that the oxygen in the cylinder would run out, when they were

away from home. This was only a worry to a few people but represented a significant problem to those who had experienced it. This appears to be a finding that is unique to this study. Discussing with the patient what to do in that kind of emergency may help alleviate some of the concerns that the patient may have about using AO in the future.

10.4 Adherence to AO

This thesis is concerned with the participant's perception of AO. But the concept of adherence to a prescribed intervention cannot be ignored. In this NHS how a patient uses this intervention translates, however unfairly, into adherence to AO. Adherence was defined in Chapter three as the extent to which a patient follows the instructions of healthcare professionals (Christenson 2004). An important point here is that for AO there is no agreed level of adherence beyond use outside the home. Research into adherence in other chronic diseases has suggested various reasons why patients do not appear to adhere to a medication or regime as directed by healthcare professionals. Gherman et al (2011) looking at diabetic patients suggested concerns about side-effects, perception of interference with daily activities and low belief in the ability to perform the required adherence all contributed to non-adherence. Stalmeier (2010) suggested that the doctor-patient interaction and patient education accounted for a large degree of adherence behaviour. Mosack and Wendolf (2011) attributed increased adherence to positive social support. William et al (2008) in a study of diabetic patients argued that being convinced of need and the effectiveness of the intervention were predictors of adherence. In COPD medication George et al (2005) also found that the effectiveness of the intervention was a predictor of adherence. Certainly within this study these reasons may explain some of the actions of the participants in this study, but the belief in ability to perform the behaviour required was not explored.

In a study looking at LTOT adherence Marien and Marchant (2011) reported on a quantitative experimental study of 46 COPD patients on LTOT. These authors concluded that apart from leaving the house less as their condition deteriorated there were no specific factors or behaviours which predicted adherence in AO. However other studies have cited weight and embarrassment as predictive of non-adherence in AO use (Ringbaek et al 1999, Eaton et al 2002).

10.4.1. Three important considerations affecting adherence

There are two important elements which emerged from this body of research which need further discussion; the current un-evidenced guidelines and the new oxygen assessment services which, in the researcher's opinion, influence the use of AO in the community, or adherence, and need to be highlighted. Additionally the pre-existing research evidence suggests that AO may not be beneficial in exercising COPD patients.

10.4.2 Un-evidenced Guidelines

The lack of evidence for the guidelines for the prescription of AO was discussed in Chapter two (2.3). This seems to be a fundamental problem. Using assessment tests which show the effects of AO in terms of preventing a rise in pulmonary artery pressure during exercise may be much more useful than the walking distance tests currently used. This is especially true in patients who only have exertional desaturation or breathlessness (Tham and Anantham 2011). Most of the research into AO has been done using the same prescription criteria as those described in the guidelines i.e. desaturation to a certain level, and an increase in walking distances/decrease in subjective breathlessness to show a response. It is therefore not surprising that the research around AO has shown such diverse results when the assessment for AO prescription is un-evidenced. This researcher would argue that the effect of this lack of evidence is that the health professionals prescribing AO have no clear idea why it is being prescribed and what the benefits are for the patient. This appears to be associated with confusion for the patient on why AO may be useful and how it should be used.

Although the report by Locke et al (1992) appears to be the basis of the prescription of AO, one important aspect advocated by these authors appears to have been discarded in modern AO assessment; the need for three baseline assessment walk tests before AO is tested. Three baseline walks ensure that any increase in walking distance is due to the extra supplementary oxygen and not due to an improvement in walking distances due to a learning effect (Morante et al 2005). During the course of this thesis the researcher visited four local oxygen assessment services to look at the

information supplied to the patient on prescription of AO. In three out of four of these clinics only one baseline test was done before AO was tried. The clinicians cited lack of time or lack of knowledge (not in the guidelines), as the reasons why more baseline tests were not performed. It is difficult not to believe that some of the patients, who were being assessed, would have received AO unnecessarily because only one baseline test was performed. It is unknown how this would translate into home use, but patients may discontinue use if AO is determined to be not helpful and certainly participants in the qualitative reported that. Three (23%) participants in the quantitative phase reported not using AO. It would seem much more sensible to use an assessment process which would be able to detect if exercising with oxygen conferred any benefits on the patient, e.g. a decrease in pulmonary artery pressure or dynamic hyperinflation during exercise. More research is required into AO prescription and identifying the COPD patients who would benefit from its use.

10.4.3. New oxygen assessment services

New community based oxygen assessment services are being commissioned within the NHS (IMPRESS 2010). This is seen as a development of the oxygen assessment services which were recommended in 2006 (BTS 2006), where oxygen prescription was supposed to be only through a specialised service, usually based in secondary care. These new community services, as explained in Chapter two, are still specialist services but are positioned in the community, making it easier for the patient to attend. The remit of these services is not only to assess new patients, and review their oxygen use on a regular basis, but also to review all patients currently prescribed supplementary oxygen. Part of the commissioned work of these services is to ensure that oxygen is being correctly used by the patient and reduce or remove supplementary oxygen if it is not. Often the service is commissioned on prospective savings which the service is expected to make from removing unused oxygen from patients. Each patient will be reviewed and their AO prescription changed depending on whether they are using AO outside the house, in tandem with records from the oxygen company around re-ordering of cylinders. So, for example, if a patient is not ordering AO because they are not apparently using oxygen outside the house, then their prescription will be reduced or stopped altogether. From the view of health economics and saving NHS resources obviously it is important to ensure that patients

are using prescribed medication optimally, but this new system is likely to have a significant impact on patients who use AO as the safety blanket discussed above.

This change in patient review makes the research done in this thesis even more relevant as for the first time the prescriber will also be reviewing the patient's oxygen usage over time. Understanding why patients decide to use or not use their AO will be a crucial part of good prescribing practice, identifying possible barriers and resolving them may improve the patient's use of the intervention, accruing the benefits of AO described in Chapter two. Disseminating the results of this thesis to healthcare professionals working in the new oxygen assessment service would be helpful in providing insights into the potential barriers experienced by patients prescribed AO.

10.4.4. AO does not have a benefit

There is existing research which suggests that AO has little benefit for users. This covers three distinct areas, all of which may affect usage.

10.4.4.1. Lack of exercise benefits

Much of the evidence about the use of AO during exercise has been equivocal (Nonoyama et al 2007). Research has not consistently demonstrated an improvement in exercise parameters with AO, which casts doubt on whether AO during exercise has any benefit. Some authors have concluded that AO has no exercise benefit despite demonstrating an initial response to AO during the baseline assessments (McDonald et al 1995). Moore et al (2011) included patients who would not be covered by the BTS guidelines, but reported no improvement in quality of life with AO. Other research has reported that AO does not improve activity in severe patients with COPD (Casaburi et al 2012), although these authors suggest that further education for patients receiving AO is imperative to optimise outcomes. Although there is no unequivocal benefit demonstrated for AO during exercise, the researcher agrees with Garcia-Talavera et al (2011) who suggest that there may be different types of patients who would benefit from using AO in exercise. As yet the assessment and prescription guidelines do not differentiate those who may benefit from those who may not. The other consideration here is whether AO increases or maintains the mobility of patients, irrespective of whether it confers an objective exercise benefit or not. COPD is incurable and patients

experience a steady decline as they get older. Research suggests that as they become less well they tend to leave the house less, especially if they have LTOT at home (Lacasse et al 2005). This may be a part of the deteriorating condition and using AO to encourage them to move outside may not be a realistic goal. At the other end of the scale, for patients with COPD who only desaturate on exercise and are not on LTOT, AO may help to maintain mobility outside the house.

10.4.4.2. The weight and aesthetics of the equipment

The participants in this qualitative study all voiced their concerns over the weight of the equipment making it difficult, if not impossible, to handle. Other research has concluded that any improvement produced by AO is counter-balanced by the weight of the equipment (Sandland et al 2008), so the patient feels no benefit. If oxygen can only be delivered through such heavy equipment it fundamentally affects the ability of the patient to use it, particularly in a COPD cohort, who tend to be older.

Participants also voiced concerns over the aesthetics of the equipment. This was one of the major findings from this study and this is discussed more fully in chapter 10.4.

10.4.4.3 Oxygen Toxicity

For some patients with hypoxic COPD there may be a theoretical danger in being prescribed supplementary oxygen. The evidence relating to any potential threat is not specific to AO (Carpagnano et al 2004) but the concept of supplementary oxygen increasing the risk of oxidative stress and subsequent lung inflammation remains. The potential problem of prescribing oxygen for hypoxic patients with hypercapnia is something which needs further investigation, as there is little research into the potential harmful effects of AO for patients with COPD. There is awareness of the need for caution when prescribing oxygen acutely and for some hypoxic patients who receive LTOT, so healthcare professionals also need to be aware that prescribing AO to hypercapnic patients may be problematic.

10.5. Adherence in AO

The three studies (Lacasse et al 2005; Sandland et al 2008; Moore et al 2011) which looked specifically at AO use at home in patients with COPD, were discussed in Chapter three, all these studies (despite their limitations) concluded that AO was not beneficial. Only Moore et al (2011) attempted to give explanations for non-use such as problems with equipment portability and difficulty changing the regulator. None of these studies specifically cited adherence as an outcome measure, but all report on lack of use outside the home. None of the studies appeared to provide instructions for the use of AO; Moore actually confirms that no instructions on use or activity were given. Sandland et al (2008) explains that they gave the patient standard advice about the use of cylinders at home, but does not comment further. The information given in the Sandland study is confusing since the idea of AO is to use it outside the house, but Sandland et al measured use every day both inside and outside the house, suggesting they viewed this as different use. It is difficult to see how any of these studies could determine what adherence was, as none set a measure against which adherence could be measured, and none gave the participants specific instructions.

Patients and healthcare professionals need to be informed what an acceptable level of adherence is deemed to be for AO. Within LTOT prescription patients are clearly told they need to use the oxygen for 15 hours per day. Within AO instructions are individual to the *healthcare professional*. There are no standardised instructions predicated on evidence based guidelines. It is difficult for patients to know what is expected of them. In the research for this thesis it was clear patients were taking the oxygen out with them, and if that was the instruction received, then they were adhering to it, what they were not doing was using it all the time when they were out of the house and the reasons for that may be very important.

10.5.1. Self-management in COPD

Rogers et al (2005) suggested that healthcare professionals view self-management as adherence with additional education. These authors argued that lay perceptions of self-management will always be different from that of healthcare professionals because lay perceptions of self-management will always everyday elements of health

and activity. Within this thesis, participants appeared to manage the medications according to their symptoms. They had devised individual strategies to help themselves to manage on a day to day basis, so what they may use on one day they may not need another. Participants reported taking AO with them and only using it if they needed it. There is a growing body of evidence around how patients do manage their conditions and how they use interventions to help them. Avdula et al (2012) argued that patients with chronic disease actively seek to self-manage in the light of considering the benefits and costs of every intervention. COPD is also known to be a variable condition with patients having good days and bad days (Kanervisto 2010). Lopez-Campos (2010) suggested that this symptom variability may lead to COPD patients deciding what medications they need for that day within a few hours of waking. Subjective breathlessness has been described as the most frightening symptom associated with COPD, both by the participants in this study and by other research (Raghavan et al 2011). Matching medications according to symptoms has been recorded in other research in COPD (Bourbeau and Bartlett 2008), and developing individualised strategies to manage their condition and integrating this into daily life has been evidenced by several studies (Chen et al 2008, Seamark et al 2004).

Other research both in COPD and other chronic conditions has promoted the importance of education in enabling patients to self-manage medicines effectively (Takemura et al 2011; Charles et al 2010; Scott et al 2011). Visse et al (2010) suggested that healthcare professionals talk about education as a means of improving self-management because it shifts the emphasis of management onto the patient. As reported above, the information provided to participants in this thesis was comprehensibly lacking.

Recent research in chronic conditions, where the patient is self-managing on a day to day basis, has highlighted the need for more patient involvement in any medical decision making and has suggested a 'patient-centred approach' (Ekman et al 2011). Bertakis and colleagues (2011) suggested that patient-centredness moves away from delivering instructions to the patient, to place an emphasis on the interaction between patient and the healthcare professional to reach a shared understanding of the condition, how it impacts uniquely on the patient, and empowering the patient to share

the responsibility of decision making. One of the cornerstones of this approach is to ensure the patient has comprehensive information about their condition and any intervention, to allow them to make informed and shared decisions (Aujoulat 2007). This puts the emphasis on understanding the patient's perspective and how those perspectives and views on their condition may change over time. Research into a patient-centred approach in chronic conditions has uncovered other influences which had not been previously identified as important. The healthcare professional-patient interaction can influence adherence significantly in that the patient's perception of the actual competency of the healthcare professional could affect how a patient uses an intervention (Sun Soo et al 2004). If the healthcare professional does not believe in the value of AO it is possible to see that this could be easily transmitted to a patient.

10.5.2. Adherence and self-management

The concept of adherence is derived from the view of healthcare professionals, who highlight what they see as the results of non-adherence; potential deterioration in condition, poor symptom control, and hospital admission (Vestbo et al 2009). But Bissonnette (2008) argued that if the patient received all the information and still decided on a different course of action then have healthcare professionals any right to label that non-adherence? Currently AO is removed if the patient's usage suggests non-use or non consumption of oxygen outside the house (depending on the recorded number of cylinders or dewars delivered over a set period).

Within COPD, AO is seen as an intervention that people self-manage. However in this researcher's view healthcare professionals, currently assess for AO sub-optimally. Inconsistent and often misleading advice is given (or not), and then patients are expected to use their AO according to our guidelines for adherence, which are not documented but are decided by hours of oxygen use outside the house. Research around patient-centredness could potentially improve the AO assessment and prescription. Identifying and understanding the patient's strategies for medication use around their perception of symptoms, including the use of AO as a safety blanket when they are away from home, is very important. This could all help the healthcare professionals help the patient self-manage their AO.

The research underpinning AO prescription is weak, because an acute response to oxygen does not predict use at home but the same assessment guidelines are re-applied by clinicians sitting on Boards deciding guidelines. The guidelines relating to AO are currently inadequate because they do not stress using repeated baseline tests, so patients who may be not helped by supplementary oxygen may still be prescribed it. There are no guidelines on specifics of AO usage, so individual prescribers are giving different advice in different areas of the UK, some of which is not informative or helpful. Patients with COPD are being encouraged to self-manage their condition so they are given AO, if they need it, to help them do so. However when they put this into action and try and self-manage, they may lose their prescribed AO because the healthcare professional does not think they are using it 'enough'. It is hard to envisage any other powerful drug being so minimally scrutinised before being prescribed to a patient.

Healthcare professionals are often as confused as the patients. The lack of guidance on potential benefits and usage has, in this researcher's opinion, led to prescribers considering AO as an add-on and not as a useful intervention. This mixed attitude towards AO has been endorsed by the quantitative research studies suggesting that AO has no benefit or is not used by patients who receive it. Lack of guidelines for the prescribers has led to lack of guidelines for the patient receiving AO.

10.5.3. Summary of this discussion

Participants in this thesis described how their perceptions of advantages and disadvantages influenced how they used their AO. Similar findings have been found in other research in to chronic conditions, where patients self-managing long-term conditions manage their prescribed interventions on symptoms and fear of symptoms. In this thesis subjective dyspnea was an important symptom. Participants self-managed around this pervasive problem. This thesis uncovered unique findings around the extensive role of the carer in the management of the AO equipment, lack of information around the use of AO, and the large degree of embarrassment felt by participants.

Adherence to an intervention is a concept which is being used more within the current health economy to provide the basis for withdrawing services from patients (IMPRESS 2010). This researcher would argue that AO is a special case since healthcare professionals do know that acute response to oxygen does not predict home use and we are unable at the moment to identify patients who would benefit at home. The present existing prescription guidelines do not emphasise the importance of more basic walking tests. We do not appear to provide adequate information or education on AO for the patient to make a reasonable self-management choice and if they do use AO as a safety blanket they are in danger of having their AO removed even if it would prevent a hospital admission. The concept of adherence in AO is therefore currently misleading.

10.6. The contribution of this thesis

The research undertaken for this thesis provides a unique insight into how participants viewed their AO, and how their perceptions influenced their use of AO. Prescribing healthcare professionals need to why they are prescribing AO and have more understanding of the patient's reasons for using or not using the intervention and this thesis can hugely contribute to that process. This research makes an important and unique contribution to the existing knowledge about using AO because it:

- Exposes that the research on which the guidelines for AO prescription rests is un-evidenced. Attention has to be drawn to inadequate prescription assessments and the need to identify physiological benefits in a baseline test, which may be more complicated than just a field walk test. Inappropriate prescription of AO may itself contribute to lack of use by the patient.
- Highlights the need for a more patient-centred approach to AO assessment and prescription. This should include the patient's view of the intervention, how it could help and the role of the family in managing the equipment.
- Highlights that patients use AO as a security blanket in the same way they are encouraged to use rescue antibiotics and steroids.

- Describes that a large percentage of participants are affected by perceived stigma and highlights the need for healthcare professionals to help patients to develop strategies to overcome this. Stigma influences patients not to use their AO equipment in the community.
- Identifies the importance of the carer in the management of AO. Without the help of available carers, some participants would be unable to use their prescribed AO at all.
- Provides healthcare professionals working in the AO area with a greater understanding of AO use from the patient's and carer's perspective, and how those perceptions impinge on their use of AO. Healthcare professionals need to understand the intervention from the view of the patient and their family, not as an isolated intervention.

10.6.1. Adding to the existing knowledge

This thesis adds to the existing knowledge about AO for different groups.

For healthcare professionals it highlights:

- The gaps in our knowledge around assessment and poor prescribing actually affecting adherence to the intervention.
- The importance of engaging patients in active discussions about their AO prescription and how/why it should be optimally managed.
- The lack of consistent information and instructions for use of AO at home.

For patients it highlights the need for:

- Better instructions on AO use and usefulness, including dependency.
- Involvement of discussions with the family around management of the equipment.
- Discussions about getting the best use of AO with variable symptoms.
- Discussions around how to manage AO if no carers are available.

For carers it highlights

- The importance of carers and their role in managing the equipment, if they are able.

- The role of AO in managing COPD in the patient.

10.7. Judging the quality of this work

In line with the mixed methods approach adopted by this thesis, the credibility of each aspect of the qualitative and quantitative pilot research studies were presented separately in Chapter six (qualitative phase) and Chapter nine (quantitative phase). The results of both phases have been incorporated and discussed together above. The researcher would argue that the integration of the findings from both phases does provide a fuller understanding of the area under study. Uncovering the same beliefs in the both phases, enabled the researcher to suggest that these beliefs are more widely held than by just one cohort of participants. The quantitative pilot study, although undertaken with a small sample size, was undertaken in participants four years after the qualitative study with different participants in different geographical areas who had been prescribed different types of AO. This does support the credibility of this mixed methods research approach, the quantitative phase enhanced the findings from the qualitative phase by confirming the qualitative findings in a different cohort of participants. The results of both phases are complimentary and this establishes the integrative efficacy as suggested by Teddlie and Tashakori (2009) (Chapter four) as a marker of credibility in mixed methods research.

Additionally undertaking both a qualitative study and quantitative phase enhanced the findings of the qualitative study by making the thesis findings more generalisable. Without the combination of the two phases of this thesis, the findings would be diminished, because the findings from the qualitative phase may be apparent in only that one group. The quantitative phase findings support the concept that the perceptions of the participants are more generalisable. The combination of the two sets of findings supports the idea of interpretative correspondence, where a study is enhanced by the use of a mixed methods approach.

10.7.1. Strengths and limitations of this research

As with any research there are strengths and limitations in this thesis which may have affected the interpretation of the findings:

Strengths

- This research contributes to the empirical knowledge already around AO by exploring and uncovering participant's use of AO.
- The researcher developed a substantive grounded theory from the qualitative findings to explain the area under study.
- The researcher utilised a mixed-methods approach to enable the use of the strengths of both methods to off-set the weaknesses of the other.
- The researcher developed a unique questionnaire to assess the presence of constructs found in the qualitative study in a different cohort of participants.
- The researcher employed an extensive cognitive interviewing study to test the questionnaire and a judges' panel to assess any changes made, which help to improve the validity of the questionnaire.
- Similar beliefs were found in a different cohort of participants in a different pilot study suggesting that the perceptions of participants with AO are generalisable.

Potential Limitations

- The qualitative study was part of a larger funded study looking specifically designing new ambulatory oxygen equipment for COPD patients. This may have biased the researcher to look for problems rather than benefits. However there was a considerable degree of agreement amongst participants on both the problems and the benefits cited. This was reflected in the speed at which categories identified by participants were saturated. The three negative cases of actually using AO out in the community were highlighted.
- Participants were prescribed oxygen from the same respiratory centre, different consultants on discharge from hospital and from different GP's. This implies that participants, who had been prescribed oxygen from the same respiratory centre, may have had similar experiences. Over the period of the four years between the two

studies, prescribing personnel and practices would have changed and this would strengthen the findings from this research. However, patients from other respiratory centres may have had other experiences and received different information, which may have affected the study findings.

- The researcher was not experienced in either research methodology when the different phases were undertaken. A more experienced researcher may have uncovered different findings. During the course of this research the researcher did take part in extensive training in research approaches and techniques which would have positively affected the design and completion of this thesis. More experienced researchers (supervisors) did oversee and advise on the research which would have helped to improve the quality of the work undertaken.
- The qualitative research used an interview approach, which may have biased the research in favour of those participants who were verbally able and could self-report
- The involvement of local Breathe Easy groups for the final pilot questionnaire may have been detrimental in that the researcher could not recruit more than 13 participants. This may be because the attendees had heard about the study so many times that they had lost interest in participating. However, BE members were keen to be involved so lack of recruitment may be due to the time of year and potential participants being on holiday and that there were fewer BE meetings over the summer.
- The final pilot study pack inviting participants to contact the researcher may have been problematic in two ways. The researcher had no control over whether it was actually delivered or not, or to whom the chairman gave the pack. The whole study has been with people with COPD and although the researcher believes the responders were from participants with COPD some may not have been. Clinically people with AO prescribed because of another lung condition, have in the researcher's clinical experience, behaviour in a similar way as people with COPD, so practically the researcher believes there would be no difference, but it would mean that people who did not have COPD were not excluded from the study. every effort was made to only involve people with a known diagnosis of COPD.

- The researcher analysed and coded the data in both studies. A different qualitative researcher confirmed the categories. The presence of the judges' panel in the CI study meant that changes were discussed with a more experienced group to ensure changes were needed. In the quantitative pilot phase the researcher coded the questionnaire alone. This means in the pilot study the researcher may have coded incorrectly or have subconsciously biased the results, which may have affected the study findings.

10.7.3. Researcher and clinician

This thesis was undertaken by a clinician working with patients with COPD. Maintaining an objective stance was part of the researcher's epistemological approach to this research, and the difficulty in maintaining that role at all times during the qualitative study is discussed in Chapter Five. It was difficult as a clinician to talk to patients about the problems with their AO equipment without wanting to suggest improvements or different strategies. Particularly as a clinician she was aware that none of the participants would probably be alive to enjoy the benefit of this research. As a researcher the role was easier, because uncovering this information could lead to improvements in care and equipment in the future. Uncovering the lack of information and instructions imparted to participants has improved the clinician's clinical practice by developing comprehensive education material for these patients.

10.7.4. This PhD as a journey for the researcher

This body of work has taken six years to complete and therefore represents a considerable journey for the researcher. During this time clinical practice has changed, but undertaking this work has allowed the researcher to critically assess how these changes have affected the prescription of AO. Pressures on the NHS change all the time and this work has emphasised strongly for the researcher the need for evidence based practice which is properly disseminated and understood by clinicians working in isolation. The need for guidelines to emphasise that that is what they are, guidelines, not immutable laws handed down from committees. On a more personal note this research process has given the researcher time to reflect on her approach to research and her philosophical approach. At the time of starting this work the researcher was completely unaware of the need to have an epistemological approach to research and

discovering she had an objective view of the world whilst wanting to perform a qualitative study appeared to be problematic in a university world, where qualitative work was being taught from a co-constructionist viewpoint. The researcher has explored and wavered between many epistemological positions over time but, with the help of her supervisors was able to understand that epistemological positions were just views, and not constricting silos that must be followed. The researcher has found her niche as a critical realist, an epistemological position which allows for an objective view of a social process.

10.8. Future research

This thesis underlines the need for further research in the assessment of prescription of AO in COPD. The accepted guidelines need to be challenged and clinicians should accept the need for further definitive research into the benefits of AO, and how to assess patients who may benefit from this intervention. Further research is needed to establish better guidelines on usage of AO. For example if further research established that the benefit of AO is to reduce pulmonary hypertension during exercise, then what should a patient be told to maximise the benefit of AO in everyday life.

The importance of the carers and their influence on the use of AO has been highlighted throughout this thesis. Further research on this aspect of self-management behaviour would be invaluable to healthcare professionals. Further research is needed to establish what kind of information would patients like to receive and how could that be delivered to be most effective. Within the qualitative phase participants spoke about the need for more information, but did not specify what that might be. Further research is needed to explore this more fully.

This work has highlighted the apparent lack of information received by patients. As part of acquiring some understanding of what people were being told, the researcher visited four different oxygen assessment centres and collected their AO patient information. The information imparted in these leaflets was very different, ranging from;

A. One leaflet which suggested that the patient should “*go out after finishing your 15 hours of oxygen (LTOT)*” –so did not mention the use of AO in allowing the patient to fulfil their 15 hours of oxygen whilst maintaining outside activities

B. One leaflet which said that AO “*will definitely improve your breathlessness*” – which may not be correct if the patient is breathless due to low exercise tolerance, or anxiety or air pollution

C. One of leaflet saying “*use AO as needed*”, so not re-enforcing specific times, flow rates or situations e.g. walking

The effect that different information has on AO use is another area for future study. Future research in this area could involve a systematic review of the information currently available to patients, highlighting the strengths and weaknesses. Trials of information provision in different formats could increase understanding of the most effective method to affect oxygen usage and behaviour.

On a personal level the researcher wishes to go forward and undertake further studies based on her developed questionnaire, to answer the question posed in section 8.2 (asking whether the findings from phase one generalisable to a wider population). It is also intended to make use of the questionnaire to develop a more predictive model of AO use, to enable prescribers to identify and resolve potential barriers to AO use at assessment. Research also needs to consider use of psychologically focused explorations into how confident patients are to use their AO, and investigate what may improve their confidence to use this intervention.

Further research into the understanding of healthcare professionals around supplementary oxygen prescription and how COPD patients self-manage, would be an invaluable asset in the changing NHS landscape. Understanding how patients with chronic disease and their families manage those conditions should be a fundamental part of prescribing such a potentially invasive intervention.

This thesis has been developed against a background of significant change in the NHS. Qualified community staff will be involved in assessing, prescribing and re-

assessing AO in the community. This is an opportunity to improve patient oxygen services. Therefore healthcare professionals need to understand the reasons why patients and their carers decide to use AO or not use AO. They need to engage the patient as an active partner in the prescription of AO and understand how that affects the patient's self-management of their condition. They need to understand how the patient's outlooks may change as the condition progresses and support the patient's AO prescription accordingly. They need to understand that breathlessness is a devastating symptom for patients and their carers and to understand how to support people with COPD to live optimally.

This research also highlights the failure of a system. AO may be a very useful intervention in the correctly identified patient group. However, the current assessment and prescribing system is based on un-evidenced guidelines which have been shown to be unable to identify those who would benefit from AO. The research exploring the effects of AO are based on the same un-evidenced guidelines. If the patient appears to fulfil the current criteria for prescription, there is no certainty that prescription will translate into use at home. The lack of evidence based guidelines translates in to a lack of appreciation for AO in healthcare professionals and this translates into a lack of comprehensive patient education on the advantages and usage of an AO system. The system fails to acknowledge the importance of AO as a 'safety blanket' for patients but actively removes the intervention if the patient is not viewed as using AO according to an adherence level set by healthcare professionals and health economic pressures.

10.9. Concluding remarks

This research set out to understand the reasons people have for using or not using their prescribed AO. A grounded theory qualitative phase was used to uncover the processes underlying the use of AO and peoples' perceptions of it. The second phase developed the questionnaire and the pilot phase uncovered that these perceptions were found in a different cohort of COPD patients with prescribed AO. However how patients use their AO outside the home and how healthcare professionals view that use is problematic. The implication in the word 'adherence' is that it is the patient who is at fault, but this research demonstrates that healthcare professionals have failed to understand how participants make decisions around why and how they use their AO.

More research is needed to identify patients who would benefit from AO. More research is needed to firmly establish the benefits of AO and the results effectively disseminated to prescribing clinicians. Clinicians themselves need more understanding of the assessment and prescription of AO as an intervention. Healthcare professionals and commissioners need to understand that actual use may not reflect the importance of AO as a safety mechanism as part of a patient's self-management. Disseminating the findings of this research will influence the future prescription of AO, and ensure health professionals, patients and carers can be actively involved in understanding and optimally using this useful intervention.

Appendices

Appendix 1: LREC approval for Qualitative Study



**ISLE OF WIGHT, PORTSMOUTH & SOUTH EAST HAMPSHIRE
RESEARCH ETHICS COMMITTEE**

DC/HPH
19 July 2006

1ST Floor, Regents Park Surgery
Park Street, Shirley
Southampton
Hampshire
SO16 4RJ

Tel: 023 8036 2863
Fax: 023 8036 4110

Email: GM.E.hio-au.SEHREC@nhs.net

Mrs Elizabeth Arnold
Physiotherapist
5 Cremyll Close
Stubbington Close
Fareham
Hants
PO14 2PN
UK

Dear Ms Arnold

Full title of study: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)?
REC reference number: 06/Q1701/61

Thank you for your letter of 05 July 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for other Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application	5.1	16 May 2006
Investigator CV		27 April 2006

An advisory committee to South Central Strategic Health Authority

Investigator CV	Dr Anne Bruton	27 April 2006
Investigator CV	Dr Bridget Dibb	08 May 2006
Protocol	2	01 July 2006
Covering Letter		09 May 2006
Interview Schedules/Topic Guides	1	17 March 2006
Letter of invitation to participant	1 - Individual Recruitment	27 March 2006
Letter of invitation to participant	1 - Focus Group	27 March 2006
GP/Consultant Information Sheets	1	27 March 2006
Participant Information Sheet: Focus Groups Part 2	1	27 March 2006
Participant Information Sheet: Focus Groups Part 1	1	27 March 2006
Participant Information Sheet: Focus Groups	2	01 July 2006
Participant Information Sheet: Individual Interviews	2	01 July 2006
Participant Consent Form: Focus	2	01 July 2006
Participant Consent Form: Interviews	2	01 July 2006
Response to Request for Further Information		05 July 2006
Focus group recruitment letter	1	27 March 2006
Collaborative Letter		27 March 2006

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1701/61	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project

Yours sincerely

Mr David Carpenter
Chair

Email: GM.E.hio-au.SEHREC@nhs.net

Appendix 2: R & D approval for Qualitative Study

Portsmouth Hospitals NHS Trust

Mrs E Arnold
Physiotherapist
5 Cremyll Close
Stubiington Close
Fareham
Hants
PO14 2PN

Portsmouth NHS R&D Consortium
R&D Office
1st Floor Gloucester House
Queen Alexandra Hospital
Southwick Hill Road
Cosham, PO6 3LY
Tel: 023 9228 6236
Fax: 023 9228 6037
www.port.ac.uk/research/nhs

24th July 2006

Dear Mrs Mayhew-Arnold

Re: COPD: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease.

MREC No: N/A LREC No: 06/Q1701/61 R&D No: PHT/2006/07ST

I have received confirmation that the above study has been processed through the Portsmouth NHS R&D Office. The Office has checked that the study has been subject to a peer review, a cost and funding review, and has received full ethical approval. On behalf of Portsmouth NHS R&D Consortium I have therefore signed off the study under the remit of 'SSA exempt' and the above named project may now commence, in accordance with the agreed protocol, [however, please note the following conditions of this approval:]

As Chief Investigator for the study, you should ensure that you and your team are fully aware of your responsibilities under the National Research Governance Framework for Health & Social Care (Dept Health, March 2005) and other professional codes of good conduct. You can access the Framework from the following web address, <http://www.doh.gov.uk/research>, but should you find yourself unsure of its requirements please do not hesitate to contact the R&D Office for support.

As this study is ongoing after April 2004, the University of Southampton will act as your official Research Sponsor.

I wish you well with your project

Yours sincerely

Professor Ken Shaw,
R&D Director
Portsmouth Hospitals NHS Trust

Appendix 3 University of Southampton Sponsorship



**University
of Southampton**

Tel: +44 (0)23 80598848/9

Ref: RSO 4327

Elisabeth Arnold
School of Health Professions and Rehabilitation Sciences
Building 45
University of Southampton
Southampton
SO17 1BJ

27 April 2006

Dear Elisabeth

Project Title: What factors influence adherence to portable oxygen systems in patients with chronic obstructive pulmonary disease (COPD)?

I am writing to confirm that the University of Southampton is prepared to act as sponsor for this study under the terms of the Department of Health Research Governance Framework for Health and Social Care (2001).

The University of Southampton fulfils the role of research sponsor in ensuring management, monitoring and reporting arrangements for research.

I understand that you will be acting as the Principal Investigator responsible for the daily management for this study, and that you will be providing regular reports on the progress of the study to the School on this basis.

I would like to take this opportunity to remind you of your responsibilities under the terms of the Research Governance Framework for researchers, principal investigators and research sponsors. These are included with this letter for your reference. In this regard if your project involves NHS patients or resources please send us a copy of your NHS REC and Trust approval letters when available.

Please do not hesitate to contact me should you require any additional information or support. May I also take this opportunity to wish you every success with your research.

Yours sincerely

Dr Martina Dorward
Research Governance Manager

cc. File
Ruth McFadyen
Supervisor/s: (if applicable)

Legal Services

University of Southampton
Highfield
Southampton
SO17 1BJ United Kingdom

Tel +44 (0)23 8059 4684
Fax +44 (0)23 8059 5781
Email legalservices@soton.ac.uk

Appendix 4 University of Southampton Insurance**University
of Southampton****Finance
Department****| Memorandum****From:** Ruth McFadyen**To:** Elisabeth Arnold**Ext:** 22417**Dept:** School of Health Professions and
Rehabilitation Sciences**E-mail:** hrm@soton.ac.uk**Date:** 11 April 2006

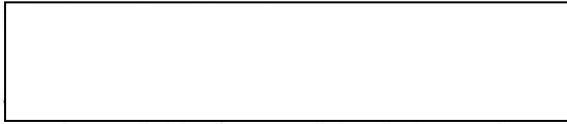
Reference: HRM/GFT/4327**Professional Indemnity Insurance****Project No:** TBA**What Factors Influence Adherence to Portable Oxygen Systems in
Patients with COPD**

Thank you for forwarding the completed insurance questionnaire for this project.

Having taken note of the information provided, I can confirm that this project will be covered under the terms and conditions of the above policy, subject to written consent being obtained from the participating volunteers and the project receiving Ethics Committee approval.

Please forward a copy of the Ethics Committee approval letter as soon as it is to hand to complete the insurance placement. Receipt of the letter will activate the insurance and the project may not commence prior to this.

Ruth McFadyen
Insurance Services Manager

Appendix 5: Participant Invitation Letter

Appendices

Portsmouth Hospitals 
NHS Trust

Respiratory Centre
Trafalgar House
Queen Alexandra Hospital Portsmouth
02392 286665

Dear

I am writing, on behalf of a researcher, to you to ask if you would be interested in taking part in a research study on portable oxygen systems and their use by patients with Chronic Obstructive Pulmonary Disease (COPD). The study is designed to look at why patients choose to use or not use their portable oxygen systems. We hope this may give us in the healthcare professions a better understanding of what is important to patients using portable oxygen.

Before you decide if you would like to participate or not, please read the attached information sheet which gives you more details on the study. Please feel free to discuss this with family or friends. If you do require any further information please phone the number above, and the researcher Lis Arnold, will ring you back.

If you would like to participate in the study, please fill in the form below and send it back to us in the envelope enclosed, and the researcher will phone you directly to make an appointment to visit you at home.

Thank you for reading this letter

Respiratory Nurse Specialist

Name

Address

Appendix 6: Participant Information Letter



School of Health Professions & Rehabilitation

Professor Roger Briggs	Head of School
University of Southampton	Tel +44 (0)23 8059 2142
Highfield	Research Office +44 (0)23 8059 4791
Southampton	Fax +44 (0)23 8059 4792
SO17 1BJ	Web www.sohp.soton.ac.uk/sohp/
United Kingdom	

Patient Information Sheet for Individual Interviews Part 1

Study title: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)?

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- **Part One** tells you the purpose of the study and what will happen if you decide to take part.
- **Part Two** gives you more detailed information about how the study is being conducted.

Please ask us if you require more information or have any questions.

The purpose of this study

Since February 2006, portable oxygen has become more widely available to people who need oxygen when they are moving around. However we know from other research that some people who have portable oxygen systems do not use them. The aim of this study is to find out why people like you decide to use your portable oxygen or not. This is to help us understand the factors that make portable oxygen difficult or easy to use. The information we gather may help us design better systems in the future.

Why have I been chosen?

We would like to speak to people who have portable oxygen systems at home. You have been approached because we believe you have a portable oxygen system. About 30 other patients who have portable oxygen at home will also be invited to participate in this study.

Do I have to take part?

This research is entirely voluntary. If you decide you want to take part please complete the form at the bottom of the accompanying letter and the researcher will contact you. You are still free to withdraw from the study at any time without giving a reason. Please be assured that any decision to withdraw will not affect the standard of care you receive either now or in the future.

What will happen if I take part?

The researcher will contact you and make an appointment to visit you at your home. She will ask you to sign a consent form and show you a list of likely questions. With your permission she will audio-tape the interview which will take approximately one hour. The questions will mainly be about your oxygen system and what you think of it, how often you use it, what you like or don't like about it.

What are the benefits of taking part?

There are no direct benefits to you personally from participating in this study. We hope that finding out more about your views on portable oxygen systems will help us find ways to make them easier to use for all patients.

Will my taking part in this study be confidential?

Yes. All information gathered in this study will be confidential. The details are included in Part 2.

This completes part 1 of the information sheet. If you are interested and considering participation please read the additional information in part2 before making any decisions. Thank-you



School of Health Professions & Rehabilitation

Professor Roger Briggs	Head of School
University of Southampton	Tel +44 (0)23 8059 2142
Highfield	Research Office +44 (0)23 8059 4791
Southampton	Fax +44 (0)23 8059 4792
SO17 1BJ	Web www.sohp.soton.ac.uk/sohp/
United Kingdom	

Patient Information Sheet for Individual Interviews Part 2

Study title: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)?

What happens if I don't want to carry on with this study?

You can withdraw from this study at any time, whether you have signed the consent form or not. You do not have to give any reason for deciding to withdraw and be assured that any withdrawal will in no way affect the health care you may receive.

What if there is a problem?

If you have concerns about any aspect of the study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the hospital.

Will my taking part in this study be confidential?

Any information you give as part of this study will be confidential. The interview tapes will be anonymised so you cannot be identified and all data will be handled, stored, processed and destroyed in accordance with the Data Protection Act 1998 and the Research Governance guidelines laid down by the University of Southampton.

Involvement of your GP

If you decide to proceed then, with your consent, your GP will be sent a letter telling him/her about the study and that you have agreed to participate.

What will happen to the results of the study?

The results of this study will be written up in the form of a report and form part of the researcher's doctoral thesis. Summarised results may also be presented to healthcare professionals and published in scientific journals. However you will not be able to be personally identified in any report or publication.

Who is funding this research?

The Department of Health and the University of Southampton are funding this research.

Who has reviewed this study?

The Isle of Wight, Portsmouth and South East Hampshire Local Research Ethics Committee and the University of Southampton have reviewed this study.

If you wish to take part in this study please complete and return the form on the accompanying letter and the researcher will contact you.

Thank-you very much for taking the time to read this Information Sheet.

Appendix 7: Semi-Structured Interview schedule

Semi-Structured Interview Schedule

How long have you had a problem with your chest?

How does it affect your life?

How long have you had oxygen?

What were you told about oxygen?

Prompt: about how to use it/how it would help?

Prompt: who prescribed it? Why?

How often do you go out?

Prompt: how do you do that?

Do you take your oxygen with you? How?

If you could change your oxygen system would you change it?

How would that help?

Is there anything else you would like to say about your AO?

Appendix 8: Consent Form


School of Health Professions & Rehabilitation

Professor Roger Briggs	Head of School
University of Southampton	Tel +44 (0)23 8059 2142
Highfield	Research Office +44 (0)23 8059 4791
Southampton	Fax +44 (0)23 8059 4792
SO17 1BJ	Web www.sohp.soton.ac.uk/sohp/
United Kingdom	

Study number:
Patient Identification Number for this trial:

INFORMED CONSENT

Title of Project: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)?

Name of Researcher: Lis Arnold

1. I confirm that I have read and understand the information sheet dated
(version) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at
any time, without giving any reason, without my medical care or legal rights being
Affected ☐
3. I understand that my GP will be informed about my participation in this study. ☐
4. I understand that all data will be anonymised and stored according to the
data protection policy laid down by the University of Southampton ☐
5. I agree that this interview may be audio-recorded ☐
6. I agree to take part in the above study. ☐

_____ Name of patient	_____ Date	_____ Signature
--------------------------	---------------	--------------------

_____ Name of Person taking consent (if different from researcher)	_____ Date	_____ Signature
--	---------------	--------------------

_____ Researcher	_____ Date	_____ Signature
---------------------	---------------	--------------------

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Appendix 9: Amended Ethics: consent for 2nd interview

National Research Ethics Service
ISLE OF WIGHT, PORTSMOUTH & SOUTH EAST HAMPSHIRE
RESEARCH ETHICS COMMITTEE

MFK

1ST Floor, Regents Park Surgery
 Park Street, Shirley
 Southampton
 Hampshire
 SO16 4RJ

11 June 2007

Mrs Elizabeth Arnold
 Physiotherapist
 Stubbington Close
 Fareham
 Hants
 PO14 2PN

Tel: 023 8036 2853
 Fax: 023 8036 4110

Email: scsha.SEHREC@nhs.net

Dear Mrs Arnold

Study title: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)?
REC reference: 06/Q1701/61
Amendment number: Version 2
Amendment date: 02 May 2007

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 11 June 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	Version 3	02 May 2007
Participant Information Sheet: Information Sheet 2 (for a second individual interview)	Version 1	02 May 2007
Participant Information Sheet: Information Sheet for Individual Interviews Part 2	Version 3	
Participant Information Sheet: Information Sheet for Individual Interviews Part 1	Version 3	02 May 2007
Notice of Substantial Amendment (non-CTIMPs)	Version 2	02 May 2007

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Elisabeth Arnold

Appendices

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

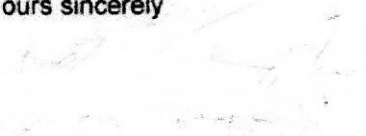
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1701/61:

Please quote this number on all correspondence

Yours sincerely



Mrs Melodie Kreindler
Committee Co-ordinator

E-mail: scsha.SEHREC@nhs.net

Enclosures List of names and professions of members who were present at the meeting
and those who submitted written comments

Copy to: *Dr Martina Dorward, Research Support Unit*

Appendix 10: Participant information sheet for 2nd Interview

 University of Southampton	School of Health Professions & Rehabilitation Sciences	
	Professor Roger Briggs University of Southampton Highfield Southampton SO17 1BJ United Kingdom	Head of School <hr/> Tel +44 (0)23 8059 2142 Research Office +44 (0)23 8059 4791 Fax +44 (0)23 8059 4792 Web www.sohp.soton.ac.uk/sohp/

Patient information sheet for a second individual interview

Study title: what factors influence adherence to ambulatory oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)

You very kindly agreed to participate in this study and have already been interviewed.

Since you were interviewed, many other people who use an ambulatory oxygen system have also been interviewed and given us their views on their system. This has enabled us to build up a picture of the freedoms and the problems that an ambulatory system seems to give to the people who use them.

The reason we are contacting you again is ask your permission to interview you again, as we would like to share with you the information we have gathered so far and discover whether or not it accurately represents your views on ambulatory oxygen.

If I wish to participate what should I do?

Fill out the form on sheet two included and send it back to the researcher in the pre-paid envelope. She will contact you to arrange a convenient time for the interview to be held in your own home. She will send you a summary of the findings for you to look at before the interview takes place.

What happens if I don't want to do this second study?

You do not have to give any reason for deciding not to do a second interview and be assured that any withdrawal will in no way affect the health care you may receive.

What if there is a problem?

If you have concerns about any aspect of the study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the hospital.

Will my taking part in this study be confidential?

Any information you give as part of this study will be confidential. The interview tapes will be anonymised so you cannot be identified and all data will be handled, stored, processed and destroyed in accordance with the Data Protection Act 1998 and the Research Governance guidelines laid down by the University of Southampton

Thank-you for your time in reading this information sheet



School of Health Professions & Rehabilitation

Professor Roger Briggs	Head of School
University of Southampton	Tel +44 (0)23 8059 2142
Highfield	Research Office +44 (0)23 8059 4791
Southampton	Fax +44 (0)23 8059 4792
SO17 1BJ	Web www.sohp.soton.ac.uk/sohp/
United Kingdom	

Patient Information Sheet for Individual Interviews Part 2

Study title: What factors influence adherence to portable oxygen systems in patients with Chronic Obstructive Pulmonary Disease (COPD)?

What happens if I don't want to carry on with this study?

You can withdraw from this study at any time, whether you have signed the consent form or not. You do not have to give any reason for deciding to withdraw and be assured that any withdrawal will in no way affect the health care you may receive.

What if there is a problem?

If you have concerns about any aspect of the study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the hospital.

Will my taking part in this study be confidential?

Any information you give as part of this study will be confidential. The interview tapes will be anonymised so you cannot be identified and all data will be handled, stored, processed and destroyed in accordance with the Data Protection Act 1998 and the Research Governance guidelines laid down by the University of Southampton.

Involvement of your GP

If you decide to proceed then, with your consent, your GP will be sent a letter telling him/her about the study and that you have agreed to participate.

What will happen to the results of the study?

The results of this study will be written up in the form of a report and form part of the researcher's doctoral thesis. Summarised results may also be presented to healthcare professionals and published in scientific journals. However you will not be able to be personally identified in any report or publication.

Who is funding this research?

The Department of Health and the University of Southampton are funding this research.

Who has reviewed this study?

The Isle of Wight, Portsmouth and South East Hampshire Local Research Ethics Committee and the University of Southampton have reviewed this study.

If you wish to take part in this study please complete and return the form on the accompanying letter and the researcher will contact you.

Thank-you very much for taking the time to read this Information Sheet.

Appendix 11: Example of open coding

Example of open coding:

Q right how are you on a day to day basis would you say

P its almost-pick a day and I'll pick you a style um, one day's good, one day's bad. Sometimes it's a great run of days, sometimes it's bad for a few days, there's no predicting it at all unfortunately. I mean I think the disease itself is of that nature, that you just cannot predict how you're going to feel on any particular day

P absolutely, and do you feel you can manage your disease yourself?

Q not personally, WE manage it but I say WE manage it 'cause without Mary I couldn't manage no

Q how long have you had oxygen in the house

P almost since, I think since 2004

Q ok and do you, how often did use that during the day

P again I'd probably say 3-4 times

Q and do you use it overnight?

Codes derived from text

Good days-bad days

No knowing how each day will be/unpredictable

Part of having COPD-unpredictability

Could not manage COPD alone manages with help

2+ years experience of oxygen

Appendix 12: Example of open coding and memoing

Transcript	Open coding	Memos
Q right how are you on a day to day basis would you say		What defines good days what defines bad days? Any relationship –does it depend on what you do or where you go or how you feel?
P its almost-pick a day and I'll pick you a style um, <u>one day's good, one day's bad</u> . Sometimes it's a great run of days, sometimes it's bad for a few days, there's <u>no predicting it at all</u> unfortunately. I mean I think the <u>disease itself is of that nature, that you just cannot predict how you're going to feel on any particular day</u>	Good days-bad days No knowing how each day will be/unpredictable Part of having COPD-cannot predict how you will feel tomorrow	Cannot predict if going to be a good or bad day- do you need to be able to predict what a day will be like? Does it make you feel less in control if you cannot predict or do you become resigned to not knowing what the day will be like? Is this different from the normal person?? What is this management, what part of the disease needs management? Does managing give more control? What role does wife play? Both in this together?
P absolutely, and do you feel you can manage your disease yourself?		
Q <u>not personally, WE manage it but I say WE manage it 'cause without Mary I couldn't manage no</u>	Could not manage COPD alone manages with help	
Q how long have you had oxygen in the house		
P almost since, I think since 2004	2+ years experience of oxygen	Old hand at oxygen? Or novice? 2 yrs of experimenting or as instructed?
Q ok and do you, how often did use that during the day		Better now?

Appendix 13: Memoing around selective coding

Memoing for selective coding

Open codes identifying

'Weight issues'

Open code: *'Cannot carry cylinder because of weight'*

(1, 194), (1, 249) (2, 185)
(3, 135), (3, 151) (4, 117) (5, 129)
(5, 151) (7, 137) (8, 87) (8, 120)
(9, 50), (9, 95), (9, 196) (9, 207), (10, 118) (10, 141), (11, 151) (11, 158), (13, 214), (15, 117) (16, 84), (16, 84) (16, 170), (17, 233) (19, 76), (25, 43), (25, 48) (25, 92), (25, 184), (26, 78), (27, 96), (27, 198)

Open code: *'cylinder is too heavy'*

(4, 129) (C 5, 155) (7, 192), (16, 129) (16, 170),

Open code: *'I could carry cylinder if necessary'*

(14, 160)

Open code: *'I can carry cylinder'*

(13, 111), (23, 108), (23, 119), (23, 159)

Participants feel they cannot carry weight of cylinder? Why?

Physical problem with Muscle weakness? Or have never done it? Is weight an actual physical barrier to lifting weight?? Seems to be an actual physical barrier to using the system?

So if they take it out with them WHAT DO THEY DO WITH AO??

Or is their inability to carry the system just an indication that they do not want to use AO? Or take it out with them?-is there any evidence of that in the study?

How many go out of the house on their own? What do they do?

Does carer always accompany them? In which case is not being able to carry the system a realisation that you cannot do everything on your own –more adjustment orientated, or does the carer presume responsibility in order to actually get on and get out of the house? both have to adjust to new situation/ or is the

No patient thought carrying system could be achievable despite good day /bad day

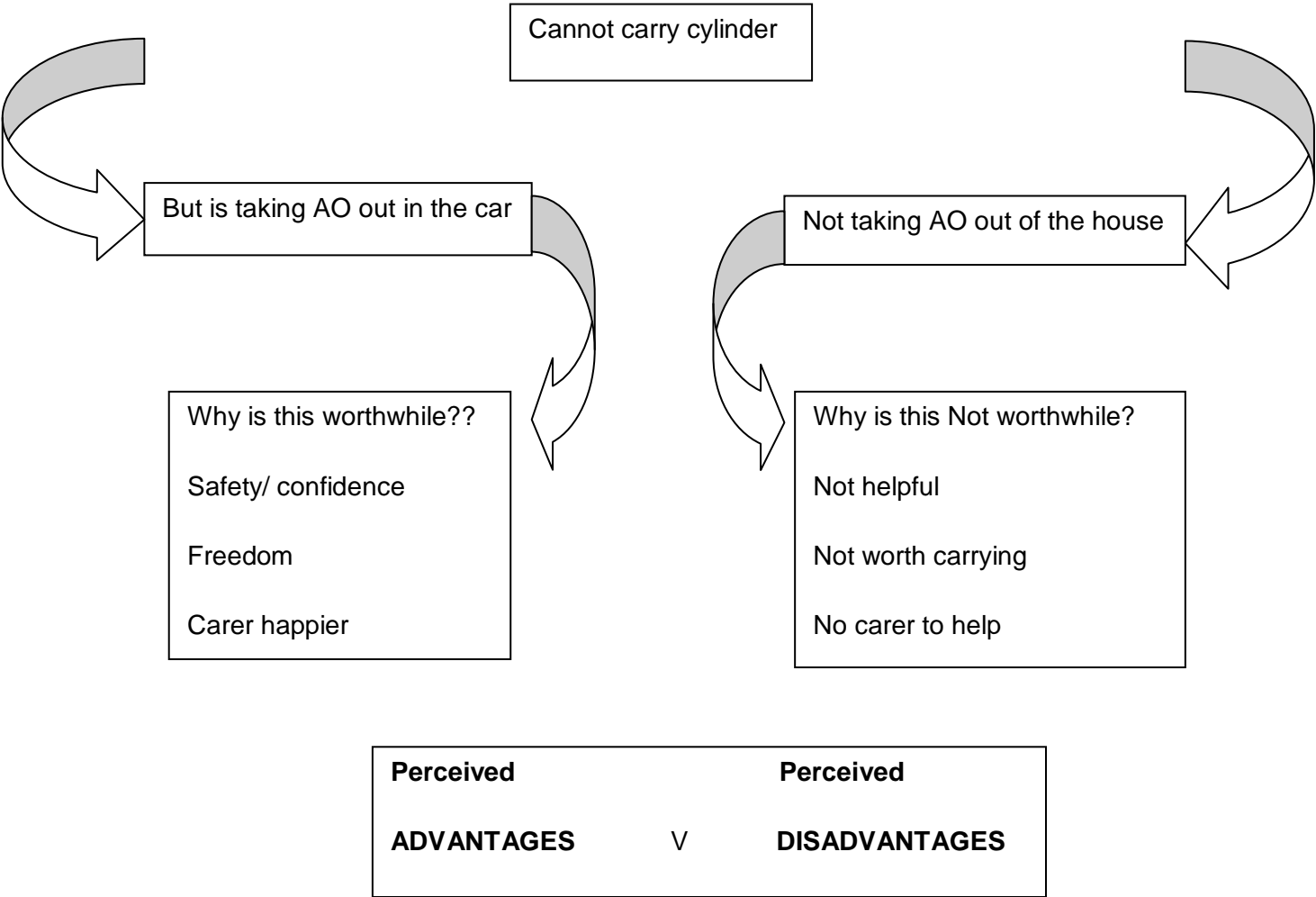
Were participants who did NOT think weight a problem actually taking AO out of the house?

But carer disagrees with this saying never carries it!

Single case: only one patient carrying and using AO out why? 13 lives alone so has to carry AO to her buggy. Only 23 carrying and using it out and about, Age when you get AO? Enables him to do something more?? His need informs wanting to use it but not physical ability to carry it, so he must be physically capable of carrying the weight and how does that differ from the others?

Core theme: weight of AO system is a physical barrier

Appendix 14: Memoing around formation of core category



UNIVERSITY OF
Southampton
School of Health Sciences

Name of Applicant	Liz Arnold
Title of Proposal	A study to pre-test a questionnaire on Portable Oxygen (PO) in participants with Chronic Obstructive Pulmonary Disease (COPD) using cognitive interviewing techniques
Name of Reviewer	Joy Conway
Reviewer's Signature	
Date review completed	25.02.10

Thank you for taking the time to complete this project review.
Please return the completed form via email to Sonia Bryant (sb13@soton.ac.uk)
/ Zena Galbraith (zg@soton.ac.uk),
Please also post the signed last sheet to Research & Enterprise Services Office,
School of Health Sciences, Building 67, University of Southampton, Highfield,
Southampton. SO17 1BJ

Appendix 16: Ethics approval for CI study



EO4/Oct 2008/ v1.0

Lis Arnold
School of Health Sciences
University of Southampton

8 June 2010

Dear Lis

Ethics Submission No: SoHS-ETHICS-2010-012
Title: Pre-testing a questionnaire using cognitive interviewing

I am pleased to confirm **full approval** for your study has now been given. The approval has been granted by the School of Health Sciences Ethics Committee.

You are required to complete a University Insurance and Research Governance Application Form (IRGA) in order to receive insurance clearance before you begin data collection. The blank form can be found at <http://www.soton.ac.uk/corporateservices/rgo/regprojs/whatdocs.html>

You need to submit the following documentation in a plastic wallet to Dr Martina Prude in the Research Governance Office (RGO, University of Southampton, Highfield Campus, Bldg. 37, Southampton SO17 1BJ):

- Completed IRGA Research Governance form
- Copy of your research protocol/School Ethics Form (final and approved version)
- Copy of participant information sheet
- Copy of SoHS Risk Assessment form, **signed**
- Copy of your information sheet and consent form
- Copy of this SoHS Ethical approval letter

Continued overleaf

Building 45
School of Health Sciences, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom
Tel: +44 (0)23 8059 7979 Fax: +44 (0)23 8059 7900 www.southampton.ac.uk/healthsciences

Appendix 17: UoS sponsorship and insurance

Ms Elisabeth Arnold
School of Health Sciences
University of Southampton
University Road
Highfield
Southampton
SO17 1BJ

RGO Ref: 7332

21 June 2010

Dear Ms Arnold

Project Title A Study to Pre-Test a Questionnaire on Portable Oxygen (PO) in Participants with Chronic Obstructive Pulmonary Disease (COPD) Using Cognitive Interviewing Techniques

This is to confirm the University of Southampton is prepared to act as Research Sponsor for this study, and the work detailed in the protocol/study outline will be covered by the University of Southampton insurance programme.

As the sponsor's representative for the University this office is tasked with:

1. Ensuring the researcher has obtained the necessary approvals for the study
2. Monitoring the conduct of the study
3. Registering and resolving any complaints arising from the study

As the researcher you are responsible for the conduct of the study and you are expected to:

1. Ensure the study is conducted as described in the protocol/study outline approved by this office
2. Advise this office of any change to the protocol, methodology, study documents, research team, participant numbers or start/end date of the study
3. Report to this office as soon as possible any concern, complaint or adverse event arising from the study

Failure to do any of the above may invalidate the insurance agreement and/or affect sponsorship of your study i.e. suspension or even withdrawal.

On receipt of this letter you may commence your research but please be aware other approvals may be required by the host organisation if your research takes place outside the University. It is your responsibility to check with the host organisation and obtain the appropriate approvals before recruitment is underway in that location.

May I take this opportunity to wish you every success for your research.

Yours sincerely

Dr Lindy Dalen
Research Governance Manager

Tel: 023 8059 5058
email: rgoinfo@soton.ac.uk

Corporate Services, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom
Tel: +44 (0) 23 8059 4684 Fax: +44 (0) 23 8059 5781 www.southampton.ac.uk

Appendix 18: Consent form for CI study**CONSENT FORM**

Study title: A study to pre-test a questionnaire on Portable Oxygen (PO) in participants with Chronic Obstructive Pulmonary Disease (COPD) using cognitive interviewing techniques

Researcher name: Elisabeth Arnold

Study reference:

Ethics reference:

Please initial the boxes if you agree with the statement(s):

I have read and understood the information sheet (date/version no.1) and have had the opportunity to ask questions about the study

☐

I agree to take part in this research project and agree for my data to be used for the purpose of this study

☐

I understand my participation is voluntary and I may withdraw at any time without my legal rights being affected

☐

I agree that the interview may be tape-recorded

☐

Name of participant (print name).....

Signature of participant.....

Name of Researcher (print name)

Signature of Researcher.....

Date.....

Appendix 19: Participant Information Sheet for CI study**Participant Information Sheet**

Study Title: A study to pre-test a questionnaire on Portable Oxygen (PO) in participants with Chronic Obstructive Pulmonary Disease (COPD) using cognitive interviewing techniques

Researcher: Elisabeth Arnold

We would like to invite you to take part in a research study. Before deciding to take part you need to understand what the study is about and what is involved. Please read this information leaflet carefully before deciding to take part in this research. Please feel free to discuss this others.

What is the research about?

This study is about asking people with COPD who have portable oxygen to read a questionnaire which has been designed to be sent to a larger national group of patients. Questionnaires are widely used to gather information but can be difficult to complete because of poorly worded or ambiguous questions. This study is designed to ask people to pre-read and comment on a questionnaire so that any possible errors in the questions can be corrected before it goes out to a larger group.

Why have I been chosen?

You are being asked to take part in this study because you have COPD and portable oxygen. The final questionnaire is designed to go to people with COPD and portable oxygen throughout the country, so it is important that the questionnaire is reviewed by people who have an understanding of the issues.

What will happen to me if I take part?

If you decide to take part the researcher will contact you to arrange an appointment to visit you at home. She will ask you to sign a consent form and then show you the draft questionnaire. She will ask you to read the questionnaire out loud, so that any questions (or answers) which are not clear will be highlighted. She may also ask you questions about the items on the questionnaire. With your permission the researcher may audio-tape the interview so that she can later check each question against all the comments that have been made. Once you have read the whole questionnaire, the researcher will leave, but will make another appointment to visit you again with the amended questionnaire, so that you can review any changes. It is thought that the interview will last up to one hour (less as the questionnaire is changed) and the interviewer may need to visit or telephone you 2-3 times in order to ensure the questionnaire is as error-free as possible.

Are there any benefits in my taking part?

There will not be any benefits to you personally from participating in this study apart from knowing that you have helped to develop an error-free questionnaire. The data gathered from the final version of the questionnaire will help to enhance the current knowledge we have about COPD people who use portable oxygen.

Are there any risks involved?

There are not envisaged to be any risks to you from taking part in this study

Will my participation be confidential?

Yes. All information gathered in this study will be confidential. Any audio-tapes will be anonymised so you cannot be identified. All data will be handled, processed, stored and destroyed according to the Data Protection Act 1998 and the Research Governance guidelines laid down by the University of Southampton.

What happens if I change my mind?

Nothing, you may withdraw from this study at any time, even if you have signed the consent form. Withdrawing from the study will not affect your legal rights or medical care.

What happens if something goes wrong?

In the unlikely case that you have a concern or complaint about this study, you should contact:

Susan Rogers (Head of Research and Enterprise Services)
Building 67

University of Southampton

Southampton SO17 1BJ

02380-597942

What happens to the results of this study?

The results of the study will be collated from the results of the final completed questionnaire. The results will be written up to form part of the researcher's doctoral thesis. Summarised results may also be presented to healthcare professionals and published in scientific publications. You will not be personally identifiable in any report. If you would like a copy of the results, please ask the researcher and she will arrange for a copy of the results to be sent to you.

Where can I get more information?

Please contact the researcher directly on the phone number below or contact

Dr. A. Bruton (Supervisor)

School of Health Sciences, Building 45

Highfield campus

University of Southampton

Southampton SO17 1BJ

02380 595283

What do I do if I want to take part?

Please contact the researcher, **Liz Arnold** either by speaking to her at the Breathe Easy meeting or **telephone: 000000000** and leave a message, she will return your call and organise a date to meet you at your home.

THANK YOU for taking the time to read this information sheet.

Appendix 20: Participant Introduction letter

Dear Breathe Easy member

We are looking to recruit people with COPD who have been prescribed portable oxygen, for a study we are undertaking.

The study we are undertaking is to pre-test a questionnaire before it is sent out to a larger number of participants. The questionnaire is designed to explore what people with COPD feel about their portable oxygen; what they feel are the advantages and disadvantages of their portable oxygen and how they cope with their oxygen every day. But we need volunteers to read the questionnaire and make sure it makes sense and has as few errors in it as possible.

If you take part in the study the researcher will visit you at home and get you to read through the questionnaire so that we can identify and correct any errors. The researcher will amend the questionnaire and then come and show you the corrected questionnaire so you can make further comments. So the researcher may come and visit you 2 or 3 times, each visit may last for about 1 hour.

If you would like to take part then please phone the researcher on and she will contact you about making an appointment to visit you at home.

Thank you very much

Appendix 21: Version 6 of the questionnaire (pre-CI study)**Questionnaire about Potable Oxygen use for people with Chronic Obstructive Pulmonary Disease (COPD)****Introduction**

This questionnaire aims to explore what people who have COPD think about their portable oxygen (the oxygen you take out of the house with you) and how they manage their portable oxygen when they do use it.

As you may know there is little knowledge about what people with COPD actually think about their prescribed portable oxygen and how useful it is. This questionnaire is designed to try and find out from you, someone who uses portable oxygen, how helpful portable oxygen is, and what you think are the advantages and disadvantages of portable oxygen you use.

This questionnaire is completely **ANONYMOUS**, so please feel free to answer the questions as truthfully as possible; the questionnaire cannot be traced back to you, and so cannot affect your treatment or prescription at all.

There is a section at the end of the survey which invites you to fill in your name and address if you wish to know the results of the survey, or would like to be considered for further surveys. If you wish to fill that in that would be fine, be assured your name will be detached and held separately from the survey data (according to the data protection policy and research governance policy at the University of Southampton), and the survey will remain anonymous.

Please read every question in the booklet and answer using the boxes provided.

Some answers require a yes or no, whereas others require you to read a statement and then mark the box which most agrees with how you feel about that statement. These questions have the instructions with them. There are areas in the questionnaire where you can write whatever you think, so please feel free to use those boxes to tell us more information.

When you have finished answering all the questions, please put the booklet **into the envelope provided** and it will come straight back to us at the University of Southampton.

Thank you very much for completing this questionnaire, it will give us invaluable information about portable oxygen, how useful you find it and what you feel are the advantages and disadvantages of the system.

Section 1

This section is about the kind of oxygen you have been prescribed to take with you when you are out of the house; your portable oxygen (not the oxygen that stays permanently in the house)

1. Portable oxygen; what kind of oxygen do you have to take with you when you leave the house?

Please tick the appropriate answer

A. Liquid oxygen

B. Cylinder oxygen

b. If you have cylinder oxygen what does the cylinder weigh?

The cylinder weighs (to nearest Kilogram)

--

2. Around the body of the cylinder of oxygen there is a label showing the capacity of the cylinder in litres, please can you write below the capacity of your cylinder

--

3. How long have you had portable oxygen?

.....yrs..... months

Do you use a converter on your portable oxygen

yes / no

4. Who prescribed your Portable Oxygen for you?

Please tick the appropriate box below

The Respiratory centre

The Hospital on discharge

Your GP

Other; please state

5. Did you receive any information or instructions on how to use your Portable Oxygen?

Please circle the appropriate box

YES	NO
-----	----

If the answer to this question is NO, please go to question 11.

6. If you did, how was any information or instructions given to you?

Please tick the appropriate box below

Someone told me

Someone gave me written instructions to read

7. Who gave you those instructions?

Please tick the appropriate answer below

The Respiratory Centre

The Hospital

The oxygen delivery man

Other, please state who

8. Did you understand the instructions that were given to you?

Please circle the appropriate answer below

Yes	No
-----	----

9. Please can you briefly write down the instructions you were given in the box below

--

10. If you were to receive some instructions, how would you like to get them?*Please circle the appropriate answer*

- a. Written instructions**
- b. By word of mouth**
- c. Face to face at home**
- d. Face to face in the clinic**

11. Did you feel confident in using the Portable Oxygen system yourself when you first received it ?*Please circle the appropriate answer below*

Yes	No
-----	----

12. If you received no instructions, how did you find out how to use the portable oxygen?*Please tick the appropriate box below*

The Oxygen delivery man helped me learn

The nurses at the respiratory centre helped me

Nurses at the GP practice helped me

I/we learnt by experience

Someone else helped me e.g. Doctor/friend

Section 2

This section is about how often you go out of the house i.e., to the shops etc

13. How often do you go outside the house to go to the supermarket, visiting, appointments, days out etc

please tick the appropriate box

Everyday	<input type="checkbox"/>
2-3 times per week	<input type="checkbox"/>
4-6 times per week	<input type="checkbox"/>
Once per week	<input type="checkbox"/>
Less than once per week	<input type="checkbox"/>
Less than once per month	<input type="checkbox"/>
Never	<input type="checkbox"/>

14. When you leave the house how do you get out and about-

this is about how you get to the supermarket, appointments etc

Please tick appropriate box

I have a car and I drive	<input type="checkbox"/>
I have a car and my spouse/partner drives	<input type="checkbox"/>
I rely on relatives to take me out	<input type="checkbox"/>
I have an electric buggy which I use	<input type="checkbox"/>
I have a wheelchair and someone pushes me	<input type="checkbox"/>
I walk	<input type="checkbox"/>
I use public transport	<input type="checkbox"/>

15. When you arrive at your destination e.g. supermarket, how do you get from the car to the inside of the shop, restaurant, friend's house?

please tick appropriate box

I walk from the car inside unaided

I walk from the car inside with help (stick, rollator)

I walk from the car inside with the help of my spouse/carer

I stay in the electric buggy

I stay in the wheelchair

I wait in the car

Section 3

This is about your portable oxygen

Do you agree or disagree with these statements;
(please tick the appropriate box below)

16. What do you think about the weight of your portable oxygen?

This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box below

	Strongly agree	agree	Neither agree or disagree	disagree	Strongly disagree
It weighs too much					
The weight is ok					

17. Does the weight of the Portable Oxygen stop you taking it out of the house?

Please circle the appropriate answer below

Yes	No
-----	----

18. How do you usually carry your portable oxygen?*Please tick the appropriate box*

Shoulder bag	
Back pack	
trolley	
Spouse/carer carries it	
Other please state	

19. What do you think about the controls on your portable oxygen?

This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box

	Strongly agree	agree	Neither agree or disagree	disagree	Strongly disagree
I think that the controls are clear					
I think that the controls are confusing					

20. Does someone else always checks the controls for you?*Please tick the appropriate box below*

Yes	No
------------	-----------

21. What do you think about the gauge on the cylinder that tells you if the tank is full or empty?

This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box

	Strongly agree	agree	Neither agree or disagree	disagree	Strongly disagree
I think that the empty/full gauge is confusing					
I think that the full/empty gauge is clear					

22. Do you always check the gauges yourself or does someone else check the gauges for you?

Please tick the appropriate box

I always check my own gauges	
Someone else checks the gauges for me	
Sometimes I check the gauges, sometimes someone else checks them	

23. Do you ever worry that the oxygen may run out whilst you are outside the house

This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
I am always worried that the oxygen may run out					
I sometimes worry that the oxygen may run out					
I never worry that the oxygen may run out					
I am so worried it may run out that I never take it out of the house with me					

24. Who checks the oxygen levels in the portable oxygen?

Please tick the appropriate box

I always check the oxygen levels myself	
Someone else always checks the oxygen levels	
Sometimes I check the levels and sometimes someone else checks them for me	

Section 4

This is about how you feel about your Portable Oxygen and whether you find it helpful.

25. How helpful do you feel your Portable oxygen system is?*Please tick the appropriate box below*

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
I think the portable oxygen is very helpful					
I think the portable oxygen is sometimes Helpful					
I think the portable oxygen is not helpful at all					

**If you feel your portable oxygen IS helpful then please go to the next question.
If you feel your portable oxygen is NOT Helpful, please go straight to question 27.**

26. Why do you feel Portable Oxygen is helpful to you?*Please tick the appropriate answer; you may have more than one reply so please tick all the answers that apply to you*

	yes	No
I feel more confident		
I feel I have more freedom to go out		
I feel safer when I'm outside the house		
AO relieves my breathlessness when I am out		
My carer feels more confident if we have AO with us		

27. Why do you find Portable Oxygen is unhelpful to you?

Please tick the appropriate answer; there may be more than one answer so please tick all the answers that apply to you

	yes	No
AO does not relieve my breathlessness when I use it		
The system is too heavy to carry		
The system is too embarrassing to use in public		
I don't feel I need it		

28. For you, does your Portable Oxygen system have more advantages, or more disadvantages?

This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box below

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
Only advantages					
Mostly advantages but some disadvantages					
Mostly disadvantages but some advantages					
Only disadvantages					

Section 5

This section is about how you use your Portable oxygen when you are out of the house

29. When I go outside the house I take my Portable oxygen with me

Please tick the appropriate box

Always

Sometimes

Never

30. When I go out with my Portable Oxygen

Please tick the appropriate box

I use Portable oxygen in the car only

I use Portable Oxygen in the car in public equally

I use Portable Oxygen on my buggy/wheelchair

I never use my Portable oxygen

31. Who carries the PO from the house to the car?

Please tick the appropriate box

I carry the portable oxygen

Spouse/carers carries the portable oxygen to the car for me

I use a trolley to take portable oxygen to the car

I use a wheelchair or buggy to carry the portable oxygen to the car

Other, please state what.....

.....

32. When you are out of the house, in public (not in the car), who carries your PO system*Please tick the appropriate box below*

I always carry my own portable oxygen

My spouse/carers carries the portable oxygen

I use a trolley to carry my portable oxygen

I put the portable oxygen system on my buggy/wheelchair

I don't take my portable oxygen out of the car

Section 6

This is about how you feel about using your Portable oxygen in public

33. How do you feel about being seen in public with an PO system?*This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box*

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
It does not worry me at all to be seen with Portable oxygen					
I does worry me a little to be seen with portable oxygen but I still use it in public					
I feel embarrassed to be seen in public with my Portable oxygen but I still use it in public					
I am so embarrassed by having a Portable oxygen that I will not use it in public					

34. Can you say why you feel embarrassed or not? Using AO in the community (outside the house or car)

This question is concerned with how you feel about the statement on the left hand side below. You may agree or disagree with the statement depending on how you feel it applies to you. Please tick the appropriate box below

	Strongly agree	agree	Neither agree or disagree	disagree	Strongly disagree
I would feel embarrassed using equipment that might make people stare					
I don't want to be seen as having anything wrong with me					
I do feel embarrassed but feel I need my portable oxygen so I use it anyway when I am out in public					
I am not embarrassed and use AO in public when needed					

Section 7

This is just about you

35. How old are you?

30-49

50-69

70-89

89-

36. Which city is nearest to you?;

37. Do you live

(please tick the appropriate box)

With a spouse or partner	
On your own	
With a relative	
In a residential care setting	
Other (please state what)	

38. Do you have oxygen at home?

Please tick the appropriate answer

A concentrator

Cylinder oxygen

39. How long have you had home oxygen

Thank you very much for completing this questionnaire

If you want to contact the researcher:

Lis Arnold

Building 45

University of Southampton

S017 IBJ

Appendix 22: Question/response excel results for round 1 CI interviews

	Question comprehension					Question response					other			
Question	C1	C2	C3	C4	No Prob	R1	R2	R3	R4	No Prob	Ref A	Skip-Ap	SkipN-Ap	Don't kn
Intro	XX				XXX									carer
1	X			XX			X	XX	X	X				
b			X	XXX	X			XXX	X	X				XX
c				XXX				X	X	X	X			X
2														
3	X	X	X	XXX			XX	XX						
4	X	X	XX	X	X	X		XX	XX					
5	XX		X		XX		X	XX		XX				
6	X	X		XX	X		X		XX	XX				X
7			XX	X	X		XX		X	XX				Adds resp
8	X		X		XX		XX		X	XX				Adds
9	X				X									XX
10	X		X		XX		XX		X	XX				adds
11	X	X	XXX	XXX				XXXX	X					
12	X			XXX	XX		XX	XX		XX				
13		X		XXX	X	X	XX	X	XX	X				adds
14		X	X	X	X			XXX	XX					Adds +
15	X		XX	X	X		X	X	X	XX				
16	X		XXX	XXX			X	XX	XX	XX				adds
17	X		X	XX	XX		XX		X	XX				Adds X
18	XX		X	X		X	XXXX			X				
19	X	X		XX	XX		XX	XX	X	XX				adds
20p7		X		XX	XX		X	XX		XX				
21p7	X	XX	XXX	XX				XXX		X				
22p7	X		XXX	X	X		X	X		XXX				
23p8	X		XX	X	XX		X	X	X	XX				

24p8	XX		XXX	XX	X		X	X	XX	XX				
24ap8	XX		XX	X	XX		X	XX	X	XX				
	C1	C2	C3	C4	No prob	R1	R2	R3	R4	No prob	Ref A	SkipA	skipN-A	Don't know
25	X		X	X	XX		XXXX			XX				
26			XX	X	XX			XX	XX	X				adds
25 p9			XX		XX			XX		X				
26 p9			X	X	XX			XX	XX	X				X
27p9	X	X	XXX	XXXX	X			XXX	XXX	X			X	
27 p10	X	X	XXX	XXX	X	X	X		XX				X	X
28 p10			XXX	XX	X			XXX	XX	X				
29 p10	XX	X	XX	X			X	XX			?????			
30 p10	X		XXX	XXX			XXX							
29 p11	X		X	X	X		XXX	X		X				
30 p11	X		X		XX		XX	XX		XX				adds
31 p11	X		X	X	XX		XX	XX		XX				adds
32 p12	X		XX		XX		XX	X	XX	X				adds
33 p12	X		XXX	XX				XXX	X	X				
34 p13	X		XXX	XX			XX	XX	X	X				
35	XX				XX		X	XX		X				
36	X		XX	X	X		XX	X		X				
37	X		X		XX			XXX		X				
38	X		XX	X	X			XXX		X				

X- participant 1; X-participant 2; X-participant 2; X- participant 4; Participant 5

Q1-; Repeats question Q2- asks for clarification; Q3- Asks for help; Q4-unable to answer question

R1- Repeats response R2- asks for clarification R3- Asks for help; R4- unable to answer

Appendix 23: Results of round 1 CI interviews and judges' panel

Question	Perceived problem from participants	Decision	Change implemented
Introduction	1-no problem 2- no problem 3-no problem 4-no problem 5- identifies words perceived as 'bad English'	Change one word	Word changed from 'little knowledge' to 'little known'
1a	1- no problem 2-unable to give answer-does not know 3- unable to give answer-does not know 4-unable to give answer-does not know 5-no problem	Add pictures to aid identification of oxygen	Change format of question to include pictures add 'do not know response'
1b	1-asks for clarification of question, Unable to answer question as does not know 2-asks for clarification of question Unable to answer-does not know 3-asks for clarification of question Unable to answer as does not know 4-asks for clarification of question Unable to answer as does not know 5-did not know the answer	Remove question	Question removed
1c	1-does not know answer 2-does not know answer 3-does not know answer 4-does not know answer 5- does not know answer	Remove question	Question removed
3a	1-5 no problems	No change	No change
3b	1-no problem 2-repeats and asks for clarification of question		

question	Does not know answer 3-repeats and asks for clarification of question Does not know answer 4-discusses with carer who supplies answer Does not know answer 5-no problems	No change Judge's panel	No changed Implemented change
4	1-no problem 2-no problem 3-repeats question and asks for clarification of question 4-asks carer 5-no problem	Some confusion over response option 1	change response options to include words (out-patients) with respiratory centre so response is more specific
5	1-no problem 2-confused about portable oxygen instructions v home oxygen so gave inaccurate response 3-no problem 4-asked carer 5-no problem	Confusion for some participants over portable and home oxygen	Question contains 'or' which might be confusing and needs more direction for portable oxygen only Re-write question
6	1-no problem 2-asks for clarification of question and ticks both boxes 3-no problem 4-re-reads question says he 'doesn't understand question' 5-no problem	Confusing question, again participants confused between portable oxygen and home oxygen	Re-word question and responses and instructions
7	1-thinks 'engineer' should be added to responses 2-no problem 3-no problem No problem 5-no problem	No change	No change
	1-no problem		

8	2-no problem 3-no problem 4-re-read question adequate answer 5-no problem	No change	No change
9	1-can't remember any instructions -left box blank 2-no problem, completed text box 3-can't remember any instructions-left box blank 4-can't remember any instructions-left box blank 5-no problem, completed text box	Leaving text box blank if cannot remember instructions so unaware if question skipped or instructions not received	Question not being answered so change question to more definitive tick answer response option
10	1-re-reads question asks for clarification of response options, adequate response 2-re-reads question and adds 'when machine is delivered' so has misunderstood question Re-reads question, adequate response Re-reads question and discusses with carer, adequate response 5-no problem	Confusion again between portable and home oxygen	Re-word question and answer format to emphasise portable oxygen
11	1-no problem 2-re-reads question, adequate response 3-re-reads question, adequate response 4-re-reads question, adequate response 5-re-reads question, adequate response	No problem	No change
11a	1-re-reads question, adequate response 2-re-reads question, adequate response 3-re-reads question, unhappy about question feels it implies lack of confidence 4-re-reads question, discussed with carer, skips response 5-completed text box	Text box skipped in some participants so would not sure if question missed or pt was not confident	Re-write or remove text box as not giving information needed and upset one participant
	1-no problem, adequate response		

12.	2-skipped 3-no problem 4-re-reads question 'doesn't make sense' skipped 5-skipped (appropriately)	Question not answered by 3 of participants,	Re-write question and answer format
13	1-queries point of question and order of responses, adds if unwell 2-re-reads question and asks for clarification of question wording adds 'out in garden' 3-no –problem 4-asks for clarification of question wording 5-no problem	Question wording causing confusion	Change order of response Change wording of question to clarify what is required, too many choices requiring different responses
14	1-queried position of question after question 13 2-ticked more than one response 3-no problem 4-no problem 5-no problem, ticks more than one box	Pts have more than one response so instructions need to reflect that	Change instructions
15	1-no problem, adequate response 2-re-read question and responses, discusses with carer adds 'trolley' as additional response 3-no problem 4-re-reads question and discusses with carer. Carer answers question 5-no problem	May need more responses	May need to include more responses
16a	1-re-reads question and answers, adequate answer 2-no problem, adequate answer 3- re-reads question and answer format, adequate answer 4-re-reads question and answer format, discusses with carer, adequate answer	This question and the one following caused some confusion in participants	?change format of likert scale to reflect format of previous questions? Move the two questions apart

	5-no problem		
16b	1-re-reads question and answers, adequate answer 2-no problem, adequate answer 3- re-reads question and answer format, adequate answer 4-re-reads question and answer format, discusses with carer, adequate answer 5-no problem, adequate answer	16a and b together may be too confusing and too close together	?change
17	1-no problem, adequate response 2-no problem, adequate response 3-no problem, adequate response 4-no problem, adequate response 5-no problem, adequate response	No problem	No problem
18	1-no problem, adequate response 2-no problem 3-no problem adds 'own bag' to responses 4-no problem 5-no problem	No problem	Add response 'own bag'
19	1-re-reads question, queries where to put response 2-re-reads question, cannot answer 3-re-read question and answer format, then answered inadequately 4-re-reads question says 'I don't understand' and skips question, answered by carer 5-no problem, adequate response	Some difficulty for participants understanding question and selecting answer	Change wording on question
19b	1-re-reads question, queries where to put response 2-re-reads question, cannot answer 3-re-read question and answer format, then answered inadequately 4-re-reads question says 'I don't	These two likert scale questions together appear to cause problems to pts	Change wording on question

	understand' and skips question, answered by carer 5-no problem, adequate response		
22 p7	1-no problem, adequate answer 2-no problem, adequate answer 3-no problem, adequate answer 4-no problem, adequate answer 5-no problem, adequate answer	No problem	No change
23p7	1-re-reads question, says 'I don't understand question' guesses response 2-re-reads question discusses with carer 3-does not understand question or answer format 4-re-reads question and discusses with carer, selects inappropriate response and carer corrects 5-queries question and answer format	Problems with this question by all pts.	Change question
21p8 A and b	1-re-reads question and asks for clarification 'difficult to understand' 2-re-reads question and discusses with carer 3-asks for clarification of question 'difficult to understand' 4-re-reads question discusses with carer selects inappropriate response 5-queries instructions for question	Problems with this question by all pts.	Change question
23 p8 A and b	1-re-reads question and responses 'difficult to understand' 2-re-reads question, adequate responses 3-re-reads question 'don't understand' 4-re-reads question, discusses with carer chooses inappropriate response 5-no problem	Problems with this question from 4 out of 5 pts.	
	1-no problem		

23c	2-no problem 3-no problem 4-no problem 5-no problem	No problem with question/answer	No change
24p8	1-no problem, adequate response 2-re-reads question, adequate response 3-reads question and selects inappropriate response 4-re-reads question, adequate response 5-no problem	No problem	No change
25	1-re-reads question suggests 'important' instead of useful in answer format 2-re-reads question emphasising 'helpful', adequate response 3-re-read question and discusses with carer 4-re-read questions adequate response 5-no problem, adequate response	No problem	No change
26	1-re-reads question and adds 'enables going outside' to responses 2-re-reads question and adds 'can go to more places' to responses 3-no problem, adequate response 4-re-reads question and discusses with carer 5-no problem	2 pts add additional responses	Add additional responses
Text box	1-skipped 2-skipped 3-skipped 4-skipped 5-skipped	Text box not completed	Remove text box
27	1-no problem, adequate answer 2-asks for clarification of question, inadequate response	£ of 5 found question confusing	Re-word question format

	3-asks for clarification, feel he has already answered question, skips response 4-feels question is confusing, re-read responses inadequate answer 5-no problem		
28p10	1-re-reads question and asks for clarification, adequate response 2-re-reads question asks for clarification, skips answer 3-queries question 'I have already answered this', misses responses 4-re-reads question 'I don't understand' skips answers 5-skips question(appropriately)	Confusing question not seen as skip question	Remove question
28p10	1-no problem, adequate response 2-no problem, adequate response 3-no problem, adequate response 4-no problem, adequate response 5-no problem, adequate response adds 'sometimes' to response format	Ps add response 'sometimes' to both answer formats	Add response 'sometimes'
29p10	1-don't know answer 2-don't know answer 3-don't know answer 4-don't know answer 5-skipped	Txt box not used	Remove text box
28p10	1-no problem, adequate response 2-re-reads question 'confusing' discusses with carer, adequate response 3-re-reads question, 'confusing if you think there are only advantages', selects inadequate response 4-re-reads question, discusses with carer, skips response	2 of 5 found question confusing	Re-write questions

	5-no problem, adequate response		
29p11	1-no problem, adequate answer 2-no problem, adequate answer 3-no problem, adequate answer 4-no problem, adequate answer 5-no problem, adds 'when needed' to response format	No problem	Add 'when needed' to response format
30	1-no problem, adequate answer 2-no problem, adequate answer 3-no problem, adequate answer 4-no problem, adequate answer 5-no problem, adequate response	No problem	No change
31	1-no problem, adequate response 2-no problem suggests adding 'normally' to question format, adequate response 3-no problem, suggests 'does anyone' Instead of 'who' in question format 4-no problem –adequate response 5-no problem, adequate response	No problem	?add 'normally' to question format??
32	1-no problem, adequate response 2-re-reads question and suggests adding 'family' to response format 3-reads question incorrectly, skips answer 4-re-reads question and responses, adequate response 5-no problem		
33	1-re-reads question and answer formats, 'difficult to understand' 2-re-reads questions and answers, 'confusing' discusses with carer, no response 3-re-reads questions and does not answer		

	4-re-read questions, guesses at answer 5-no problem		
34	1-re-read question/answers 'to difficult to answer' no response 2-re-reads question, 'don't know/don't understand' 3-re-reads question and answer format 'can't select answer' 4-re-reads question, guesses at answer 5-no problem	4 of 5 participants had difficulties with his 3 likert scales	Change format of question/answers to mirror format used before

1=participant one, 2=participant 2, 3=participant 3,4=participant 4, 5=participant 5.

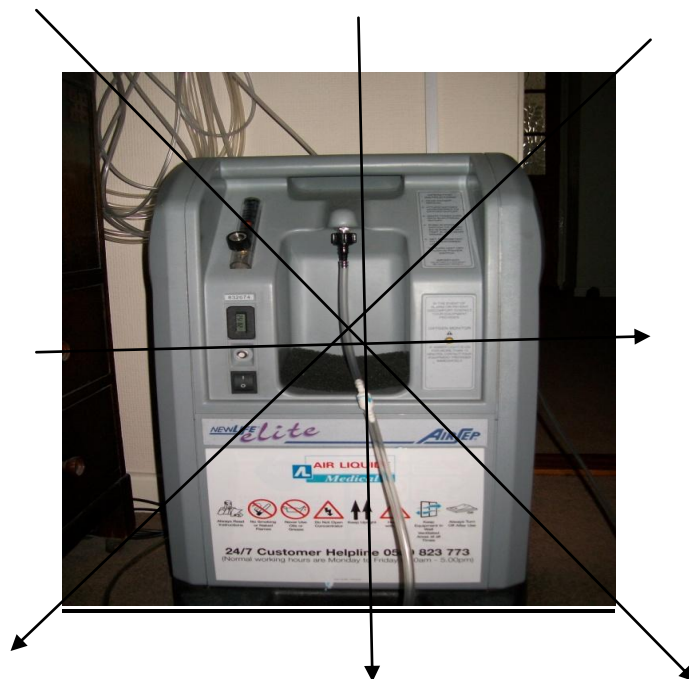
Appendix 24: Version 9 of the questionnaire (post CI study)

This questionnaire is asking questions about your

PORTABLE OXYGEN



It is NOT about your home oxygen



A questionnaire about how people with Chronic Obstructive Pulmonary Disease (COPD) use their Portable Oxygen

Introduction

This questionnaire aims to explore what people who have COPD think about their portable oxygen (the oxygen you take out of the house with you) and how they manage their portable oxygen when they do use it.

As you may know there is little known about what people with COPD actually think about their portable oxygen and how useful it maybe. This questionnaire is designed to try and find out from you, someone who uses portable oxygen, how helpful portable oxygen is, and what you think are the advantages and disadvantages of the portable oxygen you use.

This questionnaire is completely **ANONYMOUS**, so please feel free to answer the questions as truthfully as possible; the questionnaire cannot be traced back to you, and so cannot affect your treatment or prescription at all.

Please read every question in the booklet and answer using the boxes provided.

Some answers require a yes or no, whereas others require you to read a statement and then mark the box which most agrees with how you feel about that statement. These questions have the instructions with them. There are areas in the questionnaire where you can write whatever you think, so please feel free to use those boxes to tell us more information. If you want to get your wife, husband, relative or carer to help you fill this in, please do so.

When you have finished answering all the questions, please put the booklet **into the envelope provided** and it will come straight back to us at the University of Southampton.

Thank you very much for completing this questionnaire, it will give us invaluable information about portable oxygen, how useful you find it and what you feel are the advantages and disadvantages of the system. This will enable us to consider the user's perspective in future designs of portable oxygen equipment.

1. What kind of PORTABLE OXYGEN SYSTEM do you have?**a. Cylinder Oxygen**

Is delivered by your oxygen company, and you ring them when you want a new one,
Your cylinder may look like one of these below;



Please tick here if
you use portable
gas oxygen

b. Liquid Oxygen

A 'mother tank' is delivered by your oxygen company and you refill the ambulatory
carrier yourself from the mother tank. The mother tank is replaced about every 2 weeks



Please tick here if
you use portable
liquid oxygen

Please tick here if you are not sure which
kind of portable oxygen you use

2. How long were you told your PORTABLE OXYGEN cylinder would usually last?

--

3. How long have you been using PORTABLE OXYGEN?

.....years.....months

4. Who FIRST prescribed your PORTABLE OXYGEN for you?

Please tick the appropriate box below

The respiratory centre (out-patients)	
The hospital prescribed it for you to go home	
Your GP	
Other; please state	

5. Did anyone explain to you WHY you needed PORTABLE OXYGEN?

Please circle the appropriate answer below

Yes	No
-----	----

6. What instructions did you get when you first got your PORTABLE OXYGEN?

Please tick all the answers that are applicable

I was told to use it when I went out	
I was told it would help me when I went out	
I was told to use it when I was walking outside	
I was told to use it when I exercising (at pulmonary rehab)	
I was not told anything	
I was told to use whenever I was breathless in the house	

7. Who showed YOU how to use the controls on your PORTABLE OXYGEN system?*Please tick the appropriate answer below*

The respiratory Centre showed me	
The hospital staff showed me	
The oxygen delivery person showed me; face to face	
The oxygen delivery person showed my family/carers and they then showed me	
No one showed me	
Other, please state who	

8. When you were first given your PORTABLE OXYGEN system did you understand how to use the controls?*Please circle the appropriate answer below*

Yes	No
-----	----

9. Did you feel confident in using the PORTABLE OXYGEN system yourself when you first started using it?*Please circle the appropriate answer below*

Yes	No
-----	----

10. Do you think that more information on PORTABLE OXYGEN would be useful to you or your family/carers?*Please circle the appropriate answer below***a. To me**

Yes	No
-----	----

b. To my family / carers

Yes	No
-----	----

11. If you were to receive some more information on using PORTABLE OXYGEN, how would you like to get it?

Please tick the appropriate answer

Written information	
Face to face at home	
Face to face in the respiratory clinic	

12. Do you ever use your PORTABLE OXYGEN system INSIDE the house?

Please circle the appropriate answer for you below:

Always	Sometimes	Never	Only if I'm unwell
---------------	------------------	--------------	---------------------------

13. How often do YOU go outside the house into the garden, shed, courtyard or to the front gate? So not off the property.

Please tick the appropriate box

Everyday	
4-6 times per week	
2-3 times per week	
Once per week	
Less than once per week	
Less than once per month	
Never	

14. When you go outside into the garden, courtyard or to the front gate, do you take your PORTABLE OXYGEN with you

Please circle the answer below that applies to you

Always	Sometimes	Never	Only if I'm unwell
---------------	------------------	--------------	---------------------------

15. How often do you go further afield for example to the supermarket or out for appointments?

Please tick the appropriate box

Everyday	
4-6 times per week	
2-3 times per week	
Once a week	
Once a month	
I do not go out of the house	

16. Do you take your **PORTABLE OXYGEN with you when you go out further afield?**

Please circle the appropriate answer for you below;

Always	Sometimes	Never	Only if I'm unwell
---------------	------------------	--------------	---------------------------

17. When you go out

Please tick the boxes that describe what you do

I keep my Portable Oxygen in the car in case I need it	
I use my Portable Oxygen in the car AND in public	
I use a buggy when I am out so do not need to use my portable oxygen	
I keep my Portable oxygen on my buggy in case I need it	
I keep my Portable oxygen on my buggy AND use it when I go out	
There is no room on my buggy for the portable oxygen	
I cannot take my portable oxygen out as I use public transport/taxi	
I use public transport AND take my portable oxygen with me	
I don't use my portable oxygen	

18. Who carries the PORTABLE OXYGEN when you are out of the house, (not in the car)

Please tick the appropriate boxes below

I always carry my own portable oxygen	
I can carry it if I feel well	
I carry it but I need help to put the carry bag on my shoulders/back	
I can carry it but someone else has to use the controls	
My wife/husband/carer carries the portable oxygen	
I use a trolley to carry my portable oxygen	
I put the portable oxygen system on my buggy/wheelchair	
I don't take my portable oxygen out of the car	
I don't use my portable oxygen	

19. What do you carry your PORTABLE OXYGEN in?

Please tick the appropriate box

Shoulder bag (supplied by oxygen company)	
Back pack (supplied by oxygen company)	
Waist bag (supplied by oxygen company)	
Your own bag	
Trolley	
Electric Buggy	

20. What do you think about the weight of your PORTABLE OXYGEN?

Please circle the appropriate box below;

I think my portable oxygen weighs too much

strongly agree	agree	not sure	disagree	strongly disagree
----------------	-------	----------	----------	-------------------

21. Does the weight of the PORTABLE OXYGEN stop YOU carrying it out of the house on your own?

Please circle the appropriate answer below;

Yes	No
-----	----

22. Do you always check the on/off control yourself or does someone else check the controls for you?

Please tick the appropriate box

I always check my own control	
Someone else always checks the control for me	
Sometimes I check the control, sometimes someone else checks it	

23. Do you ever worry that the PORTABLE OXYGEN may run out whilst you using it are outside the house?

Please tick the appropriate answer;

Yes	No
-----	----

24. Do you trust that the full/empty gauge accurately tells you how much oxygen you have in the cylinder?

Please tick the appropriate answer

Yes	No
-----	----

25. Are you SO worried about the oxygen running out that you do not take it out of the house with you?

Please tick the appropriate answer below

Yes	No	Sometimes
-----	----	-----------

26. Who checks the oxygen levels in your PORTABLE OXYGEN?*Please tick the appropriate box*

I always check the oxygen levels myself	
Someone else always checks the oxygen levels	
Sometimes I check the levels and sometimes someone else checks them for me	

27. How helpful do you feel your PORTABLE OXYGEN system is?*Please circle the appropriate box;***I think my portable oxygen is helpful to me**

always helpful	sometimes helpful	occasionally helpful	rarely helpful	never helpful
----------------	-------------------	----------------------	----------------	---------------

28. How do you feel about your PORTABLE OXYGEN system?*Please tick the appropriate answers*

	Yes	No
I feel more confident to go out of the house		
I feel I have more freedom to go out		
I feel safer when I'm outside the house		
portable oxygen relieves my breathlessness when I am out		
My carer feels more confident if we have portable oxygen with us		
portable oxygen does not relieve my breathlessness when I use it		
The system is too heavy to carry		
The system is too embarrassing to use in public		
I do not feel I need portable oxygen		

29. Do you worry that if you start using PORTABLE OXYGEN more you may become more dependent on it?

Please tick the appropriate answer below

Yes	No
-----	----

30. Do you worry that using PORTABLE OXYGEN may have side-effects which may be harmful to you?

Please tick the appropriate answer below

Yes	No
-----	----

31. Do you feel that on balance, your PORTABLE OXYGEN system has more advantages, or more disadvantages?

Please circle the appropriate box below

I feel that portable oxygen has more advantages

Yes	No	Don't Know
-----	----	------------

32.

I feel that portable oxygen has more disadvantages

Yes	No	Don't Know
-----	----	------------

33.

I think the weight of my portable oxygen is OK

strongly agree	agree	not sure	disagree	strongly disagree
----------------	-------	----------	----------	-------------------

34. How do you feel about being seen in public with a Portable Oxygen system?*Please tick the appropriate box*

	Yes	No	Sometimes
I am so embarrassed about being seen in public with Portable oxygen that <u>I do not use it in public</u>			
I am embarrassed about being seen in public with Portable Oxygen <u>BUT I still use it in public</u>			
I am not embarrassed about being seen in public with Portable Oxygen			

35. If you do feel embarrassed is it because*Please tick the appropriate box below*

	Yes	No	Sometimes
I am worried people would stare at me			
I do not want anyone to know I need oxygen			
I do not want anyone to know I have a lung condition			

36. Please tell us how old are you*Please circle correct group below*

30-49yrs

50-69yrs

70-89yrs

89-yrs or older

37. Who do you live with?*please tick the appropriate box*

With a husband, wife or partner	
On your own	
With a relative e.g. daughter/son	
With a friend	
In a residential care setting	
Other (please state what)	

38. Do you have oxygen for use only at home (LTOT)?

Please tick the appropriate answer

1. A concentrator (+ emergency cylinder)
2. Cylinder oxygen for using when I am breathlessness
3. No nothing

39. How long have you had home oxygen

Is there anything else you wish to tell us about your portable oxygen?

**If you want to contact the researcher:
Lis Arnold MSCP MSc
Research Fellow
Building 45
University of Southampton S017 IBJ**

THANK YOU VERY MUCH FOR ANSWERING THESE QUESTIONS

Appendix 25: Ethics approval for pilot study



EO4/Mar 2011/ v2.0

Elisabeth Arnold
Faculty of Health Sciences
University of Southampton

1 June 2011

Dear Elisabeth

Ethics Submission No: FoHS-ETHICS-2011-044

Title: Pre-testing a questionnaire using cognitive interviewing and piloting the resulting questionnaire

I am pleased to confirm **full approval** for your study has now been given. The approval has been granted by the Faculty of Health Sciences Ethics Committee following Committee members review independent of the Committee Chair and Vice-Chair given the conflict of their supervisory roles for the applicant.

You are required to complete a University Insurance and Research Governance Application Form (IRGA) in order to receive insurance clearance before you begin data collection. The blank form can be found at <http://www.soton.ac.uk/corporateservices/rgo/regprojs/whatdocs.html>

You need to submit the following documentation in a plastic wallet to Dr Martina Prude in the Research Governance Office (RGO, University of Southampton, Highfield Campus, Bldg. 37, Southampton SO17 1BJ):

- Completed IRGA Research Governance form
- Copy of your research protocol/School Ethics Form (final and approved version)
- Copy of participant information sheet
- Copy of SoHS Risk Assessment form, **signed**
- Copy of your information sheet and consent form
- Copy of this SoHS Ethical approval letter

Continued overleaf

Building 67
Faculty of Health Sciences, University of Southampton, Highfield Campus, Southampton SO17 1BJ United Kingdom
Tel: +44 (0)23 8059 7979 Fax: +44 (0)23 8059 7900 www.southampton.ac.uk/healthsciences

Appendix 26: Sponsorship and Insurance



Ms Elisabeth Arnold
School of Health Sciences
University of Southampton
University Road
Highfield
Southampton
SO17 1BJ

RGO Ref: 8124

14 June 2011

Dear Ms Arnold

Project Title Pre-Testing a Questionnaire Using Cognitive Interviewing and Piloting the Resulting Questionnaire

This is to confirm the University of Southampton is prepared to act as Research Sponsor for this study, and the work detailed in the protocol/study outline will be covered by the University of Southampton insurance programme.

As the sponsor's representative for the University this office is tasked with:

1. Ensuring the researcher has obtained the necessary approvals for the study
2. Monitoring the conduct of the study
3. Registering and resolving any complaints arising from the study

As the researcher you are responsible for the conduct of the study and you are expected to:

1. Ensure the study is conducted as described in the protocol/study outline approved by this office
2. Advise this office of any change to the protocol, methodology, study documents, research team, participant numbers or start/end date of the study
3. Report to this office as soon as possible any concern, complaint or adverse event arising from the study

Failure to do any of the above may invalidate the insurance agreement and/or affect sponsorship of your study i.e. suspension or even withdrawal.

On receipt of this letter you may commence your research but please be aware other approvals may be required by the host organisation if your research takes place outside the University. It is your responsibility to check with the host organisation and obtain the appropriate approvals before recruitment is underway in that location.

May I take this opportunity to wish you every success for your research.

Yours sincerely

Dr Martina Prude
Head of Research Governance

Tel: 023 8059 5058
email: rgoinfo@soton.ac.uk

Appendix 27: Participant Information sheet for pilot study**Participant Information Sheet**

Study Title: A study to pre-test a questionnaire on Portable Oxygen in participants with Chronic Obstructive Pulmonary Disease (COPD)

Researcher: Elisabeth Arnold

We would like to invite you to take part in a research study. Before deciding to take part you need to understand what the study is about and what is involved. Please read this information leaflet carefully before deciding to take part in this research. The researcher will discuss this with you if you would like to take part, but please feel free to discuss this with others if you wish.

What is the research about?

This study is about asking people with COPD who have portable oxygen to complete a questionnaire which has been designed to be sent to a larger national group of patients. Questionnaires are widely used to gather information but can be difficult to complete because of poorly worded or ambiguous questions. This study is designed to ask people to complete the questionnaire so that any possible errors in the questions can be corrected before it goes out to a larger group.

Why have I been chosen?

You are being asked to take part in this study because you have COPD and portable oxygen. The final questionnaire is designed to go to people with COPD and portable oxygen throughout the country, so it is important that the questionnaire is reviewed by people who have an understanding of the issues.

What will happen to me if I take part?

You will be asked to complete the questionnaire and return it in the stamped addressed envelope provided. There is no further involvement.

Can I get help filling in the questionnaire?

Please feel free to get your relatives or carers to help you fill in the questionnaire if that helps you to complete it.

Are there any benefits in my taking part?

There will not be any benefits to you personally from participating in this study apart from knowing that you have helped to develop an error-free questionnaire. The data gathered from the final version of the questionnaire will help to enhance the current knowledge we have about COPD people who use portable oxygen.

Are there any risks involved?

There are not envisaged to be any risks to you from taking part in this study. The questionnaire is designed to be completed at home, so you will be able to use your medications as normal if you are breathless during this survey.

Will my participation be confidential?

Yes. All information gathered in this study will be confidential. All data will be handled, processed, stored and destroyed according to the Data Protection Act 1998 and the Research Governance guidelines laid down by the University of Southampton.

What happens if I do not want to fill in the questionnaire?

Nothing, please just discard the questionnaire.

Not completing the questionnaire will not affect your legal rights or medical care.

What happens if something goes wrong?

In the unlikely case that you have a concern or complaint about this study, you should contact:

Susan Rogers (Head of Research and Enterprise Services)
Building 67
University of Southampton
Southampton SO17 1BJ
02380-597942

What happens to the results of this study?

The results of the study will be collated from the results of the final completed questionnaire. The results will be written up to form part of the researcher's doctoral thesis. Summarised results may also be presented to healthcare professionals and published in scientific publications. You will not be personally identifiable in any report. If you would like a copy of the results, please fill in the name and address form at the end of the questionnaire researcher and a copy of the results to be sent to you.

Where can I get more information?

Please contact the researcher (Liz Arnold) directly on 00000000

If that is not sufficient please contact

Dr. A. Bruton (Supervisor)
School of Health Sciences, Building 45
Highfield campus
University of Southampton
Southampton SO17 1BJ
02380 595283

What do I do if I want to take part?

Please fill in the questionnaire and send it back to the researcher in the enclosed stamped addressed envelope.

THANK YOU for taking the time to read this information sheet.

Appendix 28: Participant Introduction letter**Participant Introduction Letter**

Dear Breathe Easy member

My name is Liz Arnold and I am a researcher at the University of Southampton. I am specifically interested in looking at how people with COPD (Chronic Obstructive Pulmonary disease) use their prescribed portable oxygen.

With the help of some people who have COPD and portable oxygen, I have put together the enclosed questionnaire. We hope this will give us more information on how you use your portable oxygen and what you think are some of the advantages and disadvantages of the portable oxygen system.

The questionnaire is quite long as it covers many aspects of your portable oxygen and how it works. You may feel that filling it in a page at a time is better for you than sitting down and doing the whole questionnaire in one go. However you decide to complete it, I would be very grateful if you could fill in the questionnaire and return it in the stamped addressed envelope enclosed.

The information we get from the questionnaire will be completely anonymous so you can answer the questions freely. If you want a copy of the results of the questionnaire study then please fill in the name and address form at the back of the questionnaire. This will be detached when we receive the completed questionnaire and kept separately, so the questionnaire cannot be identified. We will then send you a final report at the end of the study.

Thank you so much for filling in the questionnaire. The information we obtain is very important and will be used to inform health professionals how to help patients with COPD who are prescribed portable oxygen.

Lis Arnold

PhD student University of Southampton

Appendix 29: Example of excel spreadsheet used to collate pilot questionnaire responses

Example of the excel spreadsheet for the pilot questionnaire

participant	1a	1b	1c	qu 2 time	qu 3 time	4a	4b	4 c	4d
	yes/no	yes/no	D't kn	timehrs	timeyrs	yes/no	yes/no	yes/no	yes/no
1	1	0	0	2hrs	2.5	1	0	0	0
2	1	0	0	33	4	0	1	0	0
3	1	0	0	7	0.6	0	1	0	0
4	0	1	0	0	3	0	0	0	1
5	0	1	0	0	3weeks	1	0	0	0
6	0	1	0	4hours	2.6	1	0	0	0
7	1	0	0	3hrs	1.9	0	0	1	0
8	0	1	0	4hours	1.6	0	1	0	0
9	0	1	0	2 hours	6 months	1	0	0	0
10	1	0	0	2 hours	4 years	0	0	1	0
11	1	0	0	3 hours	8months	1	0	0	0
12	1	0	0	4 hours	1.5	1	0	1	0
13	1	0	0	3 hours	3.5	0	0	1	0

1= yes answer. 0=no answer 33=missed response

Appendix 30: Final questionnaire Version 10 (post pilot study)

This questionnaire is only asking questions about your

PORTABLE OXYGEN



It is NOT about your home oxygen



A questionnaire about how people with Chronic Obstructive Pulmonary Disease (COPD) use their Portable Oxygen

Introduction

This questionnaire aims to explore what people who have COPD think about their portable oxygen (the oxygen you take out of the house with you) and how they manage their portable oxygen when they do use it.

As you may know there is little known about what people with COPD actually think about their portable oxygen and how useful it maybe. This questionnaire is designed to try and find out from you, someone who uses portable oxygen, how helpful portable oxygen is, and what you think are the advantages and disadvantages of the portable oxygen you use.

This questionnaire is completely **ANONYMOUS**, so please feel free to answer the questions as truthfully as possible; the questionnaire cannot be traced back to you, and so cannot affect your treatment or prescription at all.

Please read every question in the booklet and answer using the boxes provided. Some answers require a yes or no, whereas others require you to read a statement and then mark the box which most agrees with how you feel about that statement. These questions have the instructions with them. There are areas in the questionnaire where you can write whatever you think, so please feel free to use those boxes to tell us more information. If you want to get your wife, husband, relative or carer to help you fill this in, please do so.

When you have finished answering all the questions, please put the booklet **into the envelope provided** and it will come straight back to us at the University of Southampton.

Thank you very much for completing this questionnaire, it will give us invaluable information about portable oxygen, how useful you find it and what you feel are the advantages and disadvantages of the system. This will enable us to consider the user's perspective in future designs of portable oxygen equipment.

1. What kind of PORTABLE OXYGEN SYSTEM do you have?**a. Cylinder Oxygen**

Is delivered by your oxygen company, and you ring them when you want a new one,
Your cylinder may look like one of these below;



Please tick here if
you use portable
cylinder oxygen

b. Liquid Oxygen

A 'mother tank' is delivered by your oxygen company and you refill the ambulatory
carrier yourself from the mother tank. The mother tank is replaced about every 2 weeks



Please tick here if
you use portable
liquid oxygen

Please tick here if you are not sure which kind of portable oxygen you
use

2. How long were you told your PORTABLE OXYGEN cylinder would usually last?

--

3. How long have you been using PORTABLE OXYGEN?

.....years.....months

4. Who FIRST prescribed your PORTABLE OXYGEN for you?*Please tick the appropriate box*

The oxygen assessment centre	
The hospital prescribed it for you to go home	
Your GP	
Other; please state	

5. Did anyone explain to you WHY you needed PORTABLE OXYGEN?*Please tick the appropriate answer*

Yes	No
-----	----

6. What instructions did you get when you first got your PORTABLE OXYGEN?*Please tick all the answers that are applicable*

I was told to use it when I went out	
I was told it would help me when I went out	
I was told to use it when I was walking outside	
I was told to use it when I exercising (at pulmonary rehab)	
I was not told anything	
I was told to use whenever I was breathless	

7. Who showed YOU how to use the controls on your PORTABLE OXYGEN system?*Please tick the appropriate answer below*

The oxygen assessment centre showed me	
The oxygen delivery person showed me; face to face	
The oxygen delivery person showed my family/carers and they then showed me	
No one showed me	
Other, please state who	

8. When you were first given your PORTABLE OXYGEN system did you understand how to use the controls?*Please tick the appropriate answer*

Yes	No
-----	----

9. Did you feel confident in using the PORTABLE OXYGEN system yourself when you first started using it?*Please tick the appropriate answer*

Yes	No
-----	----

10. Do you think that more information on PORTABLE OXYGEN would be useful to you or your family/carers?*Please tick the appropriate answer***a. To me**

Yes	No
-----	----

b. To my family / carers

Yes	No
-----	----

11. If you were to receive some more information on using PORTABLE OXYGEN, how would you like to get it?

Please tick the appropriate answer

Written information	
Face to face at home	
I don't want further information	

12. Do you ever use your PORTABLE OXYGEN system INSIDE the house?

Please tick the appropriate answer

Always	Sometimes	Never	Only if I'm unwell
---------------	------------------	--------------	---------------------------

13. Do you use your PORTABLE OXYGEN in the garden?

Please tick the appropriate answer

Yes	No	I don't have a garden
------------	-----------	------------------------------

14. How often do you go further afield for example to the supermarket or out for appointments?

Please tick the appropriate box

Everyday	
More than once per week	
Less than once per week	
I do not go out of the house	

16. Do you take your PORTABLE OXYGEN with you every time you go out?

Please tick the appropriate answer for you below;

Always	Sometimes	Never	Only if I'm unwell
---------------	------------------	--------------	---------------------------

17. Does PORTABLE OXYGEN relieve your breathlessness?

Please tick the appropriate box

Yes	No
-----	----

18. When you go out*Please tick the boxes that describe what you do*

I keep my Portable Oxygen in the car in case I need it	
I use my Portable Oxygen in the car AND out in public	
I keep my Portable oxygen on my electric Buggy	
I don't use my portable oxygen	

19. Who carries the PORTABLE OXYGEN when you are out of the house, (not in the car)*Please tick the appropriate boxes below*

I always carry my own portable oxygen	
I can carry it if I feel well	
My wife/husband/carers carries the portable oxygen	
I use a trolley to carry my portable oxygen	
I put the portable oxygen system on my buggy/wheelchair	
I don't take my portable oxygen out of the car	
I don't use my portable oxygen	

20. What do you carry your PORTABLE OXYGEN in?*Please tick the appropriate box*

Shoulder bag (supplied by oxygen company)	
Back pack (supplied by oxygen company)	
Your own bag	
Other please state what:	

21. What do you think about the weight of your PORTABLE OXYGEN?*Please tick the appropriate box***I think my portable oxygen weighs too much**

strongly agree	agree	not sure	disagree	strongly disagree
----------------	-------	----------	----------	-------------------

22. Does the weight of the PORTABLE OXYGEN stop YOU carrying it out of the house on your own?

Please tick the appropriate answer

Yes	No
-----	----

23. Who checks the controls on your PORTABLE OXYGEN?

Please tick the appropriate box

I always check my own control	
Someone else always checks the control for me	
Sometimes I check the control, sometimes someone else checks it	

24. Do you ever worry that the PORTABLE OXYGEN may run out whilst you using it are outside the house?

Please tick the appropriate answer

Yes	No
-----	----

25. Are you SO worried about the oxygen running out that you do not take it out of the house with you?

Please tick the appropriate answer

Yes	No	Sometimes
-----	----	-----------

26. Who checks the oxygen levels in your PORTABLE OXYGEN?

Please tick the appropriate box

I always check the oxygen levels myself	
Someone else always checks the oxygen levels	
Sometimes I check the levels and sometimes someone else checks them for me	

27. How helpful do you feel your PORTABLE OXYGEN system is?*Please tick the appropriate box;***I think my portable oxygen is helpful to me**

always helpful	sometimes helpful	occasionally helpful	rarely helpful	never helpful
----------------	-------------------	----------------------	----------------	---------------

28. How do you feel about your PORTABLE OXYGEN system?*Please tick the appropriate answers*

	Yes	No
I feel more confident to go out of the house		
I feel I have more freedom to go out		
I feel safer when I'm outside the house		
My carer feels more confident if we have portable oxygen with us		
The system is too heavy to carry		
The system is too embarrassing to use in public		
I do not feel I need portable oxygen		

29. Do you worry that if you start using PORTABLE OXYGEN more you may become more dependent on it?*Please tick the appropriate answer*

Yes	No
-----	----

30. Do you feel that on balance, your PORTABLE OXYGEN system has more advantages, or more disadvantages?*Please circle the appropriate box below***I feel that portable oxygen has more advantages**

Yes	No	Don't Know
-----	----	------------

31.

I feel that portable oxygen has more disadvantages

Yes	No	Don't Know
------------	-----------	-------------------

32.

I think the weight of my portable oxygen is OK

strongly agree	agree	not sure	disagree	strongly disagree
-----------------------	--------------	-----------------	-----------------	--------------------------

33. Do you feel embarrassed being seen in public with a PORTABLE OXYGEN system?

Please tick the appropriate box

YES	NO
------------	-----------

34. Does feeling embarrassed stop you using your PORTABLE OXYGEN system outside the house?

Please tick the appropriate box

YES	NO
------------	-----------

34. Please tell us how old are you

Please circle correct group below

30-49yrs

50-69yrs

70-89yrs

89-yrs or older

35. Who do you live with?*please tick the appropriate box*

With a husband, wife or partner	
On your own	
With a relative e.g. daughter/son	
With a friend	
In a residential care setting	
Other (please state what)	

36. Do you have oxygen for long term use only at home (LTOT)?*Please tick the appropriate answer*

YES	NO
-----	----

37. How long have you had home oxygen**38. Is there anything else you wish to tell us about your portable oxygen?**

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If you want to contact the researcher:**Lis Arnold MSCP MSc****PhD student c/o Dr A. Bruton****Building 45****University of Southampton S017 IBJ****THANK YOU VERY MUCH FOR ANSWERING THESE QUESTIONS**

Appendix 31

An example of the results from the questionnaire (version 9) completed by the same patient with a gap of four months between completions

8yes	1	1	1
8no	0		
8/9yes	1	1	1
8/9no	0		
9/10a yes	1	1	1
9/10a no	0		
9/10b yes	1	1	1
9/10b no	0		
10/11a	1	1	1
10/11b	2		
10/11c	3		
10/11d	4		
11/12a	1		
11/12s	2		
11/12n	3	3	3
11/12o	4		
12/13a	1	1	1
12/13b	2		
12/13c	3		
12/13d	4		
12/13e	5		
12/13f	6		
12/13g	7		
13/14a	1	1	1
13/14s	2		
13/14n	3		
13/14o	4		
14/15a	1	1	1
14/15b	2		
14/15c	3		
14/15d	4		
14/15e	5		
14/15f	6		
15/16a	1	1	1
15/16s	2		
15/16n	3		
15/16o	4		

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