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## Access to Electronic Thesis

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Thesis title: A preliminary investigation into the association between Chronic Obstructive Pulmonary Disease (COPD) and oropharyngeal dysphagia, and its impact on health.  
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The  
University  
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Sheffield.

**School of Health and Related Research**

**A preliminary investigation into the association  
between Chronic Obstructive Pulmonary  
Disease (COPD) and oropharyngeal dysphagia,  
and its impact on health.**

**Kelly McPhee**

**Ph.D.**

**August 2011**

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Many research projects have previously been analogised to mountain exploration; the relentless climb, the pain and anguish of striving to explore new territory, and the exhilaration of the view when the goal has been achieved. I felt this research had moments similar to climbing a mountain, but mostly felt like a rollercoaster ride with twists and turns, highs and lows, feelings of dread and pure adrenalin that took me on a professional and personal journey over the last six years. A research thesis of this magnitude is not achieved in isolation and requires guidance and support from supervisors, colleagues, family and friends. Completion would not have been possible without involvement of so many people who joined me on this challenging rollercoaster ride, whom I would like to take this opportunity to thank.

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To embark on such a journey, maintain enthusiasm through the dark tunnels and during the unexpected twists and turns of the ride, an enormous amount of determination and energy is also required from within; no matter what is thrown your way. However, when I felt I was being thrown from the ride, one poem was pinned to the wall throughout; it became my safety belt and sat me right back in the front seat to tackle the next big 'loop-the-loop', and one which I would like to share:

*You can do anything if you have enthusiasm.  
Enthusiasm is the yeast that makes your hopes rise to the stars.  
Enthusiasm is the sparkle in your eyes, the swing in your gait,  
the grip in your hand, the irresistible surge of will and energy to execute  
your ideas.*

*Enthusiasts are fighters. They have fortitude.  
They have staying qualities.  
Enthusiasm is at the bottom of all progress.  
With it, there is accomplishment.  
Without it, there are only alibis.*

*Henry Ford 1863-1947*

## **Abstract**

### *Title:*

A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health.

### *Background:*

Prevalence of oropharyngeal dysphagia in patients with COPD is under researched; with its contribution to exacerbations of the disease and impact on quality of life remaining elusive.

### *Aim of Study:*

To investigate the extent and nature of oropharyngeal dysphagia by phase of COPD, and its impact on health.

### *Objectives of the study:*

Three objectives investigated were

- subject perception of symptoms and swallowing related quality of life between normal controls and COPD (stable and exacerbation phase)
- prevalence of biomechanical dysphagia by phase of COPD (stable and exacerbation)
- prevalence of altered respiratory-swallow pattern by phase of COPD (stable and exacerbation)

### *Study Design:*

Prospective, repeated measures observational study design with a cross sectional control arm. Feasibility Testing was conducted for the three key components of the assessment process.

*Methods for Prospective Study:*

Normal controls (n=36) completed a validated questionnaire (SWAL-QOL). COPD subjects completed the SWAL-QOL, videofluoroscopy and respiratory assessment simultaneously during exacerbation phase of COPD (n=14); followed up during stable phase (n=10).

*Results:*

Descriptive and non parametric analysis revealed COPD subjects were more likely to:

- perceive their swallowing ability lower than controls ( $p < 0.01$ ) with further deterioration during exacerbations ( $p = 0.012$ )
- perceive their quality of life lower than controls ( $p < 0.01$ ) with further deterioration in two domains during exacerbation phase (Duration  $p = 0.021$ , Fear  $p = 0.043$ ).
- exhibit dysphagic characteristics significantly more for food ( $p = 0.046$ ) and drink trials ( $p = 0.035$ ); with increased penetration ( $p = 0.031$ ) and spontaneous manoeuvres ( $p = 0.044$ ) during exacerbation phase of COPD.
- use inhalation post swallow for either phase of COPD more than normative data within the literature.

*Conclusions:*

This study showed the presence of oropharyngeal dysphagia in patients with COPD; with symptoms increasing during exacerbation phase. This finding was significantly altered from the 'normal swallowing pattern' from controls within this study and from normative data found within the literature.

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# **Chapter One**

## **Introduction to Study**

## **Chapter One: Introduction to Study**

### **1.1 Introduction**

Chronic Obstructive Pulmonary Disease (COPD) is a respiratory disease with progressive decline in lung function, often punctuated by acute exacerbations when respiratory function temporarily deteriorates above and beyond the usual impairment (Donaldson & Wedzicha, 2006). Factors affecting the severity and frequency of these exacerbations, or the associated impact on quality of life are largely unknown. Furthermore, there has been increased suspicion that oropharyngeal dysphagia (swallowing difficulties) contributes to the onset, severity or frequency of acute exacerbations and subsequent decline in patients with COPD; however this has yielded little research interest to date.

The study presented in this thesis aims to investigate prevalence, define relevant factors contributing to oropharyngeal dysphagia in COPD and explores swallowing related quality of life by phase (stable or exacerbation) of the condition. This was achieved by reviewing previous literature, building on current knowledge of oropharyngeal dysphagia and the respiratory-swallow pattern to design an innovative research methodology.

Chapter one introduces the two key elements of this thesis, with an in-depth review of oropharyngeal dysphagia continuing in chapter two. Finally, this chapter summarises the study design and plan of the thesis.

## 1.2 Contribution to Body of Knowledge

This thesis provides a unique contribution to the currently limited body of knowledge in the area of oropharyngeal dysphagia and COPD, which is discussed in detail in chapters two and three. The innovative study design presented in this thesis addresses past methodological weaknesses within the literature and extends research objectives to include:

- visual analysis of oropharyngeal dysphagia simultaneously with respiratory-swallow pattern analysis *by phase* of COPD in a British population
- self-rated perception of swallowing skills and swallow related quality of life by phase of COPD

Additionally, there is no known research exploring true prevalence and nature of oropharyngeal dysphagia in patients with COPD in the United Kingdom, nor is there any known study to integrate information gathered from the three concurrent measures (self perception of swallowing skills and related quality of life, oropharyngeal swallow assessment and respiratory-swallow pattern assessment, discussed in chapter four) in patients with COPD internationally. This holistic approach aims to provide clinically relevant information on the overall swallowing function, and considers the wider implications of swallowing aberrations in patients with COPD such as phase of disease and impact on quality of life; relevant to both the professional and COPD patient/carer.

A summary of the contributions this thesis offers to the body of knowledge is summarised in table 1.

**Table 1 Summary of contribution of thesis to the current body of knowledge.**

<b>Contribution to Body of Knowledge</b>
<ul style="list-style-type: none"><li>• Consolidates and integrates current evidence regarding oropharyngeal dysphagia and respiratory-swallow pattern within COPD population.</li><li>• Provides new information on extent and nature of oropharyngeal dysphagia by phase of COPD.</li><li>• The first research known internationally and within the U.K. to measure self rated perception of swallowing skills and related quality of life concurrently with visual oropharyngeal and respiratory-swallow pattern assessment.</li><li>• Highly replicable innovative study design.</li></ul>

### **1.3 Clinical Driver**

I started work in Sheffield in 2002 as a Highly Specialist Speech and Language Therapist. My role was to develop a speech and language therapy service (swallowing and communication assessment and intervention) within the newly formed team called Assessment and Integrated Care Scheme (AICS). The AICS team's remit was to provide safe, prompt discharge from hospital with initial community support for people over the age of 65 years. As part of the team, I would assess admissions into the emergency units at the two major teaching hospitals in Sheffield (Royal Hallamshire Hospital and Northern General Hospital) for potential candidates who would benefit from the AICS service.

During this time I noticed a high readmission rate for people presenting with purulent sputum and shortness of breath, and subsequently diagnosed with an exacerbation of their pre-existing COPD. Furthermore, these patients had

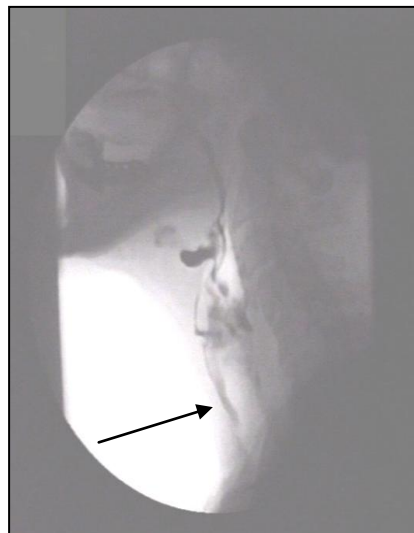
a history of recurrent chest infection; some with low body mass index (BMI) and dehydration, acknowledged as a complication of their disease (National Collaborating Centre for Acute and Chronic Conditions., 2010). Even though these symptoms mirror symptoms of recurrent aspiration pneumonia caused by oropharyngeal dysphagia (Perlman & Schulze-Delrieu, 2003), referral to Speech and Language Therapy for dysphagia assessment occurred only if their past medical history included a disease/disorder well known to cause dysphagia (such as stroke). It became apparent that the pathway for a patient presenting with an exacerbation of their COPD in Sheffield followed national guidelines for managing acute exacerbations (National Collaborating Centre for Acute and Chronic Conditions., 2010), alongside local pathways (NHS Sheffield, accessed online 2007) which were streamlined in treating exacerbations in a timely and efficient manner. As the empirical therapy (usually including antibiotics and steroids in hospitalised cases) is acknowledged to be effective, other potential differential diagnoses (such as chest infections/ pneumonia caused by oropharyngeal dysphagia) were not routinely investigated. If a percentage of admissions presenting with acute exacerbation of COPD also included potentially undiagnosed oropharyngeal dysphagia (swallowing problems), the already prescribed antibiotic intervention would treat the acute infection, but would not treat the underlying cause of the oropharyngeal dysphagia and allow recurrent chest infections to continue. However, the underlying association was not clear at a clinical level and the potential association between exacerbations of COPD and oropharyngeal dysphagia could not be explained fully within the literature.

This initiated the question:

*Does oropharyngeal dysphagia cause (some) exacerbations of COPD, or could acute exacerbations of COPD induce episodes of oropharyngeal dysphagia?*

Clinical suspicion was increased during my videofluoroscopy clinics at Sheffield Teaching Hospitals. In 2006, approximately 30% of people referred (mostly by Speech and Language Therapists) to videofluoroscopy clinics for a swallowing assessment (as described in chapter four) had a primary or secondary diagnosis of COPD. A case history noted most of those referred reported '*not eating and/or drinking for (up to) eight days*' during an exacerbation as they were '*scared of choking*', '*coughing on food/drink*', '*not being able to catch their breath during eating/drinking*', or '*too tired to eat*'. From videofluoroscopy assessment, approximately 80% were diagnosed with some level of dysphagia, with approximately half considered as 'silent aspirators' (described in chapter two) as shown in figure 1.

**Figure 1 Arrow pointing to aspiration as seen during videofluoroscopy.**



Thus, these individuals reported symptoms of, and were clinically diagnosed with oropharyngeal dysphagia. However, as the videofluoroscopy took place

in a general clinic, it was difficult to ascertain if the oropharyngeal dysphagia could be attributed solely to COPD, or as a result of co-morbidities. A review of the literature revealed oropharyngeal dysphagia in COPD has had limited research attention in the past (as discussed in the theoretical chapters two and three), and further research was required to ascertain whether COPD as a primary diagnosis was a relevant client group for identification as an 'at risk' group, which would then warrant dysphagia screening and intervention.

## **1.4 Background to the Study**

### **1.4.1 Oropharyngeal Dysphagia**

'Dysphagia' is derived from the Greek root meaning 'disordered or difficulty eating', also known as deglutitive disorders (Murry & Carrau, 2006). The Health and Social Care Information Centre (accessed online 2009)<sup>1</sup> reported dysphagia was considered the primary reason for 20,528 hospital admissions in England during 2005/6, resulting in a total of 63,204 bed days. Sheffield recorded 360 admissions for this problem resulting in 1,268 bed days for the same period. However a true estimate of hospital admissions due to oropharyngeal dysphagia is difficult to achieve due to possible mis-diagnosis, under-diagnosis, coding variations or over generalisation of diagnosis. World Health Organisation (WHO, accessed online 2009) classifies oropharyngeal dysphagia and oesophageal dysphagia within the same ICD category (R13). Also, oropharyngeal dysphagia may be coded under other headings such as pneumonitis due to food and vomit (J690),

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bacterial pneumonia not elsewhere classified (J15). Accounting for these potential coding variations, oropharyngeal dysphagia related admissions may be as high as 35,000; resulting in approximately 3,268,000 bed days in England during 2005/6. Furthermore, the figures quoted are from acute hospital records, therefore do not show figures or related health care costs within the community setting.

In 2008, the Royal College of Physicians produced guidelines stating a patient who shows clinical features of oropharyngeal dysphagia should be referred for a full clinical assessment by a trained specialist. Whilst multidisciplinary management is crucial, Speech and Language Therapists are internationally recognised as the lead profession in the assessment and management of oropharyngeal dysphagia, with the profession receiving increasing referrals (Enderby & Petheram, 2002). Relevant professional bodies have produced clinical guidelines and procedures detailing competencies required for oropharyngeal dysphagia assessment and management (Speech Pathology Australia [SPA], 2004; Royal College of Speech and Language Therapists [RCSLT], 2006; Royal College of Physicians, 2008; American Speech-Language Hearing Association [ASHA], 2010).

Oropharyngeal dysphagia has been found to contribute to pneumonia, malnutrition, poor wound healing, reduced tolerance to medical treatments and lower quality of life (Langmore, Terpinning & Schork et al., 1998; Gaziano, 2002; Murry & Carrau, 2006; Cabre, Serra-Prat, Palomera, & Almirall, et al., 2010). Furthermore, a dramatic reduction in pneumonia has been reported when systematic diagnosis and treatment of oropharyngeal



dysphagia is implemented (Langmore, 1991). The most common signs and symptoms of pneumonia caused by oropharyngeal dysphagia (or aspiration pneumonia) are frequent coughing, purulent sputum, increased shortness of breath, high fever and chest infection (Langmore, Terpinning, & Schork, et al., et al., 1998). Observational assessment of aspiration pneumonia presents similar signs and symptoms to an acute exacerbation COPD (see section 1.4.2vi), yet differential diagnosis is not yet routinely investigated.

A number of aetiologies have been attributed to oropharyngeal dysphagia in neurological and non neurological populations (Kidd, Lawson, Nesbitt, & MacMahon, 1995; Shaker, Milbrath, Ren, & Campbell, et al., 1995; Logemann, 1998). However COPD does not conform with typical neurological aetiologies; such as acute insult to the brain (e.g. stroke), nor does it conform with typical non-neurological aetiologies such as surgical/intervention induced changes (e.g. head and neck cancer, tracheostomy patients). Therefore it is difficult to generalise any of these findings in the literature to the COPD aetiology. Furthermore, the influence of respiratory status on swallowing has received little attention in non tracheostomy aetiologies. Until the evidence based is clearly established, the extent of oropharyngeal dysphagia in patients with COPD may continue to be under-diagnosed. The study detailed in this thesis aims to address this issue.

### **1.4.2 COPD**

Chronic Obstructive Pulmonary Disease (COPD) or Chronic Obstructive Airways Disease (COAD) is the preferred term for emphysema, bronchiolitis and chronic bronchitis. It is defined by the airflow obstruction that is *'not fully*

*reversible and does not change markedly over several months'* (National Clinical Guideline Centre, 2010, p. 54). COPD develops as the lungs become damaged over a long period of time. An abnormal inflammatory response to tobacco smoke and other irritants result in alveolar destruction, loss of parenchymal elasticity and bronchial inflammation; with the latter resulting in increased mucus production by the lungs which compromises their defence system. The combination of damage impedes airflow out of the lungs and impairs gas exchange, producing increasing symptoms of breathlessness.

COPD is most commonly caused by smoking, with an estimated 10% to 30% of smokers developing COPD (Voelkel, 2000). Another strong (inverse) relationship with COPD is socioeconomic status; with poor housing conditions and childhood respiratory illnesses influencing respiratory diseases later in life (Pauwels, 2000). Less common causes include genetic predisposition; such as alpha one antitrypsin deficiency (Stockley, Rennard, Rabe, & Celli, 2007), and occupational and atmospheric exposure such as welding or working within the steel industry (Meldrum, Rawbone, Curran, & Fishwick, 2005).

#### **1.4 .2i) Guidelines**

The rising prevalence of COPD and increasing burden on health resources (as discussed later) has led to guidelines for COPD diagnosis and management to become a high priority for government health initiatives. For the purposes of this thesis, U.K. guidelines and professional bodies will be

used as the main source for this study, and international guidelines referenced where appropriate.

International consensus based guidelines for COPD have been published since the 1990s; with the American Thoracic Society (ATS) (1995), European Respiratory Society (ERS) (1995), and Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) (2001) aiming to improve diagnosis and management of COPD on a global scale. Within the United Kingdom (U.K.), the British Thoracic Society (BTS) published guidelines for COPD in 1997 (Haplin, 2004), however the Department of Health also included management recommendations for patients with COPD within the generic National Standard Frameworks (NSF) under the NHS Plan (Department of Health, 2000); such as the NSF for Long Term Conditions (Department of Health, 2005a) and NSF for Older People (Department of Health, 2002) and strategies such as Chronic Disease Management (Department of Health, 2004). The Department of Health also instructed the National Institute for Health and Clinical Excellence to develop COPD guidelines for England and Wales, which were published in 2004 (National Collaborating Centre for Acute and Chronic Conditions., 2004). This aimed to provide guidelines for consistent service delivery across England and Wales, reduce overall prevalence and improve quality of life. Since the original work presented here was undertaken, a revised version has also been published (National Collaborating Centre for Acute and Chronic Conditions., 2010). Furthermore, a National Service Strategy for COPD is currently in consultation phase, due to be implemented in 2011 (Department of Health, 2010a). Therefore from 2004, the United Kingdom government policies have identified COPD as a

national priority and have encouraged Strategic Health Authorities and Primary Care Trusts to address COPD diagnosis and management at a local level.

### *Local Context*

In 2005, the diagnosis and management of patients with COPD in Sheffield was considered a priority due to the higher than national average incidence of the disease (Sheffield Health Authority and Sheffield Primary Care Groups, 2002), with Sheffield Respiratory services incorporating the COPD NICE guidelines into local practice (National Collaborating Centre for Acute and Chronic Conditions., 2004). Guidelines emphasised that management should be delivered by a multidisciplinary team, and innovative ways to reduce hospital admission rates should be explored. As such, local strategies including specialist oxygen assessment services, pulmonary rehabilitation and the Supported Early Discharge Scheme were initiated to address the increase use of health resources locally (NHS Sheffield, accessed online 2007).

Although a multidisciplinary team approach is recommended in all guidelines, limited evidence for oropharyngeal dysphagia in patients with COPD has resulted in the lack of oropharyngeal dysphagia assessments to be routinely included within care pathways.

#### **1.4 .2ii)      *Prevalence***

The NICE Clinical Guideline 101 (National Collaborating Centre for Acute and Chronic Conditions., 2010) suggests overall prevalence of COPD in the United Kingdom is estimated between 2- 4% in England and Wales.

However prevalence varies depending on age and socio-economic factors, and NICE suggest current prevalence in U.K. adults over the age of 45 years increases between 9% and 11%; showing yearly increases more so in women. The 'Lung Report III' in 2003 (British Lung Foundation, 2003) suggest early symptoms go largely undetected, or are wrongly associated with signs of ageing (for example increased breathlessness), and is therefore significantly under-diagnosed in the primary care setting. Sheffield has a higher than national overall prevalence in pockets of lower socioeconomic regions; recording 7% prevalence (Sheffield Health Authority and Sheffield Primary Care Groups, 2002).

#### **1.4.2iii)      *Morbidity***

COPD is a significant drain on health care resources. In 1990 COPD was estimated to be the twelfth greatest burden of disease globally, and predicted to rise to fifth place by 2020 (Murray & Lopez, 1996). In the United Kingdom, people diagnosed with COPD tended to access NHS services more than the non COPD population in 2000, with 80% of the COPD population accessing GP services (compared to 55% of non COPD population) (Sheffield Health Authority and Sheffield Primary Care Groups, 2002). The British Thoracic Society (2006) reported patients with COPD attended approximately 1.4

million general practice consultations with 62 million prescriptions used in the prevention and treatment of respiratory disease (with COPD as a major contributor) in 2004. Additionally, a high socio-economic burden is attributed to COPD, with an estimated 24 million working days per year lost due to the disease, at an estimated cost of £2.7billion in lost productivity (Department of Health, 2005b).

Patients with COPD also use a significant proportion of acute services in England and Wales. Acute hospital admission rates were 64% (compared to 43% of non COPD population) for 1996/7- 2000/01 (Sheffield Health Authority and Sheffield Primary Care Groups, 2002). In 2000, one in eight emergency medical hospital admissions in England were due to COPD, and the British Thoracic Society (2006) reported COPD accounted for one million inpatient bed days and a mean length of stay of 9 days in 2003. Studies also report high readmission rates for acute exacerbation, with 22% of patients with COPD being readmitted within two weeks (Adams, Melo, Luther, & Anzueto, 2000) and 40% within six months (Connors, Dawson, Thomas, & Harrell, et al., 1996).

COPD has been reported as among the most costly diseases for inpatient NHS care. The Department of Health (2005b) estimated COPD accounted for a total of £1.7 billion in morbidity costs, of which more than £800 million is used in direct NHS healthcare costs each year. Within Sheffield, COPD also rated as the second highest ranking emergency medical admission to Sheffield Hospitals with the highest length of hospital stay per patient group (Sheffield Health Authority and Sheffield Primary Care Groups, 2002).

#### **1.4.2iv) Quality of Life**

Previous research on the impact of COPD on quality of life found in the literature can be broadly categorised within medical or psychosocial models. The tendency within early research was to investigate quality of life in patients with COPD in order to predict increased use of resources (Seemungal, Donaldson, Paul, & Bestall, et al., 1998). Such studies found poor quality of life predicted the increased use of health resources and increased hospital admissions (Osman, Godden, Friend, & Legge, et al., 1997; Traver, 1998). Seemungal and Donaldson et al (1998) found quality of life was also significantly related to exacerbations, where frequent exacerbators scored lower in quality of life questionnaires. The studies mentioned used a medical model approach measuring declining lung function to account for progressive deterioration in quality of life. This may not accurately reflect or measure the impact COPD had on wellbeing; such that significant distress or deterioration in mental health or quality of life may occur during exacerbations of the condition, independent of clinical deterioration of lung function. Although not a direct aim, studies such as Ferrer and Alonso et al (1997), and Burge and Caverley et al (2000) highlighted that perceived quality of life did not always correlate with severity of COPD (or decline in lung function); a patient with mild COPD may show substantially reduced quality of life. Thus measuring lung function decline in isolation to design management protocols was no longer considered appropriate, as severity of COPD was shown to be a poor indicator of quality of life (Jones, 1995). Since the study by Burge and Caverley et al (2000), the importance of incorporating psychosocial aspects of health and wellbeing to

identify, treat and engage patients with COPD has received greater priority in national agendas (Department of Health, 2004). Therefore studies have also aimed to investigate the impact of COPD on aspects of quality of life. Such studies found patients with COPD exhibit significantly higher levels of mental health issues such as depression and anxiety which have a negative impact on quality of life than normal controls (Felker, Katon, Hedrick & Rasmussen et al., 2001; Arnold, Ranchor, DeJongste, & Koeter, 2005; Cully, Graham, Stanley & Ferguson, et al., 2006). Furthermore, severity of COPD and frequency of exacerbations was found to relate to perceived decline in physical functioning, vitality and psychological functioning. Arnold and Ranchor et al (2005) suggested severity of COPD related to self reports of deteriorating physical functioning and reduced quality of life. However, perceived quality of life and wellbeing has also been shown to be mediated by levels of personal control or self efficacy, independent of severity of COPD (Kohler, Fish, & Greene, 2002). Some studies have suggested that levels of self efficacy influenced health promoting behaviours, such as adherence to smoking cessation programs, medication regimes, and exercise programs; which in turn increased perceived quality of life (Lox & Freehill, 1999; Gifford, Bormann, Shivey, & Wright, et al., 2000; Gebhardt, van der Doef, & Paul, 2001). These findings reiterate the importance of pulmonary rehabilitation and education programs on improving quality of life and wellbeing, which are discussed later in chapters two and seven.



#### **1.4.2v) Mortality**

COPD has a high mortality, killing more women than breast cancer, and more men than prostate cancer (Haplin, 2004). The World Health Organisation (WHO) estimated 5% of all deaths worldwide were due to COPD in 2005. This makes COPD the sixth leading cause of death globally (Department of Health, 2005b), and predicted to be the third leading cause of death worldwide by 2020 (WHO, accessed online 2007).

In 2000, COPD was recorded as the fifth most common cause of death and disability in England and Wales. This accounts for approximately 30 000 deaths per year, costing the NHS £1.9 billion (Department of Health, 2005b). However these numbers may underestimate the true mortality rates, as studies have shown difficulties in estimating death attributable to COPD due to coding differences of death certificates, changes in criteria for diagnosis and where COPD may not have been the primary cause of death (Mannino, Gagnon, Petty, & Lydick, 2000; Hansell, Hollowell, McNiece, & Nichols, et al., 2003; Hansell, Walk, & Soriano, 2003). McGarvey and Matthias et al (2007) reported on mortality rates within the TORCH (Towards Revolution in COPD Health) study; a large multisite clinical trial (n=6145) conducted between 2000 and 2003. Of the 911 deaths recorded, 40% were considered related to COPD, with the most common causes of death being acute-on-chronic respiratory failure (35%), cardiovascular events (27%), and lung cancer (21%). Other studies also suggest cause of death in COPD can be attributed to pulmonary infection or pulmonary embolism (Zielinski, MacNee, Wedzicha & Ambrosino et al., 1997). Soler- Cataluna and Martinez-Garcia et al (2005) reported that mortality is strongly associated with the frequency of

severe exacerbations requiring hospitalisation. In 2003, an average of 15% of COPD patients died within 90 days of admission into an acute hospital for exacerbation (Department of Health [DoH], 2005b). Furthermore, the DoH also reported survival rates can be as low as 50%, yet can increase as high as 95% if a highly specialist multidisciplinary team in an acute care facility is available.

#### **1.4 .2vi)      *Diagnosis***

As there is no single test to diagnose COPD, diagnosis relies on spirometry assessment in conjunction with 'multi-dimensional' tools that also assess clinical features and physical examination (National Clinical Guideline Centre, 2010). Spirometry measures airflow obstruction, and is defined by *forced expiratory volume in one second* (FEV<sub>1</sub> or the amount of air you can blow out of the lungs in one second) and reduced FEV<sub>1</sub>/FVC ratio (where FVC is forced vital capacity or the total amount of air blown out of the lungs in one breath). COPD is indicated if spirometry shows post bronchodilator FEV<sub>1</sub> of less than 80% predicted (from predicted normal for age, height and sex) and there is airflow obstruction as shown by decreased FEV<sub>1</sub>/FVC ratio of less than 70% in an appropriate clinical context. As discussed earlier, definitions of severity was used from the COPD NICE Clinical Guideline 12 (National Collaborating Centre for Acute and Chronic Conditions., 2004) (highlighted in table 2) was used within the study detailed in this thesis as this was the most up-to-date guideline at the time of the recruitment phase.

However, the clinical guidelines have since been revised, and therefore relevant information is discussed in section 7.4.

**Table 2 COPD severity ratings (adapted from NICE Clinical Guideline 101, 2010: p16)**

		NICE clinical guideline 12 (2004)	GOLD 2008	NICE clinical guideline 101 (2010)
Post bronchodilator FEV1/FVC	FEV1 % predicted	Severity of airflow obstruction		
			Post bronchodilator	
< 0.7	≥ 80%		Stage 1- Mild	Stage 1- Mild*
< 0.7	50–79%	<b>MILD</b>	Stage 2- Moderate	Stage 2-Moderate
< 0.7	30–49%	<b>MODERATE</b>	Stage 3- Severe	Stage 3- Severe
< 0.7	< 30%	<b>SEVERE</b>	Stage 4- Very Severe**	Stage 4- Very Severe**

\*Symptoms should be present to diagnose COPD in people with mild airflow obstruction

\*\*Or FEV1 < 50% with respiratory failure.

Using spirometry alone has the potential of underestimating, or overestimating the impact of the disease on the patient, and is unable to confidently predict quality of life and level of disability (Jones, 2001).

Therefore a comprehensive severity assessment should also include tools that cover airflow obstruction in combination with level of impact on health status and perceived disability and burden for the individual. National Clinical Guideline Centre (2010) states COPD should be generally considered if:

- Over 35 years of age
- Current or ex smoker
- Have any of the following symptoms:
  - Exertion breathlessness
  - Chronic cough
  - Regular sputum production
  - Frequent winter bronchitis
  - Wheeze
  - No clinical features of asthma

As COPD progresses, the pattern of symptomatology will change. They may include diverse conditions such as peripheral muscle weakness, changes in sleep, mood and cognition (Hung, Wisnivesky, Siu, & Ross, 2009) in addition to direct respiratory symptoms of breathlessness; as can be measured by Dyspnoea Visual Analogue Scales (Wewers & Lowe, 1990) and Modified Borg Scale (Burdon, Jumiper, Killian, Hargrave, & Campbell, 1982) and cough as well as being effected by co-morbidities. Thus, COPD diagnosis and ongoing assessment should be holistic throughout the disease process as this will guide the intervention pathway to suit the individual's needs.

#### **1.4.2vii) Exacerbations**

An exacerbation of COPD is defined as a '*sustained worsening of patient's symptoms from his or her usual state that is beyond normal day-to-day variations, and is acute in onset.*' (National Clinical Guideline Centre, 2010, p. 351). However Donaldson and Wedzicha (2006) suggest a precise definition of an acute exacerbation is difficult to specify due to the heterogeneity and natural progression of the disease. Historically exacerbations were believed to be random events in the natural progression of the disease process; however more recently they are understood to 'cluster' together in time. Therefore patients are more likely to experience a second exacerbation soon after the first (Hurst, Donaldson, Quint, & Goldring, et al., 2009), with studies showing up to 30% of patients admitted to hospital presenting with an exacerbation are readmitted within eight weeks (Skwarska, Cohen, Skwarska, & Lamb, et al., 2000; Sethi & File, 2004).

Known potential causes of exacerbations are air pollution, allergic responses or non compliance with medication regimes and viral infections (Wedzicha & Seemungal, 2007; Wilson, 2007), but bacterial infections are most important accounting for over half of all exacerbations (Murphy, Sethi, & Neiderman, 2000; Diamantea, Nakou, Drakopanagiotakis, & Milioni, et al., 2007; Nazir & Erbland, 2009; Cosio & Agusti, 2010). Additionally, Donaldson and Wedzicha (2006) reported that the expected number of exacerbations per year was directly related to severity of COPD; with severe COPD averaging 3.43 per year compared with moderate COPD averaging 2.68 per year. Additionally, Bhowmik and Seemungal et al (2000) documented that frequent exacerbations occurred in patients who were shown to have bacteria already present in the lower airway when stable, suggesting these patients were more susceptible to exacerbations due to reduced pulmonary defences during stable phase. Furthermore, pulmonary bacterial infections in patients with COPD were associated with longer hospital admissions, faster decline in lung function, poorer mobility and reduced quality of life than in patients without bacterial infection (Bhowmik, Seemungal, Sapsford, & Wedzicha, 2000; Donaldson & Wedzicha, 2006).

The role and impact of bacterial infections contributing to exacerbations and the decline in COPD is controversial (Hirschmann, 2000; Hurst & Wedzicha, 2007). However the literature generally acknowledges the strains of bacteria most strongly associated with exacerbations in COPD; and interestingly also associated with aspiration pneumonia (discussed in section 2.7.1) are H. influenza, Strep. Pneumoniae, Staph. Aureus, P.aeruginosa, and K.pneumoniae also playing a role (Murphy, Sethi, & Neiderman, 2000;

Diamantea, Nakou, Drakopanagiotakis & Millionis, et al., 2007). Yet the mechanism by which bacterial infections lead to exacerbations is largely under researched and consequently not routinely investigated. Furthermore, acute exacerbations treated within the community setting do not routinely include chest x-ray to confirm diagnosis of an acute exacerbation, or alternatively used to exclude pneumonia. In a study by Lieberman and Liebermann et al (2002), pneumonic (PNAE) verses non pneumonic (NPAE) acute exacerbations of COPD were investigated by comparing acute and stable phase chest x-rays. They found 10% (23/240) of subjects were classified with PNAE; of which more than 50% (13/23) were further diagnosed as right sided (as seen in aspiration pneumonia discussed in section 2.7.1). However the cause of the pneumonia was not reported. As a specific cause of exacerbations are currently not identified in approximately 30% of cases (Wedzicha & Seemungal, 2007), undiagnosed recurrent aspiration as a result of oropharyngeal dysphagia may play an important role as this may increase the bacterial load, and/or alter the type or location of bacteria (Singh, 2011); whereby causing or further complicating exacerbations in some cases. Therefore oropharyngeal dysphagia as a potential contributing factor to exacerbations warrants further investigation.

#### **1.4.2viii) Current Intervention**

The most common intervention strategies currently focus on alleviating airflow obstruction, however it is acknowledged that other therapies may positively impact on quality of life, disability and symptom relief without

addressing airflow obstruction (National Collaborating Centre for Acute and Chronic Conditions., 2010). An exacerbation of COPD may require intervention in either primary or secondary care, with more severe exacerbations resulting in emergency admission into hospital, and eventually lead to death (Donaldson & Wedzicha, 2006). Intervention strategies recommended by National Clinical Guideline Centre (2010) and relevant to this study are the use of antimicrobials (in severe cases), nutritional evaluation and patient education, which are now discussed.

### *Antimicrobials*

The use of antibacterials in the treatment of patients with exacerbation of COPD is controversial and currently not routinely recommended in every case. This may be due to the literature being equivocal on benefit (Sharma & Gupta, 2004; Nazir & Erbland, 2009); most likely as a consequence of the debate surrounding the importance of the bacterial load found in both stable and exacerbative phases of COPD as discussed earlier. Nevertheless, eleven randomised controlled trials have shown positive outcomes in the use of antibiotics in patients with COPD (McCrory, Brown, Gelfand, & Bach, 2001). Studies have found that daily administration of an antibiotic for up to 12 months, or for up to a week during an acute exacerbation reduce the frequency and duration of exacerbations (Adams, Melo, Luther, & Anzueto, 2000; Wilson, 2005; Seemungal, Wilkinson, Hurst, & Perara, et al., 2008), decreased mortality, use of mechanical ventilation, and length of hospital stay (Nouira, Marghli, Belghith, & Besbes, et al., 2001; El Moussaoui, Roede,

Speelman, & Bresser, et al., 2008). Not all studies have found improvements and this may be as a consequence of differing study inclusion criteria, types of antibiotics or clinical endpoints assessed. However, studies such as the MOSAIC trial highlight that when more stringent inclusion criteria and baseline assessment by which to measure improvement is instigated, findings suggest the use of antibiotics (moxifloxacin was used for five days in the study mentioned) allow mucosal inflammation to recover, improving pulmonary defence mechanisms and thereby increasing the duration between exacerbations (Wilson, Allegra, Huchon & Izquierdo, et al., 2004).

The effectiveness of both long and short term antibiotic therapy is not surprising if one potential contributing factor of an exacerbation is due to oropharyngeal dysphagia, as discussed previously. Dependent on the type of antibiotic prescribed, long term use would mask any recurrent aspiration, whilst short term antibiotic use would clear evidence of an acute infection, enabling the patient to feel well enough to eat and drink normally again. This cycle would continue as antibiotic therapy treats the symptoms, not the cause; suggesting a plausible theory for the occurrence of 'clusters' of exacerbations as described previously.

### *Nutritional evaluation*

An association between COPD and malnutrition has been well documented within the literature (Schols, Slangen, Volovic, & Wouters, 1998; Landbo, Prescott, Lange, & Vestbo, et al., 1999; Prescott, Almdal, Mikkelsen, & Tofteng, et al., 2002), with the degree of malnutrition correlating with the



severity of the disease (Openbrier, Irwin, Rogers, & Gottlieb, et al., 1983). Known causes of weight loss and malnutrition acknowledged in the literature are decreased food intake secondary to breathlessness; increased resting metabolism due to increased energy requirements for breathing, and altered absorption of essential nutrients due to hypoxia (Schols & Wouters, 2000). A study by Schols and Slangen et al (1998) found a history of weight loss was significantly related to mortality ( $p < 0.005$ ), with survival decreasing in underweight (severe COPD) and normal weight subjects when compared to overweight and obese patients ( $p < 0.0001$ ). This inverse relationship was confirmed in later studies (Prescott, Almdal, Mikkelsen, & Tofteng, et al., 2002); where Landbo and Prescott et al (1999) found this was also dependent on stage of COPD. Conversely, the relationship between weight gain and mortality rates had mixed findings; with Schols and Slangen et al (1998) reporting increased weight significantly reduced mortality risk, however Prescott and Almdal et al (2002) found no changes in mortality risk with increasing weight.

One possible cause of weight loss and malnutrition not considered in COPD guidelines is oropharyngeal dysphagia (discussed in more detail in chapter two). Some known complications of oropharyngeal dysphagia are malnutrition, dehydration, reduced appetite, and shortness of breath (Langmore, 1991; Logemann, 1998; Leslie, Carding, & Wilson, 2003), all symptoms exhibited in COPD, particularly during exacerbations.

### *Patient education*

A multidisciplinary team approach to intervention is acknowledged to encompass physical as well as quality of life issues the patient may encounter (National Clinical Guideline Centre, 2010). Professions considered essential in the management of COPD are Doctor, Nurse (including COPD Specialist Nurse), Physiotherapist, Occupational Therapist and Pharmacist. When COPD increases in severity, professionals added to the team are Dietitian, Social Work, Mental Health Worker, Psychologist/Psychiatrist and Behavioural Nurse/Therapist.

The aim of this multidisciplinary team is to monitor progression and exacerbations, provide treatment and care as required and educate on self management and exercise advice. All this aims to avoid emergency admissions and maintain quality of life. One multidisciplinary intervention strategy is the provision of pulmonary rehabilitation (Nazir & Erbland, 2009). Although recommended by the National Clinical Guidance Centre (2010) as an important tool in maintaining health and independence, availability is variable within the United Kingdom. Yet the guidelines acknowledge such intervention strategies increase quality of life, exercise tolerance; and reduce hospital admissions and length of stay. The basic framework for pulmonary rehabilitation sessions tends to focus on exercise tolerance and strength, disease education, psychosocial support and nutritional advice. These sessions are usually operated by physiotherapy with invited sessions from dietetics and psychology. Oropharyngeal assessment and intervention is not routinely included into multidisciplinary intervention strategies for COPD, most likely due to the lack of professional awareness, robust evidence in the

literature and omission within national guidelines. However two recent studies have found the effectiveness of including oropharyngeal dysphagia assessment and education within existing pulmonary rehabilitation sessions (McKinstry, Tranter, & Sweeney, 2009; Ilsley, 2011), and are discussed in more detail in chapter two.

#### **1.4.2ix)      *Prognosis***

COPD is not a curable condition and death is most commonly due to respiratory failure, lung cancer or cardiac disease (McGarvey, Matthias, Anderson, & Zvarich, et al., 2007). The disease is progressive but the course may be punctuated by exacerbations. Although exacerbations in general recover, recovery may not be complete, hence the accelerating decline in lung function. Furthermore quality of life may deteriorate alongside exacerbations with or without measurable decline in lung function.

The long term effects of COPD are increased breathlessness, sleep disturbances, restricted mobility, decreased independence, anxiety, depression and malnutrition. Most people continue to have a slowly deteriorating level of function, with unpredictable exacerbations worsening their condition.

## **1.5 Aim and Objectives**

### *Aim of the Study:*

To investigate the nature and extent of oropharyngeal dysphagia in patients with COPD; during stable and exacerbative phases of the disease, and its impact on health.

### *Objectives of the Study:*

1. Compare perception of dysphagia symptoms and impact on swallowing related quality of life between Normal Controls and by phase of COPD (stable or exacerbation).
2. Investigate prevalence of oropharyngeal biomechanical dysphagia by phase of COPD.
  - a. Explore the nature of the oropharyngeal dysphagia by phase of COPD.
  - b. Compare the perception of dysphagia symptoms with the biomechanical analysis by phase of COPD.
3. Investigate the nature of the respiratory-swallow pattern by phase of COPD.
  - a. Compare the respiratory-swallow pattern with the biomechanical analysis by phase of COPD.

## **1.6 Study Design**

This original study used a prospective repeated measures observational study design, with a cross sectional control stage; discussed in chapters four and five.

## **1.7 Plan of thesis**

This thesis is presented in seven chapters. Chapters two and three provide the theoretical background and critique previous oropharyngeal and respiratory literature relevant to this study. These two chapters define normal swallowing and respiratory-swallow patterns, comparing against known

dysphagic populations, along with previously published COPD swallowing ability and respiratory-swallow patterns. Information gathered from the literature shaped the research questions and informed the methodology of the research conducted in this thesis. As the study presented in this thesis was conducted in 2007/8, studies pertinent to COPD and oropharyngeal dysphagia published in the literature after 2007 were included in the theoretical chapters for completeness; however were not available to influence this study's methodology. However all relevant studies are subsequently reviewed in light of this study's findings within chapter seven.

Chapter four describes the methodology of the research; using the MRC 2010 guidelines, evidence based modelling and triangulation methodology as a framework. This chapter also justifies the assessment measures used to meet the aim and objectives of this study.

Chapter five details the relevant methods employed in the study detailed in this thesis, and chapter six uses descriptive and quantitative analysis to report findings for each objective of the study.

Chapter seven discusses the findings from this study; comparing clinical and statistical relevance with findings in the literature. This chapter also reports the limitations of the study detailed in this thesis, and highlights further research required in the future.

## **1.8 Concluding Thoughts**

COPD places a significant burden on health care resources, accessing NHS services more than the non-COPD population (Department of Health, 2004).

This is commonly due to exacerbations in the condition requiring lengthy acute inpatient care. The most predominate cause of exacerbations is bacterial infection, yet oropharyngeal dysphagia as a potential mechanism contributing to the progression of COPD has yet to be thoroughly investigated. As acute exacerbations of COPD and consequences of oropharyngeal dysphagia exhibit similar medical presentations, the potential for oropharyngeal dysphagia contributing to exacerbations and/or developing as a result of exacerbations in COPD warrants further investigation.

Historically, measures identifying oropharyngeal dysphagia have been predominately led by the medical profession's desire to associate physiological cause or changes in quality of life measures with severity of disease in order to improve rates of mortality and hospital admission (Seemungal, Donaldson, Paul, & Bestall, et al., 1998). Even though these clinical outcomes are important to clinicians and patients, the final success of any intervention strategy is decided by the patient themselves. Thus a key element crucial in the investigation of associations of oropharyngeal dysphagia in patients with COPD must include patient perception of their swallowing difficulty and how this impacts on their quality of life. Whereby quality of life measures can be utilised to influence future management strategies. Therefore the study presented in this thesis aimed to explore the clinician's and patient's perspective of the association between oropharyngeal dysphagia and COPD; including health related quality of life by phase of the condition by enlisting a triangulation methodological study design.

# **Chapter Two**

## **Pre-Clinical Theory Part I:**

### **The Oropharyngeal Swallow and COPD**

## **Chapter Two: The Oropharyngeal Swallow and COPD**

### **2.1 Introduction**

Swallowing saliva, food or drink is a subconscious act that is usually taken for granted; yet it occurs up to 600 times a day and involves more than 30 cranial nerves and muscles (Perlman & Schulze-Delrieu, 2003). Classifying a swallow pattern as 'impaired' or 'dysphagic' occurs when eating and drinking becomes unsafe and/or laboured and unfit for purpose; negatively impacting health and quality of life. The identification of dysphagic characteristics is most frequently associated by risk factors, such as neurological disease or head and neck oncology. However there is a paucity of research associating COPD as a risk factor for oropharyngeal dysphagia. To appreciate the potentially devastating effects COPD may have on swallowing, it is important to first understand what is considered 'normal'. The first aim of this chapter is to summarise current knowledge to clearly establish what is considered 'a normal swallow pattern' across an adult lifespan. Secondly, definitions of dysphagia are discussed against the normal swallow benchmark, including identification of the potential consequences to health and quality of life. Thirdly, studies investigating oropharyngeal dysphagia specifically in COPD are critically reviewed; against normative data discussed in points one and two, and for methodological design and outcome. The ten studies published before protocol development and data collection completed for the study in this thesis, combined with knowledge of the normal swallow and oropharyngeal dysphagia informed the methodology enlisted in this study (see chapter four).



## 2.2 Search Strategy

A literature search was conducted to identify current knowledge and was replicated by an allied health librarian (MLEO) for accuracy. I initiated the literature search in 2006 and performed a review every three to six months throughout the research period to ensure information was up to date. Hand searches of specific journals, such as Chest and Dysphagia, and relevant websites such as the Cochrane Collaboration and NICE guidelines were also recruited. Reference lists from relevant journal articles were examined and journal articles important to this study were obtained. Keyword and Mesh searches included Anglicised and American spelling and terminology. Oesophageal dysphagia was not included within the search strategy as it was not the focus of the study detailed in this thesis. The following terms are examples of key words used to source relevant articles:

Chronic Obstructive Pulmonary Disease (COPD)	Normal swallow	Respiratory/breathing swallow pattern
Chronic Bronchitis	Normal aged swallow	Aspiration/Penetration
Chronic Obstructive Airway Disease (COAD)	Dysphagia /Swallowing Disorder	Aspiration/bacterial pneumonia

The following databases were accessed via Athens:

Pub Med	Cochrane Databases
CINAHL	Medline
Ovid	DataStar
Proquest	EMBASE

Studies published prior to protocol development and the initiation of data collection phase (2007) were used to inform the research design of this

study, however relevant articles have been published since this date and are therefore included in the critical review and in the discussion chapter for completeness.

### **2.3 The Normal and Normal 'Age Related' Swallow**

The normal biomechanical swallowing pattern has been studied for over fifty years (Martin-Harris, Brodsky, Michel, & Lee, et al., 2007; Leslie, 2010). It is most commonly described as having three main stages; oral preparatory, oral and pharyngeal (Logemann, 1988). More recently, Martin-Harris and Brodsky et al (2003) described the swallowing pattern as having 12 events, rather than three distinct (and interlinked) stages (oral bolus transport, apnoea onset, bolus position at ramus of mandible, hyoid excursion, laryngeal elevation, maximum laryngeal closure, pharyngoesophageal [PES] segment opening, maximum hyoid excursion, last PES opening, first laryngeal opening, apnoea offset, hyoid return to rest). Although this describes the fluidity and overlapping nature of the stages of the swallow; and the influence each event has on each other more effectively, most textbooks and published studies describe results using the three stage pattern. Therefore the swallowing pattern will be discussed as stages of the swallowing throughout this thesis, and is summarised in table 3.

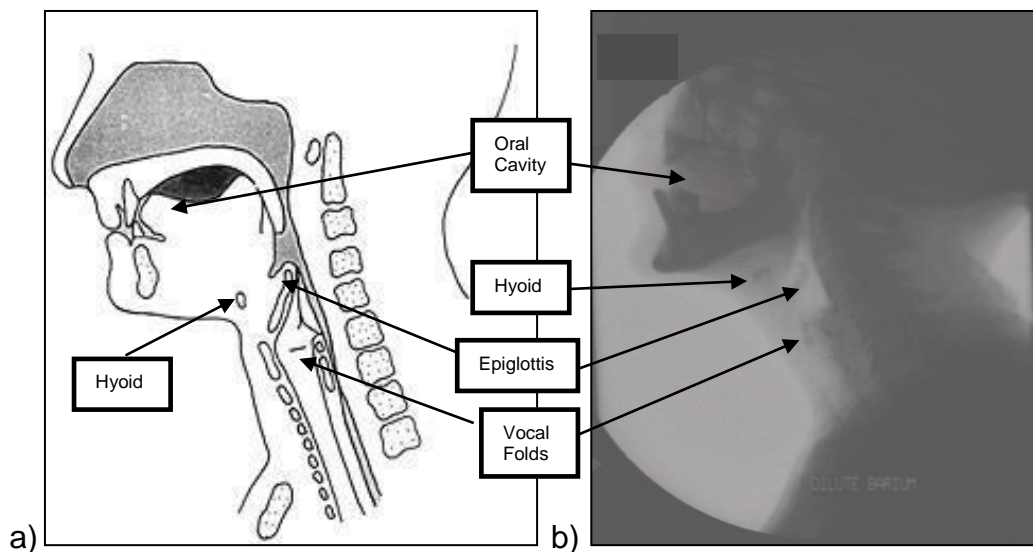
Functional variability within the normal swallowing pattern has been demonstrated to occur within and between age groups as a result of increasing evidence based research and increased use of technology (Martin-Harris, Brodsky, Michel, & Lee, et al., 2007; Butler, Stuart, & Kemp,

2009). This evidence has shown age related changes to the swallow; as a variation and not an aberration from the norm. Ageing in swallowing is generally investigated in three broad age ranges; young adult (>20 years), older (60-80 years), and elderly (80+ years) (Logemann, 1990), and the term 'normal age related swallow' is most frequently indicated from 60 years of age (Leslie, Drinnan, Ford, & Wilson, 2005). Logemann (1990) describes three types of effects on the ageing swallow:

- primary effects which are age related changes by itself
- secondary effects which are caused by a disease process in an older swallow
- tertiary effects which are changes in the older swallow due to psychosocial and environmental variables.

The following sections discuss the current knowledge base for the normal and normal aged related stages of the swallow relative to the three types of effects seen with increasing age. Figure 2 shows a) drawing and b) videofluoroscopy image of the anatomy of the swallow that will be discussed in the following sections.

**Figure 2: Labelled a) Drawing and b) Videofluoroscopy image of lateral view of oral cavity and pharynx.**



Drawing reproduced with permission by Prof. P. Enderby (2010)

### **2.3.1 The Oral Preparatory and Oral Stage**

The oral preparatory stage triggers the senses, stimulating the brain to prepare for the routine of a mealtime. The olfactory nerve initiates saliva flow in the oral cavity, making manipulation of the bolus easier. The motor and sensory control of lifting food or drink to the mouth triggers the motor cortex that food or drink is approaching the mouth. As the bolus (food or drink) enters the oral cavity, muscles and cranial nerves (V and VII) stimulate the lips, tongue, teeth and cheeks to work together to break up the food, mix it with saliva, and form it into a cohesive bolus in readiness to be transported to the posterior section of the oral cavity. Depending on the consistency of the bolus, duration of this stage may vary between two and 120 seconds (Love & Webb, 1996; Logemann, 1988).

The oral stage is initiated when the cohesive bolus has been prepared and the tongue begins to push the bolus to the posterior section of the oral cavity. The tip and blade of the tongue push the bolus against the hard palate past the pillars of fauces using a backward humping and stripping action (cranial nerve XII). The bolus is propelled using negative pressure built up in the oral cavity by increased tension of the buccal muscles and channelling of the bolus by the tongue.

The oral and oral preparatory stage are considered to be in voluntary control, where the bolus can be removed from the oral cavity or begin movement to the posterior section of the oral cavity in preparation of the pharyngeal stage of the swallow. Normative data show most people use one or two swallows to clear a 10ml bolus, irrespective of age (Leslie, Drinnan, Ford, & Wilson, 2005; Perlman & He, 2006). Respiration continues normally at this stage. Where the duration of the oral preparatory stage is dependent on the consistency of the bolus, the oral stage should not exceed one second (Logemann, 2008).

### **2.3.1i) Age related changes**

Anatomical and physiological changes have been documented within the oral stage of swallowing with increasing age. A study by Logemann (1990) found an increase of fat to muscle ratio and connective tissue of the tongue with increasing age, resulting in reduced tongue pressure. Changes in taste and reduction of salivary flow have been shown to reduce bolus control (Tracy, Logemann, Kahliras, & Jacob, et al., 1989; Logemann, 1990; Robbins,

Levine, Wood, & Roecker, et al., 1995). The reduced natural dentition with or without the use of dentures is more prevalent in the older populations resulting in reduced control of food in the mouth and increased chewing durations (Logemann, 1990; Robbins, Levine, Wood, & Roecker, et al., 1995). Logemann and Rademaker et al (1998) showed a small but significantly longer oral transit time in older adults (60-80 years) of 0.5-0.6 seconds. This has been confirmed in more recent studies (Fucile, Wright, Chan, & Yee, 1998; Leslie, Drinnan, Ford, & Wilson, 2005; Perlman & He, 2006). However, some studies report no change (Robbins, Hamilton, & Lof, 1992; Logemann, Pauloski, Rademaker, & Kahrilas, 2002) and one reported decreased oral transit times in an older population (McCullough, Rosenbek, Wertz, & Suiter, et al., 2007). These changes have been found to increase the length of mealtimes, and older adults tending to self modify their intake; such as choosing soft-moist foods to compensate for documented oral stage changes.

### **2.3.2 The Pharyngeal Stage**

The pharyngeal stage occurs when cranial nerve sensory receptors are stimulated on the faucal arches, tonsils, soft palate, base of tongue and posterior pharyngeal wall (Murry & Carrau, 2006; Logemann, 2008); initiated when the head of the bolus reaches the anterior faucal arches, or at the level of the ramus of the mandible. After stimulation, afferent fibres converge on the nucleus solitarius (sensory branch), located in the 'swallow' *central pattern generator* (CPG) of the medulla. The 'motor' swallow is then initiated

when the afferent information is passed to the nucleus ambiguus, also within the CPG. This causes the pillars of fauces to constrict, the soft palate to elevate and contraction of the superior pharyngeal constrictors. The base of tongue moves posteriorly to the pharyngeal wall to increase the pressure on the bolus to aid downward movement. Pharyngeal pressure continues with the addition of superior pharyngeal contraction, whilst the larynx elevates and tilts anteriorly (cranial nerve IX and X).

The airway is closed off and protected by superior and anterior movement of the hyoid (cranial nerve V, with VII and XII). The airway is further protected by early arytenoid to epiglottic closure (Logemann, Kahrilas, Cheng & Pauloski, et al., 1992; Gross, 2010). The epiglottis passively inverts to facilitate bolus flow laterally down around the closed airway and through the cricopharyngeal sphincter (Gross, Atwood Jnr, Grayhack, & Shaiman, 2003). The cricopharyngeal sphincter is opened by the relaxation of the cricopharyngeus muscle and elevation of the larynx, allowing the bolus to continue into the oesophagus.

The pharyngeal stage is in involuntary control and averages 750msec (Love & Webb, 1996). During this time breathing is paused due to the protective mechanisms of the pharyngeal stage; with the urge to swallow dominating the urge to breathe, adding an extra layer to the airway protection during swallow apnoea (Perlman & Schulze-Delrieu, 2003). This pause in breathing during swallowing (or swallow apnoea) is usually shorter in duration than the pharyngeal stage, and is discussed in more detail in chapter three.

### **2.3.2i)      *Age related changes***

Studies of age related changes to the pharyngeal stage of the swallow have mostly focused on timing of the swallow initiation, laryngeal excursion and closure and cricopharyngeal opening; which are now discussed. The prevalence of penetration and aspiration in normal and age related swallows is discussed in sections 2.3.3 and 2.4.3 respectively.

Consensus in the literature suggests that the onset of the swallow occurs later with increasing age, initiating more frequently at the level of the valleculae from 60 years of age (Tracy, Logemann, Kahrilas, & Jacob, et al., 1989; Logemann, 1990; Robbins, Hamilton, & Lof, 1992; Jaradeh, 1994; Murry & Carrau, 2006; Martin-Harris, Brodsky, Michel, & Lee, et al., 2007). The study by Martin-Harris and Brodsky et al (2007) quantifies this normal 'delay' to be approximately 220 milliseconds longer than the normal younger onset of pharyngeal swallow, and Aviv and Martin et al (1994) specified this delay to occur during the onset of supraglottic closure with increasing age. Conversely, Murry and Carrau (2006) found no difference in the onset of swallow between younger and older subjects. Differences found in the literature may be accounted for in study methodology; such as the use of differing bolus sizes, as Aviv and Martin et al (1994) found larger volumes were required to initiate laryngeal closure in older adults. Logemann (2008) summarised that a delayed or slow laryngeal closure has implications for timing coordination for airway protection; the longer the airway remains open during the swallow, the higher the risk of penetration and or aspiration.



Further studies by Logemann and Pauloski et al (2000) and again later in 2002 investigated changes to the timing of laryngeal excursion and closure further in older healthy volunteers using videofluoroscopy. The two studies compared healthy older male swallows (80-94 years) with healthy younger males (21-29 years) (Logemann, Pauloski, Rademaker, & Colangelo, et al., 2000); and healthy older females (80-93 years) with healthy younger females (21-29 years) (Logemann, Pauloski, Rademaker, & Kahrilas, 2002) and confirmed findings within an earlier study by DeJaeger and Pelemans et al (1994). Findings suggested significant age and gender differences with laryngeal position and hyolaryngeal movement. Logemann and Pauloski et al (2000) reported a lower laryngeal resting position in older males, and reduced laryngeal elevation and closure; even though there was a shorter cervical 2 (C2) to C4 distance in older males compared to the younger male group. In the female study (Logemann, Pauloski, Rademaker, & Kahrilas, 2002), C2 to C4 distances were also found to be shorter in older females (when compared with younger females), however laryngeal resting position was not altered by age, nor was laryngeal elevation. Interestingly, this study found older females increased their range of motion, relative to the younger female and the older male group. Combined results from the two studies suggested older females have a greater 'muscle reserve' than older males, allowing them to compensate for age related changes by using a longer pharyngeal stage and cricopharyngeal sphincter opening duration; not seen in the older male group. Most importantly, all young and older groups did not show any obvious penetration or aspiration, so whilst there were anatomical and physiological differences in the swallowing between groups, they were

all found to have functional swallows whilst medically stable. However Logemann and Pauloski et al (2002) predicted that the lack of muscle reserve, combined with reduced laryngeal elevation (of up to half a centimetre) and reduced cricopharyngeal opening, places older males more at risk of dysphagia (with or without aspiration). Furthermore, they predicted that the risk increased when older males were medically unstable. Although the two studies by Logemann and colleagues provide clinically important information, the findings must be viewed with caution as both studies used small samples; with eight adults in each group. Furthermore, information was not gathered between the ages of 30-79 years, nor swallowing pattern for a solid bolus or sequential liquid swallows.

The literature remains equivocal regarding the presence of pharyngeal residue post swallow as a result of increasing age. Some studies suggest trace pharyngeal residue is present regardless of age (Robbins, Hamilton, & Lof, 1992; DeJaeger, Pelemans, Bibau, & Ponette, 1994; Logemann, Pauloski, Rademaker, & Kahrilas, 2002; McCullough, Rosenbek, Wertz, & Suiter, et al., 2007), with Daggett and Logemann et al (2006) revealing an increasing frequency and amount of pharyngeal residue occurring with increasing age. However both viewpoints agree the pharyngeal residue is of trace or mild levels as per The Penetration-Aspiration Scale by Rosenbek and Robbins et al (1996). Variability in my opinion may be due to type of barium used, bolus type and size, and differing definitions of 'older' age groups.

**Table 3: Summary of activities by stage of the swallowing pattern.**

<b>Stage of Swallow</b>	<b>Activity (Normal swallow)</b>	<b>Duration</b>
Oral Preparatory	<ul style="list-style-type: none"> <li>• Voluntary action;</li> <li>• Bolus enters the oral cavity;</li> <li>• Preparation of bolus, ready to transport to posterior oral cavity;</li> </ul>	2-120 sec. (Love & Webb, 1996; Logemann, 1988)
Oral	<ul style="list-style-type: none"> <li>• Voluntary action;</li> <li>• Tongue pushes bolus toward posterior oral cavity, against hard palate and pillars of fauces.</li> </ul>	1 sec (Logemann, 2008)
Pharyngeal	<ul style="list-style-type: none"> <li>• Involuntary action;</li> <li>• Initiation triggered when bolus stimulates sensory nerve receptors at pillar of fauces or ramus of mandible (Murry &amp; Carrau, 2006; Logemann, 2008) or at level of valleculae</li> <li>• Hyoid elevates and tilts; larynx elevates; cricopharyngeus relaxes and opens</li> <li>• Airway closed off by 3 protective mechanisms (Logemann, et al., 1992; Gross, et al 2003; Gross, 2010).</li> <li>• Oral pressure and pharyngeal constrictors push bolus through pharynx</li> <li>• Once bolus passes through cricopharyngeus, larynx lowers and breathing resumes</li> </ul>	750msec (Love & Webb, 1996; Perlman & Schulze-Delrieu, 2003)

### **2.3.3 Does Penetration Occur During Normal and Normal Age Swallows?**

If the swallow is inefficient or wrongly timed, the bolus may penetrate into laryngeal vestibule, up to and including the level of the true vocal cords; before, during or after the swallow. The bolus then tends to be squeezed out of the laryngeal vestibule during laryngeal elevation and closure of the laryngeal vestibule, re- entering the pharynx to then enter the oesophagus.

Most recent studies concur that penetration is seen in normal swallows regardless of age; however there is still debate regarding whether the frequency of penetration increases with increasing age. Differences in opinion may be due to sample size and differing type, volume, or delivery of the bolus, or definition of penetration used as highlighted in the following studies. Robbins and Hamilton et al (1992) and Logemann and Pauloski et al (2002) found adults in both young and older age groups penetrated boluses to the level of the vocal cords with similar frequency; however conclusions were drawn from one small liquid swallow trial. Other studies using an increased number bolus trials (more representative of a normal drink) showed the older adults penetrated more frequently than younger adults (Daniels, Corey, & Hadskey, 2004; McCullough, Rosenbek, Wertz, & Suiter, et al., 2007; Allen, White, Leonard, & Belafsky, 2010), with liquids (Allen, White, Leonard, & Belafsky, 2010), with increased volume or in the 'older old' (>80 years) groups (McCullough, Rosenbek, Wertz, & Suiter, et al., 2007).

Studies in the literature also conflict regarding whether a reflexive cough is elicited during this event in normal and normal age swallows (Langmore,

Terpenning, Schork, & Chen, et al., 1998; Gross, 2010) or not (Logemann, 2008). Producing a reflexive cough from penetration of a bolus in normal and normal age is most likely; as it is elicited from sensory fibres within the pharynx, upper trachea and bronchi (Ebihara, Sekizawa, Nakazawa, & Sasaki, 1993; Morice, 2005; Teramoto, Ishii, Yamamoto, & Yamaguchi et al., 2005). Failure to produce a reflexive cough would therefore seem to result from altered sensation in this area.

In my opinion, the literature provides strong evidence to support the presence of penetration in older adults; potentially increasing with increased bolus size. Additionally, the literature does not provide strong evidence to support the theory that the reflexive cough is absent during episodes of penetration in normal and normal age related swallows. Therefore the interpretation of results of the study detailed in this thesis (chapter seven) reflect the evidence to support the presence of penetration of bolus, coupled with a reflexive cough as considered within the realm of normal and normal age related swallowing. Furthermore, quantifying the amount or depth of penetration has not yet been satisfactorily determined within the literature and therefore will be addressed with the study detailed in this thesis as an assessment measure during biomechanical analysis (see chapter five).

#### **2.3.4 Swallowing Related Quality Of Life**

Definitions of quality of life (QOL) are continuing to evolve, however it can be broadly described as 'human experiences related to overall wellbeing and satisfaction' (Burckhardt & Anderson, 2003). Quality of life is considered to

be multidimensional, encompassing psychosocial aspects of daily living. By its very nature, quality of life reports are subjective and idiosyncratic to the individual, and their unique situation or experience. This definition highlights that perceived quality of life is as equally important as traditional health status outcomes. This is confirmed indirectly in studies that compared QOL measures against objective measures to reveal the degree of impact on quality of life cannot be predicted using objective measures in isolation (Skinner, Gillespie, Brodsky, & Day, et al., 2004; McHorney, Martin-Harris, Robbins, & Rosenbek, 2006; Ding & Logemann, 2008). Similarly, this notion can be confirmed directly, such as in a study by Ekberg and Hamdy et al (2002), where subjects who were interviewed reported that they felt their psychosocial needs were as important as their swallow safety. This is also followed-up with the Department of Health and Human Services report which states quality of life is equally important as length of life (Department of Health, 2010b).

There is limited literature investigating swallowing related QOL in normal healthy adults using a dysphagia specific QOL tool, as most studies investigate known dysphagic populations, or use general health related questionnaires. As will be discussed in later in chapter four, general health questionnaires tend to focus on physical wellbeing; with only one to two questions on eating or drinking. Therefore only studies that used swallowing specific QOL tools will now be discussed.

A person, regardless of age, should not perceive any difficulties in their swallow, or attribute any biopsychosocial difficulties to their swallowing ability without the presence of one or two major disease processes (for example,

stroke) influencing their swallow; as suggested by Logemann in 2008. A study by Tibbling and Gustafsson (1991) aimed to study the effect of oropharyngeal (and oesophageal dysphagia) on quality of life in a general older Swedish population (median age 67 years) using a mail out questionnaire. Their study reports of the 0.01% (n=796) responders who reported 'hypopharyngeal dysphagic' symptoms, all felt anxious and feared choking during mealtimes, and preferred not to eat alone. However the 'hypopharyngeal dysphagia' subgroup did not differ from the oesophageal dysphagia group in terms of levels of reflux, and the questionnaire used presented difficulties in separating oesophageal symptoms from true oropharyngeal dysphagic symptoms; as only one of the 16 questions could be classified as specifically questioning oropharyngeal dysphagic symptoms: *'do you get food or drink going the wrong way?'* ; whereas neither of the two quality of life questions could be easily differentiated: *'Do you sometimes feel anxious when you have swallowing difficulties at mealtimes?'* or *'Does food sometimes stick in your throat?'* (Tibbling & Gustafsson, 1991, p. 201). Inclusion criteria, such as past medical history was not described in this study and therefore the research group may have recruited known dysphagics and/or 'at risk' groups.

In contrast to the Tibbling and Gustafsson (1991) findings, studies by McHorney and Robbins et al (2002) and Leow and Huckabee et al (2010) found no significant changes to QOL in older healthy adults. During the development of the Swallowing Quality Of Life (SWAL-QOL), McHorney and Robbins et al (2002) investigated the clinical validity of the tool by comparing age matched known dysphagics with non dysphagics (mean age= 66 years),

and found a significant difference in QOL; with known dysphagics scoring lower (therefore reduced QOL) compared with the normal healthy age group. Leow and Huckabee et al (2010) also used the SWAL-QOL and compared healthy younger adults (mean age= 25 years) with healthy older adults (mean age=72 years) excluding conditions that may affect swallowing. Leow and Huckabee et al (2010) confirmed findings in the earlier study by McHorney and Robbins et al (2002) revealing that age did not significantly influence QOL outcomes between the two age groups. It appears using a swallowing specific QOL tool and clearly defining inclusion/exclusion criteria predicts that normal age related changes to swallowing does not negatively impact on quality of life.

## **2.4 Oropharyngeal Dysphagia**

Difficulties in swallowing can occur at any stage of the swallowing process, and is termed 'dysphagia' (Perlman & Schulze-Delrieu, 2003). Dysphagia can be divided into two categories, oropharyngeal dysphagia and oesophageal dysphagia. For the purposes of this thesis, oropharyngeal dysphagia will be explored further as this was the focus of the study in this thesis. Henceforth the terms 'oropharyngeal dysphagia' and 'dysphagia' will be used interchangeably.

From an understanding of what is expected from a normal swallow and age related changes as discussed previously, it becomes easier to identify and classify dysphagic signs and symptoms, as summarised in table 4. It is usually a combination of characteristics, clinical signs and symptoms that



lead to a diagnosis of dysphagia (Daniels, McAdam, Brailey, & Foundas, 1997), and are now discussed by stages of the swallow pattern.

#### **2.4.1 Oral Preparatory and Oral Stage Dysphagia**

The oral preparatory and oral stages of swallowing may be compromised due to a number of factors, and dependent on the person's diagnosis, pre-morbid ability and prognosis. Reduced alertness level and cognitive state may also result in increased risk of dysphagic characteristics, along with poor postural control (Love & Webb, 1996; Langmore, Skarupski, Park, & Fries, 2002; Hansen & Jakobsen, 2010). Unilateral or bilateral facial weakness with/without reduced sensation can cause difficulties with the oral preparatory and oral stage of swallowing (Kidd, Lawson, Nesbitt, & MacMahon, 1995; Love & Webb, 1996; Logemann, 1998). This may include decreased awareness of food/drink in the mouth, reduced strength or range of motion of lips, cheeks and tongue (Logemann, 1988; Huckabee, 2009), resulting in difficulty coordinating, chewing the bolus, and transporting it to the back of the mouth in readiness for the oral stage. Reduced lip seal will lead to the bolus falling anteriorly from the mouth (Logemann, 1998) or residue pocketing in the oral cavity sulci post swallow. Altered saliva production may result in drooling, or conversely not enough saliva and poor dentition will interfere with bolus preparation and transport to the posterior oral cavity (Fucile, Wright, Chan, & Yee, 1998). Additionally, reduced posterior tongue strength will lead to the bolus tipping into the pharynx pre swallow initiation (Huckabee, 2009).

#### **2.4.2 Pharyngeal Stage Dysphagia**

The flow of the bolus through the pharynx may be disrupted by one or multiple complications. The swallow may be delayed, allowing the bolus to pass the level of the valleculae before ‘triggering’ the swallow (Logemann, 1998). This may lead to penetration or aspiration *before* the swallow. The swallow may ‘trigger’ in a timely fashion, however the laryngeal elevation may be slow or not completely closed off the laryngeal vestibule, thus reducing airway protection (Perlman & Schulze-Delrieu, 2003; Gross, 2010). This may lead to penetration or aspiration of the bolus *during* the swallow. If laryngeal elevation is incomplete, and/or pharyngeal constrictors are weakened, bolus residue may occur in the pharynx, leading to a sensation of ‘something stuck in the throat’; and risk of penetration or aspiration *after* the swallow (Huckabee, 2009).

**Table 4: Summary of signs and symptoms characteristic of oropharyngeal dysphagia by stage of swallow.**

<p><b>ORAL PREPARATORY AND ORAL STAGE</b></p>	<p>Poor sitting balance and posture            Reduced taste, smell            Difficulties self feeding            Altered cognition            Reduced alertness</p> <p>Drooling            Dry mouth            Reduced lip seal            Facial weakness (uni/bilateral)            Impaired chewing            Reduced/poor dentition            Reduced tongue strength (uni/bilateral)            Reduced oral sensation</p>
<p><b>PHARYNGEAL STAGE</b></p>	<p>Problems triggering swallow            Reduced velopharyngeal closure            Pharyngeal weakness (uni/bilateral)            Reduced sensation            Slow laryngeal elevation            Reduced laryngeal closure            Reduced cricopharyngeal opening            Reduced pharyngeal constriction</p> <p>Laryngeal penetration            Laryngeal aspiration</p> <p>Coughing on food/drink/saliva            Choking on food/drink/saliva            Food/drink sticking in throat            Wet/gurgly voice            Shortness of breath post swallow            Multiple clearing swallows (4+)</p>

### **2.4.3 Should Episodes of Aspiration be Considered Dysphagic?**

Aspiration is defined as the bolus entering the laryngeal vestibule, and continuing through the true vocal cords towards the lungs. The effects of aspiration vary from person to person; dependent on the frequency and nature of the aspiration, as well as the person's general health, mobility, cognition, pulmonary status and ability to clear the aspirated material (Langmore, 1991).

Whether healthy individuals normally aspirate food or drink remains controversial. Some studies suggest healthy individuals normally aspirate either trace amounts and/or on an occasional basis (Huxley, Viroslav, Gray, & Pierce, 1978; Gleeson, Egli, & Maxwell, 1997; Beal, Chesson, Garcia, & Caldito, et al., 2004; Butler, Stuart, & Kemp, 2009), whilst others state aspiration is abnormal in healthy individuals and should be classified as a dysphagic characteristic (Robbins, Hamilton, & Lof, 1992; Allen, White, Leonard, & Belafsky, 2010). Butler and Stuart et al (2009) investigated normal healthy individuals (n=40) swallowing food and drink boluses using Flexible Endoscopic Evaluation of the Swallow (FEES) and found 11/168 swallows were silently aspirated. On closer inspection of the reported data, the 11/168 swallows aspirated could be further analysed to provide an estimate per volunteer. Although not stated explicitly within Butler and Stuart et al's (2009) article, one can infer from their table that 11/168 swallows occurred from one female (n=10), and three to six males (n=11). There are also a number of methodological weaknesses which may have influenced the results. This was part of a larger study which included simultaneous manometry assessment. The authors suggest the combined diameter of the two catheters (6.2mm) is similar to the Leder and Suiter (2008) study which showed no effect of a nasogastric tube on swallowing. However, Leder and Suiter (2008) assessed the effect of the nasogastric tube using videofluoroscopy, thus only one tube was in situ. Additionally, the Butler and Stuart et al (2009) study is not explicit on the positioning of subjects during the study; however usual protocol for manometric studies dictates assessment whilst in a supine position. If manometric measures were taken

simultaneously with FEES as stated, the subjects were most likely assessed in a reclined position. Furthermore, the subjects were sprayed in the nasal cavity with lidocaine for ease of catheter placement, and the liquid bolus was delivered via a syringe (for volume control) through the catheter. Combining a (probable) reclined position with an anaesthetised nasopharynx and the use of syringe boluses naturally increases the risk of aspiration, and therefore in my opinion, results from this study should be reviewed with caution.

Studies comparing normal healthy subjects of differing ages have shown no statistically significant findings of aspiration during bolus trials (Robbins, Hamilton, & Lof, 1992; Logemann, Pauloski, Rademaker, & Colangelo, et al., 2000; Logemann, Pauloski, Rademaker, & Kahrilas, 2002). Evidence on the normal healthy swallow led Marik and Kaplin (2003) to conclude that ageing by itself does not increase the risk of aspiration. However, the increase of disease and disorder seen in older people increases the risk of dysphagia with or without the presence of aspiration. Furthermore, studies that have suggested that aspiration is found in normal swallows agree aspiration occurs infrequently and in trace amounts. If this is the case, healthy individuals tend to also have normal mobility and pulmonary defence mechanisms (as will be discussed in section 2.7.1) and therefore have capacity to cope with these minor, infrequent episodes. However, if normal aspiration is coupled with disease, such as deteriorated lung function, pulmonary defence mechanisms may be reduced or ineffective. Therefore the issue may not be whether aspiration is a normal occurrence or not, but perhaps premorbid condition, the frequency of aspiration, and whether it

leads to any detrimental consequences should be the focus of further investigation.

#### **2.4.3i)        *Silent aspiration***

Reflexive coughing from food or drink is the most noticeable sign of aspiration, normally elicited from sensory fibres found in the pharynx, larynx or large bronchi (innervated by vagus nerve) (Ebihara, Sekizawa, Nakazawa, & Sasaki, 1993; Morice, 2005). However silent aspiration (no obvious sign of aspiration such as absent reflexive cough) can occur in approximately half of cases already known to aspirate (Leslie, Carding, & Wilson, 2003; Ramsey, Smithard, & Kalra, 2005). These studies found silent aspiration in known dysphagics, the majority of cases included stroke, traumatic brain injury and tracheostomy. However these studies use a small sample size and report small percentages of silent aspiration. None of the studies were designed to investigate prevalence within general populations.

Some studies suggest silent aspiration is also a common occurrence within the normal healthy population (Huxley, Viroslav, Gray, & Pierce, 1978; Gleeson, Egli, & Maxwell, 1997; Beal, Chesson, Garcia, & Caldito, et al., 2004), however these studies have a several methodological weaknesses. Whilst subjects were sleeping, a radiotracer was injected (either continuously or using a timed bolus feed) via a tube placed in the nasopharynx, which was later located in the body via scintigraphy. All studies have shown some level of silent aspiration using this method. However, the method of injecting a bolus into the nasopharynx excludes the oral preparatory and oral stage of

the swallow, losing important sensory and motor information to aid timing and coordination of the swallow as discussed earlier. The tube is placed past the known level for swallow initiation (ramus of the mandible or valleculae) therefore excludes a natural 'trigger' of the swallow. Also, it is unnatural to have a fluid bolus injected into your pharynx via your nose whilst sleeping. Results by this method are unable to differentiate the possible causes of the radiotracer being found in the lungs by either oropharyngeal aspiration, or caused by reflux. The results using this research methodology also do not enlighten us to what happens at the actual time of the swallow, during saliva swallows during normal sleep, or for saliva or bolus swallows when alert. These factors limit the validity of their findings and in my opinion the results from this style of methodology should be viewed with caution.

In my opinion, the literature has not provided strong evidence to prove aspiration exists within a normal healthy or normal older population.

Therefore the study within this thesis concurred with evidence to suggest that any episode of aspiration is considered abnormal thereby categorising it as a dysphagic characteristic; and is therefore reflected in the interpretation of the results for the study detailed in this thesis.

## **2.5 Causes of Dysphagia**

Signs and symptoms of dysphagia usually result from changes or damage to muscles, nerves or structures used in the swallowing process, as described earlier. Dysphagia may occur as the result of a number of aetiologies, ranging from generalised weakness to neurogenic and surgical intervention. Newly diagnosed dysphagia as a result of disease or disorder may resolve due to neuroplasticity of the brain (Logemann, 2008). However, if the disease is progressive, swallowing ability is likely to deteriorate also. It is important to identify causes of dysphagia due to its serious consequences (discussed later in section 2.7), and has important implications for managing healthcare costs and improving quality of life and wellbeing. A diagnosis of dysphagia is usually identified within medical diagnoses, allowing professionals to monitor 'at risk' conditions and offer treatment in a timely manner. There has been only one known study; published after data collection for this thesis, that has indicated COPD as a causative factor for oropharyngeal dysphagia (Cvejic, Harding, Churchward & Turton, et al., 2011), and will be discussed in more detail section 2.8.

## **2.6 Dysphagia Intervention**

Once oropharyngeal dysphagia has been identified, specific intervention strategies are indicated based on three broad factors; cause of the dysphagic characteristics, prognostic indicators and co-morbidities, and patient preference. Information from these three factors combine to form recommendations which aim to increase the efficiency and safety of the



swallow, and improve quality of life. Intervention may include one or multiple strategies; such as strengthening exercises (of the oral cavity and/or pharynx), swallowing manoeuvres, postural techniques, or modification to food and fluid consistencies (Logemann, 1993; Groher, 1990; Murry & Carrau, 2006; Logemann, 2008; Huckabee, 2009).

There is a paucity of research investigating the efficacy of dysphagia management. However the limited evidence within the literature suggests successful management of dysphagia in 'at risk' populations can significantly reduce rates of pneumonia and the long term use of health resources (Langmore, 1991; Crary, Carnaby, Groher, & Helseth, 2004). Compensatory techniques such as postural techniques (chin tuck or head rotation) and swallowing manoeuvres (supraglottic and effortful swallow) have been shown to reduce or eliminate the incidence of bolus aspiration (Logemann, Kahrilas, Kobara, & Vakil, 1989; Logemann & Kahrilas, 1990; Logemann, 1999). Similarly, altering bolus consistency to either reduce the need for chewing, increase cohesion and/or increase viscosity of the bolus to improve oral control has shown to improve oral stage dysphagia and consequently reduce or eliminate aspiration (Logemann, 1998). Studies have also compared incidence of pneumonia when using a postural technique (chin tuck) with fluid modification (thickened fluids). In studies by Logemann and Robbins et al (2008) and Robbins and Gensler et al (2008), a postural technique (chin tuck) was compared with fluid consistency modification for incidence of aspiration in patients with either dementia or Parkinson's disease. These studies found aspiration was more effectively eliminated when fluid was

modified to a 'honey' thick<sup>2</sup> consistency in both conditions; however Robbins and Gensler et al (2008) also explored incidence of pneumonia over three months and found rates were lower for fluids modified to a 'nectar' thick<sup>3</sup> consistency, followed closely by a 'chin tuck' strategy. Both studies recruited patients with reduced cognitive ability which may have resulted in compliance issues when using the 'chin tuck' technique. Also, the difference between the modified fluid that was shown to be aspirated the least ('honey' consistency) versus the modified fluid shown to have the lower incidence of pneumonia ('nectar' consistency) over three months may have been due to the 'honey' consistency fluid requiring the least amount of oral stage control; and therefore is least likely to aspirate before the swallow is initiated (Huckabee & Pelletier, 1999). However as this consistency is more viscose than the 'nectar' consistency fluid, it is therefore harder to clear any residue that may remain in the pharynx post swallow; increasing the risk of aspirating post swallow from pharyngeal residue.

These results highlight the need for careful consideration of the three factors discussed at the start of this section. Understanding the individual's dysphagic characteristics is essential when recommending an intervention. Robbins and Gensler et al (2008) also reported the fluid modification groups were subsequently diagnosed with increased frequency of dehydration, urinary tract infections and fever than the 'chin tuck' group, and Logemann and Robbins et al (2008) commented that the 'chin tuck' technique recorded the highest level of patient preference. This highlights the need to include the

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<sup>2</sup> 'Honey' Thick fluid refers to the U.S.A term for the level of modification used to thicken fluids. This is equivalent to 'Stage 2' thickness fluids within the U.K. (British Dietetic Association, 2009)

<sup>3</sup> 'Nectar' Thick fluid refers to the U.S.A term for the level of modification used to thicken fluids. This is equivalent to 'Stage 1' thickness fluids within the U.K. (British Dietetic Association, 2009)

third factor of patient preference when recommending a dysphagia intervention, however this was not explored further in these studies. However, a study by Pownall (2009) investigated differences in quality of life scores for stroke subjects using either 'chin tuck' technique or thickened fluids, and found subjects rated their quality of life as significantly lower when randomised to the modified fluid consistency groups compared to the 'chin tuck' strategy group. This has implications for patient compliance (of using the thickener) and the sequelae of health complications (such as dehydration and aspiration pneumonia) (Low, Wyles, Wilkinson, & Sainsbury, 2001; Whelan, 2001) as also noted in the Robbins and Gensler et al (2008) study. These findings also concur with a study by McHorney and Robbins et al (2002) who found patients who were recommended either modified food or drink consistencies reported lower quality of life, and reduced compliance to recommendations. This suggests that patient preference and improving quality of life is a key factor in the success of health status outcomes for dysphagia intervention.

The majority of studies enlist a medical model approach, investigating a narrow field of health status outcomes such as rates of aspiration pneumonia, with even fewer studies investigating the impact on quality of life. Furthermore, the limited research on intervention strategies focuses on acknowledged 'at risk' groups; such as dementia, stroke or cancer, and therefore findings cannot be generalised to the COPD population. Research into treatment strategies specifically for dysphagia characteristics found in COPD are in their infancy. Two recent studies (published after data gathering stage for the study detailed in this thesis) have outlined findings for the

inclusion of swallowing assessment and education into existing pulmonary rehabilitation groups for COPD (McKinstry, Tranter, & Sweeney, 2009; Ilesley, 2011) and are discussed in more detail in section 2.8. Finally, there are few studies within the literature that measure the use of spontaneous manoeuvres in subjects as a characteristic of determining (potential) undiagnosed dysphagia, as seen within the study detailed in this thesis and explored further in chapter seven.

## **2.7 Implications of Dysphagia**

The biopsychosocial impact of dysphagia is significant, however the medical profession tends to focus on the medical impact of dysphagia. As a result, one of the most researched implications of dysphagia is aspiration, as this can result in the most visual medical complications with potential hospitalisation and death (Gupta & Kant, 2009). Even though aspiration can have significant cost implications for health resources, other implications; such as malnutrition, dehydration and reduced quality of life can indirectly incur long term consequences for the individual (and carer) and health services. The following sections discuss the wider implications of dysphagia, focussing on two of the most common repercussions acknowledged when dysphagia is left unmanaged; aspiration pneumonia and reduced quality of life.

### **2.7.1 Aspiration Pneumonia**

Aspiration pneumonia is defined as a bronchopneumonia caused by aspiration of a bolus and subsequent colonisation of bacteria in a specific bronchopulmonary segment (Marik, 2001; Murry & Carrau, 2006). It is associated with high morbidity and mortality, with increasing risk in the older population. It is the fifth leading cause of death in the U.S. (>65 years), increasing to third leading cause of death with age (85+ years) (Robbins, Gensler, Hind & Logemann, et al., 2008).

Pneumonia is usually prevented by pulmonary defence mechanisms. The normal swallowing mechanism (as discussed earlier in section 2.3) and protective cough prevent entry of foreign material into the lower airway, but if penetration occurs, the reflexive cough will be supplemented by host defences such as mucociliary clearance and epithelial phagocytic cells (aided by immunoglobulins) (Gleeson, Egli, & Maxwell, 1997). Yet pneumonia may develop if sufficient foreign material penetrates to the lower airways and overwhelms the host defences. Historically, bacteria shown to cause aspiration pneumonia have been anaerobic, such as *Peptostreptococcus*, *Bacteroides*, *Fusobacterium* and *Prevotella* (Bartlett & Gorbach, 1975); bacteria usually found colonising the oropharynx. More recently however, pathogens associated with community acquired and hospital acquired pneumonias have also been shown to also cause aspiration pneumonia (Marik, 2001). However there are multiple factors which contribute to aspiration pneumonia in addition to aspiration itself (Langmore, Terpenning, Schork, & Chen, et al., 1998). Presumably if a healthy person aspirates a food or drink bolus, there are low levels of

bacteria present alongside strong pulmonary defence mechanisms. When a disease or disorder is introduced into this scenario, impairment of the pulmonary defence mechanisms, and/or an increase in the amount aspirated coupled with factors such as poor mobility or cognition, and this may result in the body being unable to clear the aspirated material, which may lead to pneumonia. Nevertheless, when all contributing factors are considered, oropharyngeal dysphagia is classified as the major pathophysiologic mechanism which leads to aspiration pneumonia (Marik & Kaplin, 2003); along with people who are less mobile, depressed and/or have altered saliva flow (secondary to their disease and medication) also increasing their risk for dysphagia and aspiration pneumonia. A study by Pikus and Levine et al (2003) investigated patients who are known aspirators and found they are significantly more at risk of developing pneumonia within six months. Similarly, a study by Martin-Harris (2008) found that people with dysphagia are seven times more likely to develop aspiration pneumonia, especially if seen during videofluoroscopy examination.

Aspiration pneumonia in normal and normal older populations has been investigated in the literature since the 1970's (Bartlett & Gorbach, 1975). However, not all studies differentiate between aspiration pneumonia (bacterial aspiration caused by oropharyngeal dysphagia) and aspiration pneumonitis (chemical pneumonia caused by aspiration of gastric contents). They also do not separate normal 'healthy' elderly from their research groups, thereby containing comorbidities acknowledged to be at high risk of aspiration pneumonia. Therefore it is difficult to draw conclusions based on

the results of these studies on true bacterial aspiration pneumonia rates in the normal healthy population.

To date, progressive respiratory disease has not been extensively evaluated as a primary condition at risk of dysphagia leading to aspiration pneumonia. Yet patients with COPD, as a direct consequence of the condition, have reduced defence mechanisms (for example reduced mucociliary clearance especially if continuing to smoke). A study by Langmore and Terpenning et al (1998) and again later in Langmore and Skarupski et al (2002), investigated predictors of aspiration pneumonia in nursing home residents aged 65 years and older (49% 85+ years). They found COPD was the second strongest predictor of aspiration pneumonia (odds ratio 2.49 95% C.I. 2.27, 2.72), closely behind suctioning (odds ratio 2.55, 95% C.I. 2.06. 3.15). Dysphagia is not systematically explored in patients with COPD, yet estimated incidence of pneumonia in the COPD population in the UK for 1996-2005 was 22.4 per 1000, with an increased risk for exacerbation for moderate ( OR= 1.28 ) and severe COPD (OR= 2.74) that required hospital admission (Muellerova, Boudiaf, Hagan, & Chigbo, et al., 2007). Furthermore, pneumonia was rated the highest cause of death in respiratory illnesses in 2002 (British Lung Foundation, 2003).

However most figures of pneumonia in COPD do not allow exploration of type or cause of pneumonia and it is therefore assumed that rates of aspiration pneumonia is included as a subgroup of the total figures quoted. Similarly, in a study by Xavier and Diniz et al (2002), causes of oropharyngeal dysphagia were categorised, with COPD as a subgroup of the 'respiratory group'. Furthermore, diagnosis of aspiration pneumonia was also

a subgroup within a larger group containing bronchiectasis and lung fibrosis, making it impossible to attribute any findings of aspiration pneumonia exclusively to COPD. Nevertheless, one possible theory is that pneumonia caused by oropharyngeal dysphagia induces an exacerbation, as postulated in a study by Veeramachaneni and Sethi (2006). However Hurst and Wedzicha (2007), and Guidelines for COPD (National Collaborating Centre for Acute and Chronic Conditions., 2010) dispute this and suggest other pathologies that 'mimic' exacerbations (such as pneumonia) should be considered as the primary diagnosis, and do not affect the underlying COPD disease process.

In my opinion, evidence to suggest if acute exacerbations of the disease place the patient at increased risk of dysphagia with or without aspiration pneumonia, or conversely if aspiration may trigger acute exacerbations is largely under researched and warrants further investigation.

### **2.7.2 Quality Of Life**

When people are diagnosed with oropharyngeal dysphagia as a result of disease or disorder, diet and/or fluid modification or strategies may be required to improve safety and efficiency of the swallow, as described earlier in this chapter. However, the dysphagic symptoms and/or the recommendations that follow may affect the perceived quality of life for the individual. In a study by Ekberg and Hamdy et al (2002), 42% of nursing residents with dysphagia reported a fear of eating alone, increased anxiety during mealtimes and 35% reported avoiding eating in public. Similarly, in a



study by Bladon and Ross (2007), 45% of subjects (n=95) with HIV/AIDS in a clinic in South Africa reported a reduced quality of life, with dysphagia increasing fear, anxiety and reduced pleasure of eating. As mealtimes are usually considered a social event, the impact may extend to caregivers. The use of altered utensils or dependence on caregivers may exert additional stress on the individual or family member. In a study by Miller and Noble et al (2006) the impact of dysphagia was assessed in subjects with Parkinson's disease and found that subjects reported feeling guilty and selfish for creating additional burden on family members regarding shopping for specific foods, mealtime preparation and dependence with feeding. The psychosocial impact further included withdrawal of social events such as eating at a friend's home or at a restaurant. Carers also reported a lowered quality of life, commenting on the disruption on family life and increased concern for their partner choking or losing weight. Furthermore, Low and Wyles et al (2001) found non compliance of recommendations (by either patient or carer) may create conflict between the patient and caregiver, in addition to the health implications. However some of these studies used self report symptoms of dysphagia within a general population and did not always confirm reports of dysphagia with clinical assessment (Ekberg, Hamdy, Woisard, & Wuttge-Hannig, et al., 2002; Bladon & Ross, 2007). However when Miller and Noble et al (2006) compared perceived findings with clinical evaluation, they reported a discrepancy between the two measurements; leading the researchers to suggest that swallowing impairments do not need to be severe to impose a significant impact on quality of life. In another study assessing known dysphagics, Khaldoun Woisard et al (2009) assessed for

the impact on swallowing related quality of life in various aetiologies. They found that perceived symptoms of dysphagia did not differ between the post stroke and the head and neck cancer groups; yet perceived quality of life was found to differ. Subjects post stroke reported a significantly lower eating duration, however subjects in the head and neck cancer group (post surgical intervention) rated their eating desire, and fear as significantly lower.

Along with the symptoms of dysphagia, intervention may have an impact on quality of life also. Modifications to diet consistency have been shown to decrease the overall desire to eat and drink (McHorney, Robbins, Lomax, & Rosenbek, et al., 2002; Miller, Noble, Jones, & Burn, 2006; Bladon & Ross, 2007). However, many studies have used quality of life outcomes to show the effectiveness of intervention strategies; with the majority of studies exploring intervention within oncological aetiologies. Findings have revealed dysphagia significantly negatively impacts quality of life outcomes before intervention (Lovell, Wong, Low, & Ngo, et al., 2005); more specifically within the fatigue, burden, and sleep domains (Greenblatt, Sippel, Levenson, & Frydman, et al., 2009), during intervention (Roe, Leslie, & Drinnan, 2007), but with improved quality of life outcomes post surgical intervention (Bandeira, Azevedo, Vartanian, & Nishimoto, et al., 2008; Greenblatt, Sippel, Levenson, & Frydman, et al., 2009). Furthermore, dysphagia intervention in other disease states have also shown to improve quality of life (Nagaya, Kachi, & Yamada, 2000; El Sharkawi, Ramig, Logemann & Pauloski et al., 2002). Two known publications have used swallowing related quality of life in COPD to measure the effectiveness of pulmonary rehabilitation programmes, and they are explored in more detail in section 2.8.

It is clear from the literature that dysphagia affects quality of life; irrespective of aetiology, and intervention has proven to increase quality of life. However a standard intervention 'package' is unlikely to be effective due to differing morphology and prognosis of differing diseases or disorders affected by dysphagia (Miller, Noble, Jones, & Burn, 2006; Davis, 2007). Additionally, the literature has shown that subjects with varying aetiologies have different aspects of quality of life affected; specific to their own condition and individual to their own psychosocial environmental support structure. This highlights the inability to generalise swallowing related quality of life findings to other conditions.

## **2.8 Oropharyngeal Dysphagia in COPD: A Literature Review**

This section reviews known studies specifically investigating oropharyngeal dysphagia in patients with COPD. A total of sixteen articles have been published from 1987 to present in peer review journals as broadly summarised in table 5; with eight published as full studies (Coelho, 1987; Stein, 1990; Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, Stangl, & Corbridge, 2002; Terada, Muro, Ohara, & Kudo, et al., 2010; McKinstry, Tranter, & Sweeney, 2009; Cvejic, Harding, Churchward, & Turton, et al., 2011; Ilsley, 2011). Five studies have been published as summaries only; either as abstracts for conference poster presentations (Carney, Sheppard, & Laframboise, 2005; Mahoney, Foo, Goudge, & Scott, et al., 2004); abstract only provided in English (Matsuda, Teramoto, Ohga, & Tomita, et al., 2004), or only as a letter to the editor (Teramoto, Kume, &

Ouchi, 2002; Kobayashi, Kubo, & Yanai, 2007). The remaining three publications were editorials (Harding, 2002; Singh, 2011) and one systematic review (O'Kane & Groher, 2009). In an attempt to review full articles, all primary authors were contacted by email to request consent to access full publications of their work. Carney and Sheppard et al (2005) responded that there was no other accessible data for their study, Kobayashi and Kubo et al (2007) provided a copy of the abstract, and there was no response from Matsuda and Teramoto et al (2004). An abstract by Cvejic and Harding et al's (2004) was later published as a full study, and therefore the review in this thesis refers only to the full article (Cvejic, Harding, Churchward & Turton, et al., 2011). Due to the limited number of full studies published, all types of publications are included in this review. Studies investigating the association of oesophageal dysphagia, gastro-oesophageal reflux disease (GORD) or chemical aspiration pneumonia in COPD exclusively were not included in this literature review as this was not the focus of the study in this thesis. However, two studies investigated gastro-oesophageal reflux as a contributing factor to oropharyngeal dysphagia in COPD, and have therefore been included in this review ( Stein, Williams, Grossman, & Weinberg, et al., 1990; Terada, Muro, Ohara & Kudo, et al., 2010).

Due to the innovative nature of this research thesis, it is essential to detail and discuss methodology used previously in order to justify the methodological design used within the study detailed in this thesis. All relevant articles reviewed in this section are summarised in table 6; alongside key articles investigating respiratory-swallow patterns in COPD (discussed in the next chapter). Additionally, key points found in the literature

regarding COPD induced swallowing changes are summarised alongside key points for normal and normal age swallow in table 7; which can also be located at the end of chapter three.

Six publications including one systematic review and one editorial occurred since 2007; hence after protocol development and data collection for the study detailed in this thesis. However they are included within this review for completeness, and are also discussed in chapter seven.

**Table 5: Summary of publications from 1987 to present investigating oropharyngeal dysphagia in patients with COPD.**

		Total
Publication Type	Full Study	8
	Abstract Only	3
	Letter to Editor Only	2
	Editorial	2
	Systematic Review	1
Country of Origin	USA	6
	Australia	4
	Japan	4
	UK	1
	Canada	1
Type of Study	Prevalence Only	-
	Nature Only	9
	Both Prevalence and Nature	2
	Intervention	2
Use of Control Group	No controls	6
	Case Control	3
	Historical	2
	Normative	1
	Not documented	1
Research Sample Size	<15	2
	16-30	6
	30+	5

### **2.8.1 Systematic Review and Editorials**

One systematic review has been published recently, which reviewed seven articles that investigated oropharyngeal dysphagia in patients with COPD (O'Kane & Groher, 2009). They reviewed studies investigating oropharyngeal dysphagia and respiratory patterns in COPD (Shaker, Ren, Townsend, & Dodds, et al., 1992) which was also conducted for the purposes of this thesis, however the literature review of respiratory- swallow patterns in patients with COPD was reviewed separately and discussed in chapter three. O'Kane and Groher (2009) graded the literature using the 'Levels of Evidence Grading Chart', adapted from the 'Oxford Centre of Evidence Based Medicine' (University of Oxford, accessed online 2011). Findings revealed no studies in this area were graded as Level A; as random control trials. However three were graded Level B; cohort and case control studies (Shaker, Ren, Townsend, & Dodds, et al., 1992; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Kobayashi, Kubo, & Yanai, 2007), three at Level C; case series (Coelho, 1987; Stein, Williams, Grossman, & Weinberg, et al., 1990; Good-Fratturelli, Curlee, & Holle, 2000), and one at Level D; expert opinion (Harding, 2002). The review within this thesis included more publications for oropharyngeal dysphagia and respiratory-swallow patterns in patients with COPD; incorporating abstracts, expert opinion and full studies published up to 2011 (Teramoto, Kume, & Ouchi, 2002; Mahoney, Foo, Goudge, & Scott, et al., 2004; Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Carney, Sheppard, & Laframboise, 2005; Gross, Atwood, Ross, & Olszewski, 2009; McKinstry, Tranter, & Sweeney,

2009; Terada, Muro, Ohara & Kudo, et al., 2010; Cvejic, Harding, Churchward & Turton, et al., 2011; IIsley, 2011; Singh, 2011).

Editorials by Harding (2002) and Singh (2011) reviewed the evidence for oropharyngeal dysphagia in patients with COPD, with reference to specific articles within the same publication (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Cvejic, Harding, Churchward & Turton, et al., 2011).

Whilst Singh (2011) summarised the evidence in dysphagia as a contributing factor in increasing the bacterial load during exacerbations, Harding (2002) summarised that the use of a multidisciplinary research team, robust inclusion criteria and use of methodological design which assesses multiple components concurrently strengthens the validity of results. However both editorials concluded there is a paucity of research in this field and further investigation is warranted.

### **2.8.2 Members of Research Group**

Most studies used relevant multidisciplinary team members when developing and conducting their research; including a speech and language therapist and respiratory physician as either the primary or secondary author.

However three studies had a uniprofessional teams of respiratory physicians only (Stein, Williams, Grossman, & Weinberg, et al., 1990; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara, & Kudo, et al., 2010). As will be discussed in chapter four, using expert clinical professionals to develop study design and conduct assessment procedures is crucial in strengthening

clinical validity of the study. In view of the complex nature of the swallowing process, in my opinion a multidisciplinary team is essential.

### **2.8.3 Geographical Origin**

Six publications originated from research conducted within the United States of America (Coelho, 1987; Stein, Williams, Grossman, & Weinberg, et al., 1990; Good-Fratturelli, Curlee, & Holle, 2000; Harding, 2002; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; O'Kane & Groher, 2009).

Four publications originated each from Japan (Teramoto, Kume, & Ouchi, 2002; Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara & Kudo, et al., 2010) and Australia (Mahoney, Foo, Goudge, & Scott, et al., 2004; McKinstry, Tranter, & Sweeney, 2009; Cvejic, Harding, Churchward & Turton, et al., 2011; Singh, 2011), with one abstract from Canada (Carney, Sheppard, & Laframboise, 2005). One article has been recently published within the United Kingdom which explored rehabilitation of dysphagia in COPD patients (Ilsley, 2011). However, the literature review revealed a paucity of research to date investigating prevalence or the nature of dysphagia in a British population as detailed in this thesis.

### **2.8.4 Research Questions, Aims and Objectives**

As research in this field is still in its infancy, previously published research has been dominated by investigating prevalence and the nature of



oropharyngeal dysphagia in patients with COPD (Coelho, 1987; Good-Fratturelli, Curlee, & Holle, 2000; Cvejic, Harding, Churchward & Turton, et al., 2011). However within this topic, several studies aimed to explore broad aspects; such as severity of COPD (Carney, Sheppard, & Laframboise, 2005), or phase of COPD (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara & Kudo, et al., 2010) in assessing the impact of COPD on swallowing ability. Conversely, other studies that have focused on investigating one specific element of the swallow; such as Stein and Williams et al's (1990) study which aimed to explore cricopharyngeal function, and four studies which investigated the initiation of the swallow reflex in patients with COPD (Teramoto, Kume, & Ouchi, 2002; Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara & Kudo, et al., 2010).

Two publications have assessed intervention strategies for dysphagic patients with COPD. Studies by McKinstry and Tranter et al (2009) and Ilsley (2011) aimed to evaluate the outcomes of including swallowing assessment and education into pulmonary rehabilitation sessions.

The research questions and objectives covered in the current literature have initiated research in the nature of dysphagia in COPD and outcomes of pulmonary rehabilitation; however there are still many questions left unanswered. The literature to date has mainly focused on one or two clinical components contributing to dysphagia in COPD. Studies have not yet explored patient perspectives and impact of oropharyngeal dysphagia on quality of life; nor has clinically relevant data been compared to the patient

perspective to understand the impact of dysphagia from a combined clinical and patient perspective, thereby providing a truly holistic approach to exploring the nature and prevalence dysphagia has by phase of COPD. The aim of the study detailed in this thesis addresses some of these acknowledged gaps in knowledge.

### **2.8.5 Study Design**

All studies reviewed were categorised as observational studies. Of those stating study designs, all were prospective except for the study by Good-Fratturelli and Curlee et al (2000); who used a retrospective approach.

Studies by Coelho (1987), Mokhlesi and Logemann et al (2002) and Carney and Sheppard et al (2005) specified the use of consecutive sampling; however Stein and Williams et al (1990) reported their study used neither randomised nor consecutive sampling.

The use of age matched controls completing the same methodology strengthens clinical validity of a study, and was enlisted in three studies (Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Terada, Muro, Ohara, & Kudo, et al., 2010; Cvejic, Harding, Churchward, & Turton, et al., 2011). Six studies did not include a control group (Coelho, 1987; Good-Fratturelli, Curlee, & Holle, 2000; Carney, Sheppard, & Laframboise, 2005; Kobayashi, Kubo, & Yanai, 2007; McKinstry, Tranter, & Sweeney, 2009; Ilsley, 2011), with two studies using historical controls to compare against the researched group (Stein, Williams, Grossman, & Weinberg, et al., 1990; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002), or compared the research

group against normative data (Mahoney, Foo, Goudge, & Scott, et al., 2004). Only one study divided COPD subjects further into stable and exacerbation phase (Kobayashi, Kubo, & Yanai, 2007); however this was not a repeated measures design as it was not the same patient followed up. Random controlled trials or descriptive studies do not appear to have been used to explore dysphagia in patients with COPD to date.

## **2.8.6 Methods**

### ***2.8.6i) Sample Size and Demographics***

All studies recorded data using small samples, ranging from eight to 78 adult subjects in the research group, with mean age ranging from 50-77 years. Of the four studies reporting gender ratios within the research groups, there were a high percentage of males in each study ranging between 86-100% of the total sample (Coelho, 1987; Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Kobayashi, Kubo, & Yanai, 2007).

### ***2.8.6ii) Inclusion and exclusion criteria***

Confounding factors were not always clearly stated in all studies, creating challenges comparing the selection criteria for the research and control groups. Most of the studies used the main inclusion criterion for the research group as diagnosis of COPD as per recognised guidelines for the specified country of origin. A few of the studies defined the inclusion of COPD patients

further in terms of severity and type of COPD (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002), or by phase of COPD (Carney, Sheppard, & Laframboise, 2005; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara, & Kudo, et al., 2010). However definitions of exacerbation phase differed between studies. Inclusion criteria for the two Japanese studies into the exacerbation phase COPD group specified subjects were to be clinically stable when assessed (Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara, & Kudo, et al., 2010). Although not stated in Matsuda and Teramoto et al's (2004) abstract, the same inclusion criteria is likely given the similar methodology. The 'exacerbation' phase for this group of studies is defined as more than three exacerbations in a 12 month period. Whilst this is not providing information during acute exacerbation phase as reported in Carney and Sheppard et al's (2005) abstract, their aim was to report any differences in swallowing reflex times between frequent and non frequent exacerbators.

Excluding co-morbidities known to cause dysphagia from the study is a crucial step towards ensuring valid results. However confounding variables, such as age and co-morbidities are difficult to completely exclude from this population (Stein, Williams, Grossman, & Weinberg, et al., 1990), as majority of people diagnosed with COPD are over 50 years of age, and likely to have one or more medically pathologies (Langmore, Skarupski, Park, & Fries, 2002). Earlier studies, such as Coelho (1987) and Good-Fratturelli and Curlee et al (2000) used inclusion criteria that was too broad and allowed co-morbidities known to cause dysphagia into the research group. More recent studies have overtly described criteria to ensure co-morbidities that may

cause dysphagia were excluded, such as tracheostomy, history of neurological or head and neck surgery or dementia (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara, & Kudo, et al., 2010). This provides the most homogeneous group possible for the target aetiology; and was enlisted for recruitment criteria for the study detailed in this thesis (see section 5.6 and 5.7).

### **2.8.6iii) Recruitment**

All studies recruited subjects within an outpatient hospital clinic. Two studies recruited mild to severe COPD patients (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Cvejic, Harding, Churchward, & Turton, et al., 2011), with three studies recruiting either moderate to severe COPD only (Stein, Williams, Grossman, & Weinberg, et al., 1990) or advanced COPD only (Coelho, 1987; Mahoney, Foo, Goudge, & Scott, et al., 2004). The study by McKinstry and Tranter et al (2009) recruited within pulmonary rehabilitation, and reported that approximately 78% of their research group was diagnosed with COPD; with the remaining subjects classified as 'chronic respiratory disease'.

Demographical information provided further information on subjects recruited and information on inclusion criteria discussed earlier; such as Coelho's (1987) study. Of the 14 patients included in the research group, 13 had tracheostomies and five were ventilator dependent. It is widely accepted tracheostomies increase the risk of dysphagia (Shaker, Milbrath, Ren, & Campbell, et al., 1995; Mokhlesi, Logemann, Rademaker, & Stangl, et al.,

2002), thereby increasing the difficulty to draw conclusions on the actual cause of the dysphagia (as a consequence of the tracheostomy or COPD) due to the heterogeneous nature of the groups as discussed earlier.

#### **2.8.6iv)      *Assessment procedure***

Previous studies reveal there is not a clear standard in the use of measures to identify dysphagic characteristics in COPD. However the majority of studies enlisted videofluoroscopy as the main assessment tool. Only one study included a 'bedside examination' for an oral stage assessment (Coelho, 1987).

The Swallowing Provocation Test (SPT) combined with submental electromyography (SEMG) was used by three studies (Kobayashi, Kubo, & Yanai, 2007; Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Terada, Muro, Ohara, & Kudo, et al., 2010). However both methods have methodological weaknesses as will be discussed in section 4.3.3iv).

Few studies enlisted multiple methods within their assessment procedure. Mokhlesi and Logemann et al (2002) and later studies (McKinstry, Tranter, & Sweeney, 2009; Ilsley, 2011) included self report symptom questionnaires and compared against videofluoroscopy or flexible endoscopic evaluation of swallow (FEES). This also included a disease specific quality of life questionnaire using the SWAL-QOL (Swallowing Quality Of Life), or basing questions from the SWAL-QOL in the latter two studies. Additionally, Cvejic and Harding et al (2011) combined three methods of analysis to simultaneously assess swallow and respiration; using submandibular

electromyography, videofluoroscopy and respiratory inductance plethysmography. Using a combination of methods to assess multiple factors of the swallow is recommended (Harding, 2002), and multiple methodology was enlisted in the study detailed in this thesis; discussed in chapter four.

#### **2.8.6v)        *Bolus trials and delivery***

Most studies assess the swallow using two to three different consistencies; normal fluid, semi-solid and solid bolus trials, with a minimum of two trials per bolus (Coelho, 1987; Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002). These studies also used the most natural delivery system for the bolus, which is via a spoon or cup. This is in direct contrast to the study by Kobayashi and Kubo et al (2007) which reports using the same method detailed in Ebihara and Sekizawa et al's (1993) study of using a syringe to deliver the bolus, injected via a catheter placed in the nasopharynx during 'altered consciousness'. The disadvantage of delivering a bolus via a syringe and nasopharyngeal catheter omits two stages of the swallowing process, therefore altering the validity of the study as discussed earlier (see section 2.4.3i).

## **2.8.7 Results**

Results from the studies can be categorised into four broad areas; overall prevalence of dysphagia, nature of the oropharyngeal dysphagia, prevalence of penetration and/or aspiration and effectiveness of intervention strategies; which will now be discussed.

### ***2.8.7i) Prevalence***

Prevalence of dysphagia within the COPD population is important to investigate, so as to provide a clear picture of the accuracy of identification rates for this disorder. Two studies in this review aimed to provide prevalence of oropharyngeal dysphagia in patients with COPD. These studies reported an estimated prevalence range between 2% (Good-Fratturelli, Curlee, & Holle, 2000) and 3% (Coelho, 1987) of the sampled population in the recruitment periods of three years and 18 months respectively. Both studies recruited from patients referred to videofluoroscopy for suspected dysphagia, which was a subpopulation of 4% (Good-Fratturelli, Curlee, & Holle, 2000) and 5% (Coelho, 1987) of the total COPD population within the allocated recruitment timeframes. This recruitment strategy will obtain prevalence for the referred population, but not for a general COPD population. Furthermore, this sampling technique also relies on the referrer's knowledge of dysphagic symptoms at bedside examination, or patient reporting skills, and does not allow for silent aspiration or subjects under reporting. To gain an understanding of true prevalence, recruitment from the general COPD population is essential. To



date there has not been a study sampling from a general COPD population in order to estimate true prevalence, as will be addressed in the study detailed in this thesis.

### **2.8.7ii) Oropharyngeal dysphagic characteristics**

The majority of studies had either primary or secondary aims of defining dysphagic characteristics found in the sample population. Coelho (1987) reported on dysphagic characteristics further by documenting if they were observed as dysphagic but exhibiting a functional swallow; and this was defined as no aspiration observed.

Dysphagic characteristics were noted in both the oral and pharyngeal stages of the swallow. Oral stage dysphagic characteristics noted were increased chewing duration, fatiguing quickly (Coelho, 1987) and oral residue (Good-Fratturelli, Curlee, & Holle, 2000). Dysphagic characteristics noted in the pharyngeal stage were delayed pharyngeal initiation (Coelho, 1987; Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Mahoney, Foo, Goudge, & Scott, et al., 2004), slower laryngeal elevation (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002), reduced hyoid elevation (Cvejic, Harding, Churchward, & Turton, et al., 2011), and pharyngeal residue (Good-Fratturelli, Curlee, & Holle, 2000; Mahoney, Foo, Goudge, & Scott, et al., 2004; Cvejic, Harding, Churchward, & Turton, et al., 2011). Additionally, Mokhlesi and Logemann et al (2002) attributed the observed pharyngeal dysphagia to lower laryngeal resting position and lower mid swallow position than normals ( $p < 0.001$ ). They also

noted the use of spontaneous manoeuvres, such increased airway closure duration; suggesting that COPD subjects compensated for the delayed initiation of swallow and slower laryngeal elevation and closure, by holding the larynx in an elevated position for longer. As this was seen in stable phase COPD subjects, it remains uncertain if this technique remains effective at protecting the airway during exacerbations; and will be explored further in the study detailed in this thesis.

A few studies investigated specific dysphagic characteristics, such as cricopharyngeal sphincter function (Stein, Williams, Grossman, & Weinberg, et al., 1990) and timing of the swallowing reflex initiation (Matsuda, Teramoto, Ohga, & Tomita, et al., 2004; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara, & Kudo, et al., 2010). Stein and Williams et al (1990) found 17/25 COPD subjects with 'marked' clinical dysphagia, and 21/25 Moderate-Severe COPD subjects exhibiting cricopharyngeal dysfunction compared to 14/128 unmatched historical controls. However it was difficult to interpret this article and understand the overall findings, as they did not define 'clinical dysphagia' and utilised an oropharyngeal assessment technique (videofluoroscopy) to assess cricopharyngeal function without reporting the standardised assessment protocol as seen in Logemann (1993). If cricopharyngeal dysfunction was attributable to oropharyngeal dysphagia, videofluoroscopy assessment would require analysis of the hyoid movement and laryngeal elevation and closure as the potential cause of the cricopharyngeal dysfunction (Huckabee, 2009). Whereas Stein and Williams et al (1990) reported that their subjects' cricopharyngeal dysfunction was attributed to aspiration of reflux, and suggested this was an oropharyngeal

dysphagic characteristic. However Stein and Williams et al (1990) have confused oropharyngeal aspiration with aspiration caused by laryngopharyngeal reflux (or oesophageal reflux); which is normally attributed to oesophageal dysphagia. Furthermore, they reported 10/25 subjects proceeded to have cricopharyngeal myotomies which resolved the swallowing issues, whereas cricopharyngeal dysfunction due to oropharyngeal dysphagia would not have been resolved with this surgical procedure.

The swallowing reflex in 'frequent exacerbators' (exacerbation group) was explored in three studies (Matsuda, Teramoto, Ohga, & Yomita, et al., 2004; Kobayashi, Kubo, & Yanai, 2007; Terada, Muro, Ohara, & Kudo, et al., 2010). Kobayashi and Kubo et al (2007) compared frequent exacerbators with non frequent exacerbators, whilst Matsuda and Teramoto et al (2004) and Terada and Muro et al (2010) compared frequent exacerbators against age matched controls. Longer latency times for onset of swallowing reflex was found in all exacerbation groups which were statistically significant; and relative risk ratios of 2.8 (95% CI 1.5-5.0) (Matsuda, Teramoto, Ohga, & Yomita, et al., 2004) and 6.24 (95% CI 0.90-43.34) (Terada, Muro, Ohara, & Kudo, et al., 2010). However the definition used in these set of studies for swallow onset time differs from the acknowledged initiation of swallow in normal swallows, as discussed in section 4.3.3iv.

### **2.8.7iii) Penetration and aspiration**

Penetration and aspiration of a bolus could only be reported if a study's methodology allowed for visualisation of the bolus through the pharynx during a swallow. Thus six studies were able to comment (Coelho, 1987; Stein, Williams, Grossman, & Weinberg, et al., 1990; Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Carney, Sheppard, & Laframboise, 2005; Cvejic, Harding, Churchward, & Turton, et al., 2011), however Stein and Williams et al (1990) did not report rates of penetration or aspiration. Of those that did, three separated data for rates of penetration and aspiration. Similar proportions of subjects penetrating were seen in Mahoney and Foo et al (2004); reporting 25% (2/8) of subjects penetrated, and in Good-Fratturelli and Curlee et al (200) with 27% (21/78) of subjects, and a higher proportion reported in Carney and Sheppard et al's (2005) study with 48% (10/21) subjects seen to penetrate.

Reports of aspiration exclusively varied, ranging from no subjects aspirating (Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002; Mahoney, Foo, Goudge, & Scott, et al., 2004); versus 21% (3/14) of subjects in Coelho (1987); 41% (32/78) in Good-Fraturelli and Curlee et al (2000); and 48% (10/21) of subjects aspirating in Carney and Sheppard et al (2005). The study by Cvejic and Harding et al (2011) combined scores and reported 38% (6/16) of their study penetrated and/or aspirated. Penetration and/or aspiration was also noted to be more prevalent for liquids than solid boluses in the COPD groups (Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002).

Cvejic and Harding et al (2011) is the only study to assess the long term impact of rates of penetration and/or aspiration in patients with COPD. Interestingly, they found COPD patients with penetration/aspiration (n=6) had more negative health outcomes compared to COPD patients without any penetration/aspiration (two had hospitalisations and two deaths,  $p=0.05$ ); with a non significant difference reported for aspiration only versus no aspiration seen ( $p=0.07$ ). However the follow-up reported in this study was a telephone based interview conducted with the COPD subject, 36 months post initial assessment. This consisted of patient report of number of hospitalisations over the three year period; however there was no documentation of any intervention provided by the research team or the local Speech and Language Therapy department.

Of the studies that used age matched healthy control groups, Mokhlesi and Logemann et al (2002) stated their control group did not show any evidence of dysphagia, however Stein and Williams et al (1990) reported 11% (14/128) of control subjects with mild cricopharyngeal dysfunction, and 7% (1/15) of Cvejic and Harding et al's (2011) control group were reported to have either penetrated or aspirated.

As the reported mean ages from the group are over 65 years of age, a degree of penetration of the bolus is expected and still considered within the normal age related swallow as discussed in section 2.3.3 and summarised in table 7. However controls used in studies reviewed in this section, and the general consensus of published normative data reports aspiration should not be evident within a normal and normal aged swallow, therefore the findings

of aspiration in the COPD groups are clinically significant and warrant further investigation.

#### **2.8.7iv)      *Effectiveness of intervention strategies***

Two studies investigated the effect of including oropharyngeal dysphagia assessment and education into existing pulmonary rehabilitation sessions; and assessed effectiveness using the Swallowing Quality Of Life (SWAL-QOL) questionnaire as an outcome measure. McKinstry and Tranter et al (2009) reported a significant improvement in levels of understanding of dysphagia and swallowing related quality of life as measured pre and post one hour education sessions. Furthermore improvement was shown to be maintained in three quality of life domains (Burden, Symptoms and Food Selections) three months after completing the education sessions. These findings concur with a later study that also investigated assessment and education sessions within a pulmonary rehabilitation setting (Ilsley, 2011). Interestingly both reported using clinical assessment with and without instrumental analysis, yet neither commented nor compared findings with the perceptions recorded from the subjects.

## **2.9 Concluding Thoughts**

Whilst what is expected from a normal and normal 'age related' swallows is well documented, controversy continues regarding definitions of dysphagic characteristics. On considering the strength of the evidence documented within the literature, it is my opinion that a swallow may initiate at the level of the valleculae; and minor, infrequent episodes of penetration of a bolus should be considered normal within older adults. However the literature does not provide convincing evidence to support the theory that episodes of aspiration occur within normal and older adults; and is therefore considered a dysphagic characteristic within the study detailed in this thesis. Once clear definitions were established, the literature could then be compared with studies investigating oropharyngeal dysphagia in patients with COPD.

A literature review revealed a dearth of publications specifically investigating swallowing disorders in patients with COPD; with over half being published after protocol development and data collection for the study detailed in this thesis. Nevertheless, the review revealed 'proof of concept' in this area is still in its infancy and requires further investigation. To date there have been no known British studies to investigate the nature of oropharyngeal dysphagia in patients with COPD, nor any known studies investigating swallowing changes by phase of COPD using a repeated measures design, or evaluating the impact of dysphagia on quality of life. Furthermore exploration not only into the presence of oropharyngeal dysphagia in this population is still required, but also any detrimental effects this may have on health and quality of life is warranted.

# **Chapter Three**

## **Pre-Clinical Theory Part II:**

### **The Respiratory-Swallow Pattern and COPD**



## **Chapter Three: The Respiratory- Swallow Pattern and COPD**

### **3.1 Introduction**

The importance of the respiratory system during swallowing is often understated or, at best, considered an adjunct to the swallowing assessment. However more recently the respiratory system has been shown to influence the timing of the swallow and generate the appropriate amount of subglottic pressure to ensure a safe swallow (Gross, Atwood, Ross, & Olszewski, et al., 2009). Hence any alterations to the finely tuned coordination between respiration and swallowing may affect the efficiency and safety of the swallow. Even though the respiratory-swallow pattern is now acknowledged as an interconnected working mechanism, previous research tended to explore each mechanism as stand alone systems (Martin-Harris, 2008). Even fewer investigated how they interact or impact on each other (Gross, Atwood, Ross, & Olszewski, et al., 2009). A normative respiratory-swallow pattern is acknowledged within the literature; however alteration to the respiratory-swallow pattern due to COPD, is surprisingly under researched. Furthermore, there appears to be a paucity of research in the repercussion of deviating from the predominant pattern; on the nature of dysphagia or on health outcomes.

This chapter reviews the literature exploring the relationship between respiration and swallowing to establish the existing evidence base and to inform the study design utilised in this thesis; summarised in tables 6 and 7 at the end of the chapter. This evidence is then used in this thesis as a benchmark to compare against studies exploring alterations due to behavioural changes, or disease and disorder. Finally, three studies have

been found which investigate the impact of the respiratory-swallow pattern specifically in COPD (Shaker, Ren, Townsend, & Dodds, et al., 1992; Gross, Atwood, Ross, & Olszewski, et al., 2009; Cvejic, Harding, Churchward, & Turton, et al., 2011), and are discussed in light of the normative information.

## **3.2 Anatomy and Physiology**

The human system is unable to breathe and swallow at the same time, revealing a synergistic relationship between the respiratory and swallowing mechanisms. Historically, it was thought that swallowing and respiration worked alongside each other in a 'turn taking' style. More recently, studies suggest respiration and swallowing are more than just a 'turn-taking partnership', but an 'integrated paradigm', where respiration provides afferent information to the swallow process (Gross, Atwood Jnr, Grayhack, & Shaiman, 2003); discussed in chapter two . It is now understood that Central Pattern Generators (CPG) for breathing and swallowing within the medulla share neurons and therefore influence each other's action. The breathing-swallowing pattern is largely controlled by the brainstem with some cortical control, which can be seen during volitional swallows (Kelly, Huckabee, Jones, & Carroll, 2007), most likely recruiting from planning areas for the swallow such as the cingulate cortex, and frontal operculum.

### **3.2.1 Swallow Apnoea**

During the pharyngeal stage of the swallow, the larynx is tightly sealed and respiration is temporarily inhibited due to airway protective mechanisms which prevent the bolus entering the respiratory tract (discussed previously

in chapter two). This temporary inhibition of respiration during the pharyngeal stage is known as a 'swallow apnoea'. In a recent study, the swallowing system was shown not only to rely on respiration inhibition to perform swallow apnoea during the pharyngeal stage of the swallow, but also to provide sensory information for the crucial timing of the apnoea (Gross, Atwood Jnr, Grayhack, & Shaiman, 2003). The timing of the swallow apnoea is understood to occur via the synergy between thoracic and laryngeal sensory information. Afferent impulses (from the sensory branch of the vagus nerve) situated in the thorax are carried to the medullary centre. There it crosses with efferent fibres of the recurrent laryngeal nerve, which initiates airway protection (vocal fold adduction) milliseconds before the respiration is inhibited (Perlman & Schulze-Delrieu, 2003). There is little understanding or research into neuronal mechanisms influencing respiratory inhibition, however one study suggests  $\alpha_2$ -adrenergic receptors may have an inhibitory effect on respiration during swallow (Yamanishi, Takao, Koizumi, & Ishihama, et al., 2010).

Martin- Harris and Brodsky et al (2005) found onset of swallow apnoea to start during the oral preparatory stage, when the bolus is entering the mouth, and offset usually occurring in the late stages of the pharyngeal stage of the swallow. Durations of swallow apnoea ranged from 0.50 sec to 10.02 sec (Md= 1sec), with extreme outliers in the older subjects. Klahn and Perlman (1999) suggested gender and viscosity differences vary the duration of swallow apnoea. They suggest males require a longer pharyngeal stage due to anatomical differences, however this is disputed in more recent studies

(Hiss, Treole, & Stuart, 2001; Gross, Atwood Jnr, Grayhack, & Shaiman, 2003; Logemann, 2008).

### **3.3 The Normal Respiratory-Swallow Pattern**

The respiratory-swallow pattern is a term used for the respiratory phase surrounding the swallow apnoea (and hence surrounding bolus movement through the pharynx). Martin-Harris and Brodsky et al (2005) provided a normative model for an adult breathing-swallow pattern. They describe four main respiratory-swallow patterns surrounding the swallow apnoea;

- Inhalation - (swallow apnoea) - Inhalation (INH/INH)
- Inhalation - (swallow apnoea) - Exhalation (INH/EXH)
- Exhalation - (swallow apnoea) - Exhalation (EXH/EXH)
- Exhalation - (swallow apnoea) - Inhalation (EXH/INH).

These four patterns have also been described at the moment swallow apnoea is initiated; as mid exhalation (EXH/EXH), end exhalation (EXH/INH), mid inhalation (INH/INH) or end inhalation (INH/EXH) (Charbonneau, Lund, & McFarland, 2005).

The majority of studies investigating the respiratory phase post swallow concur that the predominant pattern in normal healthy adults is to exhale post swallow (Selley, Flack, Ellis, & Brooks, 1989; Smith, Wolcove, Colacone, & Kreisman, 1989; Shaker, Ren, Townsend, & Dodds, et al., 1992; Martin, Shaker, & Dodds, 1994; Paydarfar, Gilbert, Poppel, & Nassab, 1995; Preiksaitis, Mayrand, Robins, & Diamant, 1996; Klahn & Perlman, 1999; Gross, Atwood Jnr, Grayhack, & Shaiman, 2003; Martin-Harris,

Brodsky, Michel, & Ford, et al., 2005). Smith and Wolcove et al (1989) and Paydarfar and Gilbert et al (1995) went further to document the irregular breathing pattern compared to resting respiration and a resetting phase of respiration post swallow.

Exhalation post swallow requires the swallow to be initiated during either mid or high lung volumes, thus placing the onset of swallow in either mid exhalation or end inhalation (and hence post swallow exhalation). However two studies suggested swallows are more efficient when onset of swallow apnoea occurs during mid to end exhalation (McFarland, Lund, & Gagner, 1994; Charbonneau, Lund, & McFarland, 2005; Martin-Harris, 2008).

Swallow onset at end exhalation would result in an inhalation post swallow respiratory phase, in direct contrast to the exhalation post swallow studies. These studies report a swallow is benefitted by mid to low lung volumes, suggesting this produces least diaphragmatic resistance, and thereby providing the least amount of resistance on laryngeal elevation. Whereas Paydarfar and Gilbert et al (1995), and further expanded in Gross and Atwood et al (2003) and later in Gross and Steinhauer et al 2006 suggested the coupling of exhalation post swallow with higher lung volume (INH/EXH) is required to stimulate subglottic mechanoreceptors, and therefore attain adequate subglottic pressure for a safe and efficient swallow. The studies by Gross and Atwood et al (2003), and Gross and Steinhauer et al (2006) postulate that the larynx has more than a ventilatory function, but also provides essential neurosensory regulation for swallowing. These findings are confirmed in Martin-Harris and Brodsky et al (2003) where they proposed protection of the airway is enhanced during exhalation (swallow onset), as

the arytenoid to vocal fold position is slightly adducted during exhalation, becoming a 'protective set point' for laryngeal closure during the swallow process, and avoids inhaling (potential) residue in the pharynx post swallow. This theory is supported by physiological findings, suggesting recruitment from the supplementary motor area and insular cortex (and indirectly from basal ganglia and thalamus) for respiratory and swallowing regulation plays a crucial role in inhibiting inhalation post swallow (Dziewas, Soros, Ishii, & Chau, et al., 2003; Huckabee, Deecke, Cannito, & Gould, et al., 2003), and further protecting the airway during pharyngeal transit of the bolus (Hukuhara & Okada, 1956; Shaker, Ren, Townsend, & Dodds, et al., 1992).

Differences in findings may be due to protocol differences related to small sample size, physiological factors such as differing bolus consistency or delivery, or terminology used to describe the lung volume post swallow. The studies investigating swallow apnoea at onset of swallow do not comment on post swallow respiration phase, so it may be possible that 'end exhalation' phase may still (briefly) exhale post swallow. This would still place respiration in exhalation phase post swallow, although it would not conform with theories suggesting higher lung volumes are required to activate subglottic mechanoreceptors.

### **3.3.1 Age related changes**

Normal healthy older adults have shown a general deterioration of respiratory muscle mass and function with increasing age. Previous studies demonstrate decreased chest-wall compliance and lung elasticity, and

increased atrophy in expiratory muscles (more than inspiratory muscles) with increasing age (Kim & Sapienza, 2005). These changes result in the respiratory muscles working harder to maintain breathing. Although there is clear evidence to support a general decline in respiratory function in an older population, evidence as to whether the documented decline is a contributing factor on altering the respiratory-swallow pattern remains unclear. As with studies on the normal healthy respiratory-swallow pattern, it is difficult to compare findings regarding age related changes as studies have not explicitly detailed definition; such as age or sample size, or have differing bolus trials or outcome measures.

The literature remains equivocal regarding age related changes impacting the duration of swallow apnoea. Shaker and Ren et al (1994) and Martin-Harris and Brodsky et al (2003) reported no change in duration of swallow apnoea, however in their later study (Martin-Harris, Brodsky, Michel & Ford, et al., 2005), they found age accounted for 18% of variation in swallow apnoea duration, with the elderly group (over 81 years) using a longer swallow apnoea (mean 1.69sec S.D. 1.14sec) when compared with a younger group (21-40 years) (mean 1.04sec, S.D.0.24 sec),  $p < 0.01$ . Other studies also suggested older adults had longer swallow apnoea duration times due to the 'normal ageing slowing process' (Hiss, Treole, & Stuart, 2001; Hirst, Ford, Gibson, & Wilson, 2002; Leslie, Drinnan, Ford, & Wilson, 2005). However none of the studies found (or reported) evidence of dysphagia or aspiration accompanying the increase in swallow apnoea observed.

As with duration of swallow apnoea, there is no consensus within the literature regarding age related changes in post swallow respiration phase. However, the majority of studies suggest the respiratory-swallow pattern is not significantly altered with age (Zamir, Ren, Hogan, & Shaker, 1996; Hiss, Treole, & Stuart, 2001; Hirst, Ford, Gibson, & Wilson, 2002; Charbonneau, Lund, & McFarland, 2005; Leslie, Drinnan, Ford, & Wilson, 2005; Kelly, Huckabee, Jones, & Carroll, 2007;). Contrary to these findings, Shaker and Ren et al (1992) and Martin-Harris and Brodsky et al (2005) found older adults used inhalation post swallow significantly more than younger adults.

The majority of studies analysed the respiratory-swallow pattern indirectly, using techniques such as surface electromyography (McFarland, Lund, & Gagner, 1994; Preiksaitis, Mayrand, Robins, & Diamant, 1992; Hiss, Treole, & Stuart, 2001; Charbonneau, Lund, & McFarland, 2005; Gross, Atwood, Ross, & Olszewski, et al., 2009). Whilst these studies provide valuable information, there is a need to confirm these findings using visual confirmation of the swallow as none of the studies were able to report on the nature of biomechanical dysphagia, or rates of aspiration due to changes of the respiratory-swallow pattern. The weaknesses of using non visual instrumentation to assess the swallow are discussed further in section 4.3.3iv.



### **3.4 Alterations to the respiratory-swallow pattern**

Deviations from the normal swallowing pattern can be described within two broad categories; physiological factors, or disease or disorder, which are now discussed.

#### **3.4.1 Physiological factors**

The respiration-swallow pattern has been argued to be controlled by volitional versus non volitional swallow, alertness level and bolus volume. Findings appear to conflict, however when further analysed, the differences are mostly due to terminology used to describe study design and results, this also increases the difficulty to compare findings. There are varied definitions for terms such as alertness levels, and 'volitional' swallows (reactive versus self timed, or reflexive) (Nishino & Hiraga, 1991; Kelly, Huckabee, Jones, & Carroll, 2007).

Studies exploring altered respiratory-swallow pattern with differing bolus type, volumes and timing of delivery have shown varied findings. Paydarfar and Gilbert et al (1995) studied the impact of timing of the swallow and found 'respiratory phase resetting' occurs post swallowing as compared to the respiratory phase at rest. They also noted swallow apnoea duration reduced if a liquid bolus swallow is initiated during late expiration phase, compared to swallows initiated during late inhalation or mid exhalation phase. Whereas Hirst and Ford et al (2002) studied the effect of different bolus volumes in an older swallow (Mean age= 73 years), with 5ml, 20ml and 100ml liquid bolus delivered via syringe, straw or cup. They found that exhalation phase

predominated post swallow, occurring on an average 64% of all swallows (range 44%-91% for differing volumes). These results confirmed previous findings by Paydarfar and Gilbert et al (1995), who suggest that these alterations do not occur to the respiratory-swallow pattern with differing bolus types. Contrary to these findings, however, Dozier and Harris et al (2006) suggested the respiratory-swallow pattern can be altered by bolus volume, suggesting large (50ml) sequential swallows of liquid increased the use of inhalation post swallow when compared with smaller (5ml) single historical swallows. These findings may be due to bolus volume, but equally may be due to task dependent variability (Preiksaitis, Mayrand, Robins, & Diamant, 1992; Nishino, Hasegawa, Ide, & Isono, 1998). Although exhalation during and post swallow predominated, a non significant increase in the use of inhalation post swallow was noted with increased liquid volume, type of delivery of bolus (cup and straw) and with a solid bolus. Similarly, more recent studies investigating respiration-swallow patterns with a solid bolus revealed the importance of the finely tuned relationship between breathing and swallowing, especially during the oral preparatory and oral stage; with increased variation of respiratory pattern for foods that require chewing (Palmer & Hiimae, 2003; Matsuo, Hiimae, Gonzalez-Fernandez, & Palmer, 2008; Gross, Atwood, Ross, & Olszewski, et al., 2009). Conflicting findings between Martin-Harris and Brodsky et al (2003) and Martin-Harris and Brodsky et al (2005) also support the theory that respiratory patterns are potentially affected by bolus volume, and/or sip drinking versus sequential. This is also confirmed in a recent study by Cvejic and Harding et al (2011) discussed later in section 3.5.

Alteration to the respiratory-swallow pattern has been explored further as a result of postural changes, with conflicting results. McFarland and Lund et al (1994) found a significant difference in respiration phase post swallow between two positions; late exhalation post swallow in upright position compared with early exhalation post swallow when subjects were positioned 'on hands and knees' during the swallowing task. Ayuse and Ayuse et al (2006) confirmed posture alters the predominant pattern. Results suggested a reclined position by 60 degrees in combination with chin tuck position significantly increased swallow apnoea duration ( $p < 0.001$ ), however respiratory phase post swallow was not recorded.

#### **3.4.2 Disease or disorder**

The neural respiratory-swallow coupling can also be seen through studies investigating deviations to the normal pattern due to damage or disease. Charbonneau and Lund et al (2005) studied respiratory- swallow cycle in patients post laryngectomy. They found exhalation post swallow was maintained, even though the laryngeal structures had been removed and the requirement for airway protection was no longer necessary in this patient population (due to neck breathing); with no significant differences observed between the laryngectomy group and the normal control group. This finding suggests there is stability in respiratory inhibition during swallowing post surgery. In contrast to Charbonneau and Lund et al's findings, Terzi and Orliowski et al (2007) found significant alterations to the predominant respiratory-swallow pattern; with only 50% of tracheostomy patients studied

producing exhalation post swallow compared to 100% of swallows in the healthy control group ( $p < 0.0001$ ). As part of Terzi and Orilowski et al's (2007) study, they also explored the impact of mechanical ventilation on the respiratory-swallow pattern and found shorter swallow durations and fewer swallows per bolus. However methodological weaknesses to this study include the heterogeneous nature of the group; as there are varied neurological conditions sampled, and failure to document the respiratory-swallow pattern before tracheostomy. Therefore I suggest the findings are ambiguous regarding the cause of the alterations. However other studies are in agreement with Terzi and Orilowski et al's (2007) findings of altered respiratory-swallow pattern in neurological disorders. Hadjikoutis and Pickersgill et al (2000) studied respiratory phase post swallow in patients with spinal, neurological and peripheral impairment, and also found deviation to the normal pattern irrespective of site of lesion, and noting inhalation occurring more frequently post swallow in the motor neuron disease group, and also with increased severity of dysphagia. Butler and Stuart et al (2007) also included rates of aspiration alongside alterations in the respiratory-swallow pattern exclusively in stroke patients; demonstrating an association between severity of dysphagia and inhalation respiratory phase post swallow. They found stroke patients with known dysphagia without aspiration used inhalation post swallow (3.0%) more than normal controls (0.1%), and stroke patients with aspiration used inhalation post swallow the most out of the three groups (9.0%).

Alterations in the respiratory-swallow pattern have also been investigated in other neurological disorders. Parkinson's disease is a known disorder which

interrupts the breathing pattern of the individual, and therefore has implications on providing efficient swallow apnoea. Pinnington and Muhiddin et al (2000) found that exhalation was used post swallow in 80% of Parkinson's disease patients during drink swallows compared to 99% of controls. A study by Gross and Atwood et al (2008) also found a higher frequency of inhalation during the swallow and also post swallow in patients with Parkinson's disease compared to controls; however they assessed using solid bolus trials.

### **3.5 Relevance to COPD**

COPD may impact on the intricate timing of the respiratory-swallow pattern due to altered lung capacity and physiology, as discussed in chapter one. There appears to be three studies to date that have exclusively investigated the respiratory-swallow pattern specifically in patients with COPD; either in stable Moderate-Severe COPD (Gross, Atwood, Ross, & Olszewski, et al., 2009), in exacerbation phase with follow up in stable phase (Shaker, Ren, Townsend, & Dodds, et al., 1992) or examined during stable phase (Cvejic, Harding, Churchward, & Turton, et al., 2011). The latter study simultaneously assessed the respiratory-swallow pattern in patients with COPD alongside biomechanical analysis; therefore the respiratory-swallow pattern findings are reported in this section, with the biomechanical analysis reported earlier in chapter two. These studies are clinically relevant to this thesis, and are therefore discussed in detail and included in summarised in table 6 at the end of the chapter.

All three studies compared a COPD cohort with healthy control groups; however they all used varying bolus consistencies. Cvejic and Harding et al (2011) assessed subjects using liquid bolus trials at four volumes (5ml, 10ml, 20ml and 100ml), Gross and Atwood et al (2009) compared semi-solid and solid bolus trials across groups in COPD (n= 25) with age matched control (n=25), and Shaker and Ren et al (1992) compared dry swallows (saliva) in COPD (n=10) with a healthy young (18-34 years) (n=10) and healthy older (65-83 years) (n=11) group. The latter study also evaluated water trials; however these were completed only by the control groups and therefore will not be detailed in this section.

Shaker and Ren et al (1992) experienced a low retention for the COPD group (12/22) and the young healthy for respiratory rate 30-34 bpm (6/10) with no explanation by the authors. Inclusion and exclusion criteria were also not detailed in their study. However Gross and Atwood et al (2009) and Cvejic and Harding et al (2011) maintained adequate retention of subjects; with Cvejic and Harding et al (2011) losing only three subjects during the 36 month follow-up, and documented strict recruitment criteria ensuring known aetiologies associated with dysphagia were excluded from research and control groups.

Surface electromyography (SEMG) was used for pharyngeal phase swallow assessment in all studies, along with plethysmography or pneumobelt to assess respiratory phases during swallow initiation and post swallow.

However Cvejic and Harding et al (2011) combined the information from the SEMG along with videofluoroscopy assessment to measure onset of the swallow; improving on the methodological weakness of using SEMG in

isolation. The advantages and disadvantages of using SEMG exclusively to assess swallowing is discussed later in chapter four, however to reiterate the main disadvantage of using SEMG is the inability to visualise the swallow, dysphagia characteristics and any penetration and /or aspiration occurring, thus adding an extra element of error in timing the respiration and swallow components accurately.

Although analysing swallows of differing bolus types, two studies found the COPD group used inhalation *during the swallow and post swallow* significantly more than the control groups (Shaker, Ren, Townsend, & Dodds, et al., 1992; Gross, Atwood, Ross, & Olszewski, et al., 2009); whereas in Cvejic and Harding et al (2011), the use of inhalation increased only *during* the swallow. Contrary to Cvejic and Harding et al's (2011) findings, Shaker and Ren et al (1992) found inhalation post swallow was used significantly more in the COPD group than the older healthy group ( $p<0.001$ ), as well as inhalation during the swallow ( $p<0.05$ ). Furthermore, two studies revealed statistically significant differences between bolus types. Gross and Atwood et al (2009) found the COPD group used inhalation post swallow more on semi-solid than solid boluses ( $p=0.001$ ) and had a shorter swallow apnoea on semi-solid than solid boluses ( $p=0.03$ ); whereas Cvejic and Harding et al (2011) found an increased use of inhalation during the swallow occurred during large liquid trials (100ml,  $p=0.01$ ).

From the combined findings from the three studies, three main areas of impairment to the swallow-respiratory pattern is highlighted in patients with COPD, with one study recording further aberration from older healthy control group (Shaker, Ren, Townsend, & Dodds, et al., 1992). Firstly, the COPD

group generally swallowed significantly more during inhalation; or inhaled post swallow significantly more than their normal control group. Secondly, swallows for food requiring chewing occurred more during inhalation. Thirdly, the COPD group inhaled post swallow significantly more on semi-solids than solids (Gross, Atwood, Ross, & Olszewski, et al., 2009); or used inhalation during the swallow during large liquid trials (Cvejic, Harding, Churchward & Turton, et al., 2011). These aberrant findings in the respiratory- swallow pattern observed in patients with COPD may account for dysphagic characteristics, and increase the risk of aspiration leading to pneumonia. Only Cvejic and Harding et al (2011) assessed the respiratory-swallow pattern alongside visual biomechanical analysis, and therefore had capacity to analyse any relationship between the two. However this was not reported within the study's findings.

The respiratory-swallow pattern has been shown to be altered from the normal pattern in patients with COPD in the three studies, yet none assess whether the swallow may still be functioning adequately; maintaining health and quality of life. Combining the respiratory assessment concurrently with a robust objective direct swallow assessment (such as videofluoroscopy) would ensure accurate conclusions regarding the timing of the swallow with respect to the respiratory phase as shown in Cvejic and Harding et al (2011); however evaluating the relationship between biomechanical dysphagia and respiration, and the effect of spontaneous manoeuvres would provide further information on the effectiveness of the overall respiratory- swallow pattern used.



### **3.6 Summary of Chapter**

Respiration shares neural receptors with the swallowing central pattern generator (CPG), and has been proven to play a key role in influencing the onset and duration of the swallow. Consensus suggests the predominant respiratory phase most frequently used in normal healthy adults is exhalation post swallow; with the swallow apnoea initiation during mid to high lung volumes (Gross, Steinhauer, & Zajac, 2006). This pattern is likely to continue despite atrophy of respiratory muscles and decreased chest wall excursion seen with increasing age (Kelly, Huckabee, Jones, & Carroll, 2007).

Alteration to the respiratory- swallow pattern has been shown during behavioural changes such as bolus volume or texture, and due to disease or disorders. Conflicting findings between Martin-Harris and Brodsky et al's 2003 and 2005 findings may also highlight task dependent variability in respiratory phase post swallow. Studies using patient diagnostic groups such as stroke, Parkinson's disease and laryngectomy also reveal an alteration in the predominant respiratory-swallow pattern due to the disease process.

Three studies were found investigating the respiratory-swallow pattern specifically in COPD. Of which, two found an increased frequency of inhalation post swallow for varied bolus volumes and textures with altered swallow apnoea duration (Shaker, Ren, Townsend, & Dodds, et al., 1992; Gross, Atwood, Ross, & Olszewski, et al., 2009); with one study finding inhalation during the swallow altered during large liquid volumes (Cvejic, Harding, Churchward & Turton, et al., 2011).

The literature predicts inhalation post swallow; coupled with increasing age and disease increases the risk of aspiration. Although a direct causal

relationship between altered respiratory-swallow pattern and increased risk of oropharyngeal dysphagia has been clinically suspected; the nature of the biomechanical dysphagia, or detrimental health outcomes such as aspiration or reduced quality of life have not been documented in the literature and therefore not yet confirmed. The literature eludes to, but does not investigate the nature of oropharyngeal dysphagic symptoms caused by an altered respiratory-swallow pattern in patients with COPD, or assessment of functionality of the swallow by phase of COPD. These findings suggest further research is required in exploring the respiratory-swallow pattern concurrently with the oropharyngeal swallow. Methodologies documenting the respiratory-swallow pattern can provide a solid base to support further research, and enable further investigation into the impact of an altered respiratory- swallow pattern on the swallow in the stable and exacerbative phases of COPD. Although too late to influence the protocol development and methodological design, the study by Cvejic and Harding et al (2011) provides similar aspects to the study's methodology detailed in this thesis.

### **3.7 Pre-Clinical Theory I and II: Concluding Thoughts**

Chronic Obstructive Pulmonary Disease (COPD) is a progressive respiratory disease with reduced pulmonary defence mechanisms and exhibits periods of decline during exacerbations of the condition. Causes of exacerbations are currently not identified in 30% of cases; with bacterial infections as a contributing factor considered controversial in the literature, and antibacterial intervention showing mixed results. Yet the mechanism leading to bacterial infection is largely under researched. Undiagnosed aspiration pneumonia due to oropharyngeal dysphagia may play a significant role in increasing the bacterial load found in the lungs during exacerbations; however how oropharyngeal dysphagia contributes to the onset or frequency of acute exacerbations, severity of the overall condition or impact on swallowing related quality of life is largely unknown. Furthermore COPD guidelines discussed in chapter one currently do not acknowledge the potential devastating impact of oropharyngeal dysphagia in patients with COPD, nor do care pathways routinely include oropharyngeal assessment for this population. This may be due to the dearth of evidence within the literature, as shown in chapters two and three.

Nevertheless a total of eighteen key studies were found investigating either oropharyngeal dysphagia or respiratory-swallow pattern in patients with COPD (summarised in table 6); eleven of which were published before protocol development for the study detailed in this thesis. Combining these pertinent studies with normative data acknowledged within the literature to occur within normal and normal age related swallows (summarised in table 7) highlighted gaps within the literature and informed the methodological

design of the study detailed in this thesis; which is now discussed in the following chapter.

**Table 6: Summary of literature investigating oropharyngeal dysphagia and respiratory-swallow pattern in patients with COPD.**

a) Oropharyngeal Dysphagia in patients with COPD:					
Author (Year) Article Title Country of Origin Type of Publication	Sampling Method Sample Size (n) Mean Age	Inclusion/ Exclusion criteria	Study Type Methodology	Results	Comments
<p><b>1. Coelho C., (1987)</b> Preliminary findings on nature of dysphagia in patients with COPD</p> <p>USA</p> <p>Full Article</p>	<p>Prospective consecutive sampling</p> <p>n=14 Advanced COPD (12 males)</p> <p>mean age=68y</p> <p>no controls</p>	<p><i>Incl:</i> Referred for swallowing assessment. Primary diagnosis of COPD</p> <p><i>Excl:</i> Neurogenic or myopath history</p>	<p>Cross sectional</p> <p>Oral phase assessment.</p> <p>Videofluoroscopy (normal fluid, semi-solid and solid)</p>	<p>Descriptive:</p> <p>3/14 Aspirated</p> <p>7/14 Swallow dysfunction without aspiration</p> <p>4/14 Normal swallow</p>	<p>14/ 289 COPDs referred for swallowing assessment in 18 month period.</p> <p>13/14 research group had a tracheostomy and 5/14 were ventilator dependant</p> <p>Subjects were assessed between clinical exacerbation and stable phase</p>
<p><b>2. Stein and Williams et al (1990)</b> Cricopharyngeal dysfunction in COPD</p> <p>USA</p> <p>Full Article</p>	<p>Prospective Non consecutive, non randomised</p> <p>n=25 COPD (Mod-Severe) 50+ years</p> <p>n= 128 unmatched historical control</p>	<p><i>COPD Incl:</i> Historical data including 'food stuck in throat', aspiration pneumonia</p> <p>Frequent COPD exacerbations</p> <p><i>Control Excl:</i> Known dysphagia and pulmonary disease</p>	<p>Cross sectional</p> <p>Videofluoroscopy or Cineradiography (bolus type not stated)</p> <p>Chest X-Ray</p>	<p>Descriptive:</p> <p>17/25 COPD marked dysphagia</p> <p>21/25 COPD had CP dysfunction, 10 proceeded to CP myotomy</p> <p>5/17 COPD GERD</p> <p>COPD FEV1 did not correlate with CP dysfunction</p> <p>14/128 controls Mild CP dysfunction</p>	<p>Clinical dysphagia not defined</p> <p>Selection bias of research group</p> <p>Use of unmatched non randomised controls from previous videofluoroscopy assessment</p> <p>Combining pharyngoesophageal assessment information inappropriately</p>

<p><b>3. Good-Fratturelli and Curlee et al (2000)</b> Prevalence and nature of dysphagia in VP patients with COPD referred for videofluoroscopy</p> <p>USA</p> <p>Full Article</p>	<p>Retrospective</p> <p>n= 78 (male) mean age= 69y</p>	<p><i>Incl:</i> Referred for swallowing assessment; Primary diagnosis of COPD</p> <p><i>Excl:</i> not stated</p>	<p>Cross sectional</p> <p>Videofluoroscopy (normal fluid, thick fluid, puree, paste, solid)</p>	<p>Descriptive</p> <p>66/78 dysphagic Liquid &gt;Solid</p> <p>32/78 Aspirated</p> <p>21/78 Penetrated</p> <p>44/78 penetrated or aspirated</p> <p>High percentage of silent aspiration.</p>	<p>84/1996 COPD referred for videofluoroscopy 1992-1995.</p> <p>No control group.</p> <p>Research group was 100% male</p> <p>Limited exclusion criteria</p>
<p><b>4. Mokhlesi and Logemann et al (2002)</b> Oropharyngeal deglutition in stable COPD</p> <p>USA</p> <p>Full Article</p>	<p>Prospective consecutive sampling</p> <p>n=20 Stable, hyperinflated COPD (19 men) Mean Age= 69y 16/20= FEV1&lt;50% predicted</p> <p>n= 20 historical controls (age and gender matched)</p>	<p><i>Inclusion:</i> Diagnosis of COPD (ATS); FEV1≤65% predicted; FEV1/FVC Ratio ≤70%; ≥55years old; Smoke ≥30 pack years</p> <p><i>Exclusion:</i> Other respiratory diseases; Tracheostomy within last 3 months; Intubated; Head and Neck Cancer; CNS muscle pathway disease; Oesophageal disease; Increased alcohol consumption; Diabetic</p> <p>Control Group:</p> <p><i>Excl:</i> Dysphagia, respiratory disease, neurology history, smoking, GORD,</p>	<p>Case-control</p> <p>Chest X-Ray PFT</p> <p>Dysphagia questionnaire Videofluoroscopy (normal fluid and paste)</p> <p>Pulse Oximetry</p> <p>Controls:</p> <p>Videofluoroscopy</p>	<p>Analytic</p> <p>No aspiration for either group</p> <p>9/20 COPD prolonged airway closure</p> <p>longer pharyngeal delay</p> <p>27/648 Pearson correlation significant for Correlated swallow variables with respiratory variables (statistics not reported)</p> <p>Laryngeal elevation was reduced COPD&gt;Normals (p&lt;0.001)</p> <p>Controls= no dysphagia</p>	<p>Only reduced laryngeal elevation was statistically significant.</p>

<p><b>5. Harding (2002)</b> Oropharyngeal dysfunction in COPD: The need for clinical research</p> <p>USA</p> <p>Editorial</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>	<p>The association between COPD and dysphagia has not been systematically investigated.</p> <p>Using multiple methods overcomes weaknesses of individual assessments</p>	<p>Editorial commenting on Mokhlesi et al's study</p> <p>Discusses oropharyngeal and oesophageal dysphagia studies</p>
<p><b>6. Teramoto and Kume et al (2002)</b> Altered swallowing physiology and aspiration in COPD.</p> <p>Japan</p> <p>Letter to Editor</p>	<p>Not stated</p> <p>N=48 COPD</p> <p>Control group not stated</p>	<p>Not stated</p>	<p>Not stated</p> <p>SPT</p>	<p>8/48 COPD subjects showed abnormal swallow function therefore at risk of aspiration</p>	<p>Full study not available</p> <p>combines conclusions of oropharyngeal oesophageal dysphagia</p>
<p><b>7. Mahoney and Foo et al (2004)</b> Chronic obstructive pulmonary disease and dysphagia; the effects of varying bolus viscosity, swallowing mode and level of lung hyperinflation.</p> <p>Australia</p> <p>Abstract only</p>	<p>Prospective</p> <p>n= 8 stable COPD mean age= 67y</p> <p>no controls</p>	<p><i>Incl:</i> Severe COPD with no bronchodilator reversibility ; no exacerbation in previous 4 weeks;</p>	<p>Cross sectional</p> <p>Videofluoroscopy</p> <p>PFT</p>	<p>Descriptive</p> <p>Pen/Asp scale: score 2- 1/8 score of 3- 1/8</p> <p>Delayed initiation- level of valleculae</p> <p>Pyriiform residue post swallow</p>	<p>Full study not available</p> <p>Initiation at level of valleculae normal for 60+ years.</p>

<p><b>8. Matsuda and Teramoto et al (2004)</b> A study of swallowing function in patients with COPD.</p> <p>Japan</p> <p>Abstract only</p>	<p>Not stated</p> <p>n= 48 COPD</p> <p>n=48 Control (age matched)</p>	<p>Not stated</p>	<p>Case control</p> <p>S-SPT</p>	<p>Analytic</p> <p>18/48 COPD swallowing dysfunction</p> <p>Latent Time COPD&gt;Normals</p>	<p>Full study not available</p> <p>Use of S-SPT and definition of 'delay pharyngeal response' inaccurate</p>
<p><b>9. Carney and Sheppard et al (2005)</b> The Penetration/Aspiration risk in patients presenting with an acute exacerbation of COPD.</p> <p>Canada</p> <p>Abstract</p>	<p>Prospective consecutive sampling</p> <p>n=21 COPD no controls</p>	<p><i>Incl:</i> Acute exacerbation COPD</p> <p><i>Excl:</i> not specified</p>	<p>Cross sectional</p> <p>Videofluoroscopy (normal fluids)</p> <p>Spirometry</p>	<p>Descriptive</p> <p>10/21 Penetration</p> <p>10/21 Aspiration +/- Silent</p> <p>No relationship between COPD severity and Pen/Asp rating</p>	<p>Full study not available</p>
<p><b>b) Oropharyngeal dysphagia in patients with COPD: Studies published after protocol development and data collection for the study detailed in this thesis:</b></p>					
<p><b>Author (Year)</b> <b>Article Title</b> <b>Country of Origin</b> <b>Type of Publication</b></p>	<p><b>Sampling Method</b> <b>Sample Size (n)</b> <b>Mean Age</b></p>	<p><b>Inclusion/ Exclusion criteria</b></p>	<p><b>Study Type Methodology</b></p>	<p><b>Results</b></p>	<p><b>Comments</b></p>
<p><b>1. Kobayashi and Kubo et al (2007)</b> Impairment of the swallowing reflex in exacerbations of COPD.</p> <p>Japan</p> <p>Letter to editor</p>	<p>n= 50 stable COPD divided:</p> <p>(n= 25 1+ exacerbation /12 months; 22 male mean age= 75y</p> <p>n=25 stable; 21 male mean age=77y</p>	<p><i>Incl:</i> not stated</p> <p><i>Excl:</i> current smokers; oral corticosteroids; H+N cancer; neuromuscular disease; oesophageal disease</p>	<p>Cross sectional</p> <p>S-SPT</p> <p>(1ml water injected into nasal catheter)</p> <p>Delayed Latent time of swallowing reflex &gt; 3 sec</p>	<p>Analytic</p> <p>Longer Latent Time Exac&gt;Stable (p&lt;0.001)</p> <p>22/25 Exac vs 8/25 Stable impaired response (&gt;3sec) (p&lt;0.001)</p> <p>Relative Risk 2.8, (95% C.I. 1.5-5.0)</p>	<p>Full study not available</p> <p>All subjects were clinically stable</p> <p>Placement of catheter not stated</p> <p>Definition of delay pharyngeal response inaccurate</p>



<p><b>2. McKinstry and Tranter et al (2009)</b> Outcomes of dysphagia intervention in a pulmonary rehabilitation.</p> <p>Australia</p> <p>Full Article</p>	<p>Not stated</p> <p>n= 253 Group 1</p> <p>n= 383 Group 2</p> <p>n= 55 Group 3</p> <p>no controls</p>	<p><i>Incl:</i> Enrolled in 8 week Pulmonary Rehabilitation Program between 2002-2007 with COPD and chronic respiratory disease</p> <p>Group1: Attendance of 1hour education and successful completion of questionnaires</p> <p>Group 2: Completed basic dysphagia screening and self report questionnaire</p> <p>Group 3: Completed individual dysphagia assessment and pre and 3month post SWAL-QOL</p> <p><i>Excl:</i> Not stated</p>	<p>Cross sectional</p> <p>Dysphagia screen and self report questionnaire</p> <p>SWAL-QOL</p>	<p>Analytic</p> <p>Group 1: Pre 5/11 vs Post scores 8/11 (p&lt;0.001)</p> <p>Group 2: 104/383 subjects exhibited or reported dysphagic symptoms and went on to individual assessment.</p> <p>Group 3: Stat sig improvement Burden (p&lt;0.009) Physical Problem (p&lt;0.012) Food Selection (p&lt;0.016)</p>	<p>Exclusion criteria not stated</p> <p>Contents of dysphagia education programme not stated</p> <p>Approx 78% of sample seen for education and screen diagnosed with COPD.</p> <p>Individual assessment results not reported</p>
<p><b>3. Terada and Muro et al (2010)</b> Abnormal swallowing reflex and COPD exacerbations</p> <p>Japan</p> <p>Full Article</p>	<p>Prospective</p> <p>n= 67 Stable COPD mean age= 73y</p> <p>n= 19 Control (age matched) mean age= 70y</p>	<p><i>COPD incl:</i> Stable COPD</p> <p><i>COPD Excl:</i> add. respiratory disease; malignancy; otorhinolaryngeal; stroke; active inflammation disorder; change in COPD medication; use of corticosteroids; LTOT use; ventilation</p>	<p>Case Control</p> <p>STS-SPT</p> <p>CRP</p> <p>LFT+ABG</p> <p>Sputum sample (COPD)</p> <p>GERD self report questionnaire (COPD)</p>	<p>Analytic</p> <p>0/86 response to 2<sup>nd</sup> stage SPT (2ml injection)</p> <p>22/67COPD vs 1/19 Control delay response 1<sup>st</sup> stage SPT (0.4ml injection) RR=6.24(0.90-43.34, p=0.02)</p> <p>COPD vs Control CRP p=0.38</p> <p>CRP: COPD delay RR= 2.72 (1.46-</p>	<p>All COPDs clinically stable at time of testing</p> <p>STS-SPT given supine and injected at end exhalation</p> <p>STS-SPT design flawed</p> <p>Definition of delay &gt;3sec inaccurate</p> <p>Inappropriate combination of oropharyngeal and oesophageal information</p>

		<p><i>Control excl:</i> Respiratory comorbidities; comorbidity affecting swallow;</p>		<p>3.98) vs COPD normal RR= 1.56 (0.92-2.19), p=0.04</p> <p>Freq. Of Exacerbations: COPD delay RR=2.82 (1.92-3.72) vs COPD normal RR=1.56 (0.92-2.19), p=0.007</p> <p>Incidence of exac requiring add. medical support: 14/22 COPD delay vs 10/45 COPD normal RR= 2.86 (1.52-5.38), p&lt;0.001</p> <p>GERD: COPD delay RR= 6.75 (3.84-9.66) vs COPD normal RR=4.10 (1.98-2.22), p=0.04</p>	
<p><b>4. Cvejic and Harding et al (2011)</b> Laryngeal penetration and aspiration in individuals with stable COPD.</p> <p>Australia</p> <p>Full Article</p>	<p>Prospective</p> <p>n= 16 stable COPD</p> <p>n= 15 control (age matched)</p>	<p><i>Incl:</i> Doctor diagnosis of COPD; FEV1/FVC ratio ≤70% predicted; TLC, FRC, RV plethysmography ≥120% predicted Stable COPD for preceding 4 weeks &gt;10 year pack history</p> <p>Control: normal lung function, non smoker, no history of respiratory, neurology or reflux disease</p> <p><i>Excl:</i> No history of swallowing difficulty, neurological or gastroesophageal</p>	<p>Case control</p> <p>Videofluoroscopy (5, 10, 20, and 100ml liquid trials)</p> <p>EMG</p> <p>Intranasal and inductive plethysmography</p> <p>Pulse Oximetry</p>	<p>Analytic</p> <p>6/16 COPD Pen/Asp; 1/15 Control Pen/Asp (p=0.04)</p> <p>4/16COPD Asp vs 1/15 Asp only (p=0.07)</p> <p>EXH/EXH 11/16 COPD and 10/15 Control for 5, 10 and 20ml</p> <p>INH/EXH 10/16 COPD vs 3/15 controls for 100ml</p>	<p>Combined biomechanical and respiratory-swallow pattern assessment</p> <p>Number of trials per volume/subject not recorded</p> <p>Resp phase vs pen/asp not analysed</p> <p>Large proportion group 3 excluded (47%)</p>

		disease, head and neck surgery, LTOT, current smokers			
<b>5. Ilsley (2011)</b> Dysphagia and chronic obstructive pulmonary disease.  UK  Full Article	Prospective  n= 20  no controls	<i>Incl:</i> Attend Breathing Space, referred to speech and language therapy	Cross sectional  Pre and post questionnaire (8 questions)	Improvement noted for all questions relating to education program, between 10% (drinking) to 61% oral hygiene)	Service evaluation article
<b>6. Singh (2011)</b> Impaired swallow in COPD  Australia  Editorial	N/A	N/A	N/A	Further research with larger cohorts required to quantify the extent of difficulty, identify risk factors and evaluate intervention.	Editorial commenting on Cvejic et al's study.

c) Respiration-Swallow Pattern in Patients with COPD:					
Author (Year) Title of Article Country of Origin Type of Publication	Sample size Age range	Inclusion/Exclusion Criteria	Methodology	Results	Comments
<p><b>1. Shaker and Ren et al (1992)</b> Coordination of deglutition and phases of respiration: effect of aging, tachypnea, bolus volume and chronic obstructive pulmonary disease.</p> <p>USA Full Article</p>	<p>n= 22 Exac COPD age=46-72y, reassessed in stable phase (10/22)</p> <p>Controls:  n=10 Young Healthy group  Age=18-34  n=11 Older healthy group  Age=63-83</p>	<p>Not stated</p>	<p>Respirography  SEMG  Position: Upright and (controls only) Supine  Saliva Swallow: All Groups  Water Swallow: 15x 5ml syringe water trials: Younger Group only  Respiratory Rate: Younger Group Only</p>	<p>Swallows analysed:10/22 COPD analysed (due to drop out rate)</p> <p>Exac COPD&gt; Stable COPD Inhalation post swallow p&lt;0.05</p> <p>COPD&gt; Older swallow initiation in exhalation p&lt;0.05</p> <p>Exac COPD &gt; Older Inhalation post swallow p&lt;0.01</p> <p>Older&gt;Younger swallow initiation in inhalation p&lt;0.05</p>	
d) Respiration-swallow pattern in patients with COPD- Studies published after protocol development and data collection for the study detailed in this thesis:					
<p><b>2. Gross and Atwood et al (2009)</b> The coordination of breathing and swallowing in chronic obstructive pulmonary disease.</p> <p>USA Full Article</p>	<p>n= 25 COPD (all male; 6 Moderate, 19 Severe)  mean age= 69y  n= 25 Control (12 male)  mean age= 64</p>	<p>Excl:  Tracheostomy; NG; Neuro/degen; dementia; exac COPD; cardiac; metabolic.</p>	<p>Controls and COPD: Semi solid and solid bolus trials; volume controlled  Inductance plethysmography and nasal thermistry  SEMG</p>	<p>COPD&gt;Control Inhalation post swallow on Solids p=0.002 COPD&gt;Control Inhalation post swallow Semi Solids p=0.001 Semi solid&gt;Solid COPD inhalation post swallow p=0.001 Semi solid&lt;Solid COPD swallow apnoea duration p=0.03</p>	

**Table 7: Summary of findings for normal, normal age, and COPD swallow and respiration patterns.**

	<b>Normal Swallow</b>	<b>Normal Age Swallow</b>	<b>COPD</b>
<b>Definition of Age</b>	20-59	60+	Usually 50+ (National Clinical Guideline Centre, 2010)
<b>Oral Preparatory Stage</b>		Increased Chewing	
<b>Oral Stage</b>		Initiation >60 years 1-2 sec (Logemann, 2008)	
<b>Pharyngeal Stage</b>	Initiation <1 sec (Logemann, 2008)  Laryngeal elevation <80 years is 2cm males vs 1½ cm females (Logemann 2008)	Initiation <1 sec (Logemann, 2008)  Laryngeal elevation >80 years is 1½ cm males. No change for females (Logemann 2008)	Lower laryngeal position mid swallow (Mokhlesi et al, 2002)  Use of spontaneous protective manoeuvres (Mokhlesi et al, 2002)
<b>Respiration</b>	Exhalation post swallow (Gross, et al 2003) (Martin-Harris, et al 2005)	Swallow apnoea increases with age (Leslie et al, 2005) (Martin-Harris B. et al, 2005)	Inhalation post swallow significantly more than healthy controls (Gross,et al, 2009)

# **Chapter Four**

## **Methodology**

## Chapter Four: Methodology

### 4.1 Introduction

Several methodologies were employed within this study, informing the development of each stage of the study. This included a literature review, feasibility testing, and a prospective longitudinal study including a cross sectional control research arm. This chapter discusses the research methodology using the Medical Research Council (MRC) (2000), and the revised MRC (2010) framework for defining and developing a complex intervention. The complexity of the research is defined using the framework's criteria, and the methodology is further developed in the modelling phase using 'between methods' triangulation (Denzin, 1978) and evidence based practice modelling (Sackett, Rosenberg, Gray, & Haynes, et al., 1996). Justification of tools to measure the identified key components which address the aim and objectives of the study in this thesis (summarised in table 8) is also discussed.

**Table 8: Aim and objectives of study**

<b>Aim of Study</b>
To investigate the nature and extent of oropharyngeal dysphagia in COPD; during stable and exacerbative phases of the disease, and its impact on health.
<b>Objectives of the study</b>
<ol style="list-style-type: none"><li>1. Compare perception of dysphagia symptoms and impact on swallowing related quality of life between Normal Controls and by phase of COPD.</li><li>2. Investigate prevalence of oropharyngeal biomechanical dysphagia by phase of COPD.<ol style="list-style-type: none"><li>a) Explore the nature of the oropharyngeal biomechanical dysphagia by phase of COPD</li><li>b) Compare the perception of dysphagia symptoms with biomechanical analysis by phase of COPD</li></ol></li><li>3. Investigate the nature of the respiratory-swallow pattern by phase of COPD.<ol style="list-style-type: none"><li>a) Compare the respiratory-swallow pattern with biomechanical analysis by phase of COPD.</li></ol></li></ol>

The MRC guidelines note complex studies frequently require original research to be undertaken. This is highlighted within the feasibility and

evaluation stages of the framework undertaken within this study and discussed in previous chapters, revealing a lack of clear evidence base within the literature.

## **4.2 Medical Research Council Framework**

In 2000, the MRC developed a framework for defining and developing complex interventions. The guideline describes a complex intervention as being

*'built up from a number of components, which may act both independently and inter-dependently..... and not easy to precisely define the active ingredients' (p. 2).*

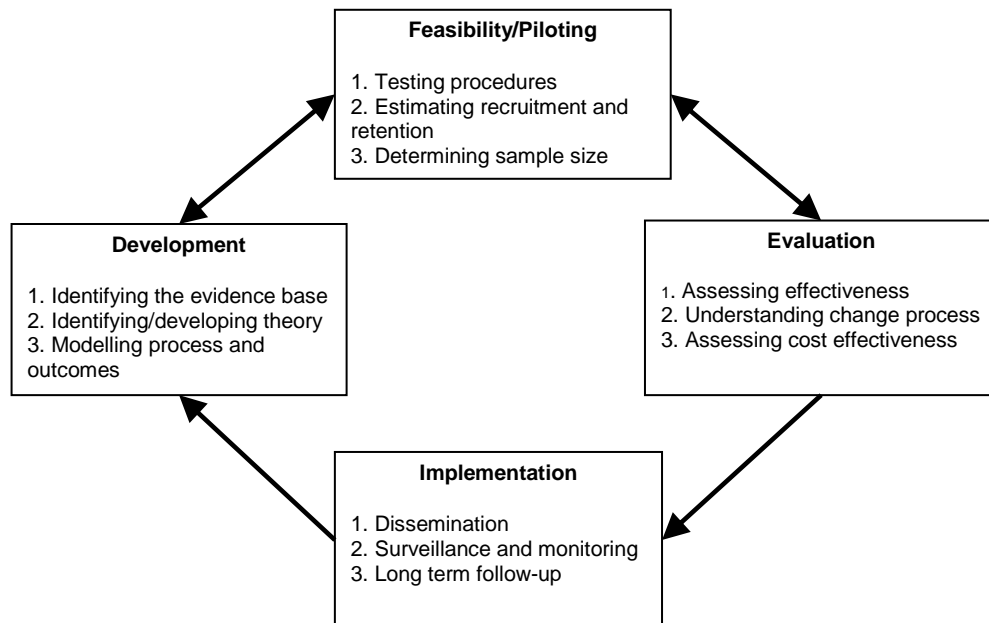
The complex nature of oropharyngeal dysphagia (discussed previously in chapter two) and COPD (discussed previously in chapter one) complies with the definition of a complex intervention within this framework. Additionally, the study intends to improve patient care using triangulation methodology and evidence based practice to assess three inter-dependent components in order to define potential 'active ingredients' (patient perception, respiratory-swallow pattern and biomechanical swallow); further satisfying criteria stated within the framework.

A review of the MRC framework was published in 2010, containing two important changes pertinent to this study. Firstly, the revised framework recognised the importance and inclusion of varied methodologies; such as cross sectional studies, rather than focusing exclusively on a clinical trials template; such as randomised controlled trials. Secondly, the framework provided a less linear model to the research process; as shown in figure 3,



thereby further highlighting the importance of the development and feasibility stages in the research process.

**Figure 3: Framework for development and evaluation of complex interventions (Medical Research Council, 2010).**



## **4.3 Development**

### **4.3.1 Identifying the evidence base**

The first stage of the study detailed in this thesis was to explore relevant theory, and establish a benchmark to inform the aim of the research. This stage aims to establish the extent of the evidence base; highlight strategic design issues and confounding factors that may arise. Previous studies investigating the normal swallowing and respiration processes were utilised as a benchmark to explore deviations due to disease or disorder, types of methodology and the design employed, and use of valid tools for measuring specified outcomes. The literature review also served to highlight the paucity of research and many aspects of the association with oropharyngeal

dysphagia and COPD still requiring investigation. Results from the literature search were documented in chapters two and three. The review concluded a lack of evidence published within the literature which explores the association between oropharyngeal dysphagia by phase of COPD. Furthermore, there do not appear to be studies which concurrently measure respiratory-swallow pattern and biomechanical swallow alongside patient perception of swallowing ability and quality of life by phase of COPD; internationally or within the U.K., as presented in this study.

#### **4.3.2 Identifying/developing theory**

A novel and innovative theory was developed from identifying gaps in the evidence base during the first stage of the research process. The revised MRC framework states:

*'A vitally important early task is to develop a theoretical understanding ..... by drawing on existing evidence and theory, supplemented if necessary by new primary research.... There may be lots of competing or partly overlapping theories and finding the most appropriate ones will require expertise in the relevant disciplines' (2010, pg 8).*

The MRC framework (2000) also suggests complex interventions are 'marked by a paucity in high quality literature', and is likely 'original research will have to be undertaken in the early phases'. Conclusions drawn from the literature review; in combination with clinical expertise and patient observation, led to my opinion that the evidence in this specialist field needed to be supplemented by further original research. An extensive theoretical stage was deemed essential within this study, as the evidence

does not provide a clear understanding of the 'mechanisms of action'; resulting in assessment of oropharyngeal dysphagia not routinely instigated for patients with COPD. Thus, an exploratory 'proof of principle' study was warranted to investigate the prevalence of oropharyngeal dysphagia in a COPD population, and identify the key components causing this association to occur.

### **4.3.3 Modelling process and outcomes**

Modelling phase describes the standardisation of the research delivery by delineating the key components to the study, and defining how they relate to and impact on each other. This stage is crucial in order to develop a reproducible protocol that can relate overall aims of the study to the results. In this study, this was achieved by using an evidence base practice model and triangulation methodology, which are now discussed.

#### **4.3.3i) Evidence Based Practice Model**

Research methodology employed in this thesis complies with the Evidence Based Practice model as outlined by Sackett and Rosenberg et al (1996). This model integrates best available evidence presented in the literature, with clinical expertise, and patient values and preferences as shown in figure 4.

**Figure 4: Evidence Based Practice Model (Roddam and Skeat, 2010).**



This study has incorporated all three fields within the design of this study:

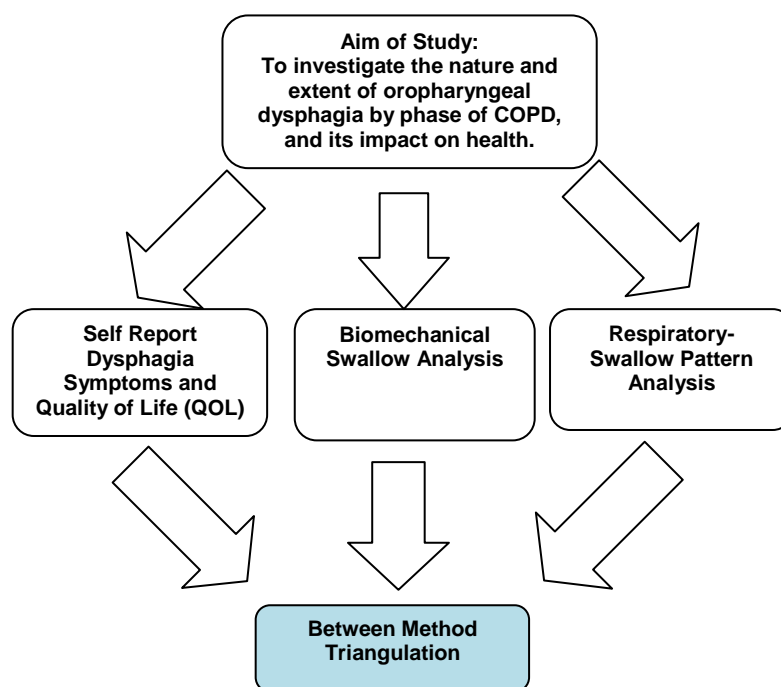
- **Best Available Evidence** – Current policies and guidelines in assessment of oropharyngeal dysphagia in COPD have been reviewed for relevance to oropharyngeal dysphagia and documented in chapter one. Pre-clinical theory chapters reviewed the literature of what has been established in this field, and what requiring further research.
- **Patient Experience** - This study incorporates the patients' perceptions of their swallowing skills and any changes in quality of life due to swallowing impairment. Feasibility testing of the questionnaire, as discussed in section 4.4 included a qualitative analysis of patient views regarding suitability of the questionnaire, and was used to inform the 'Evaluation' stage.
- **Clinical Expertise** – I have extensive experience in oropharyngeal dysphagia assessment, including videofluoroscopy assessment. Other specialist professionals were recruited for advice particularly on

respiratory and radiology, and other areas relevant to the study aim and methodology chosen. Together this clinical expertise added to the development of the methodology.

#### **4.3.3ii)      *Triangulation Model***

Triangulation methodology is the use of two or more methods to investigate a research question. One type of triangulation, as described by Denzin (1978) is 'between-method' triangulation. This involves utilizing contrasting research methods to enhance confidence in results and test the degree of external validity. In this study, between-method triangulation was employed to address the main aim of this study, which was to identify the nature and extent of oropharyngeal dysphagia by phase of COPD using three previously validated and contrasting methods, as shown in figure 5. Exploring oropharyngeal dysphagia from differing perspectives increases the richness and complexity of the research.

Figure 5: Between-Method Triangulation Model.



The three key components identified from the theoretical stage as potential 'active ingredients' for triangulation were;

- patient's perspective of dysphagia symptoms and impact on quality of life.
- assessment of the biomechanical swallow
- respiratory-swallow pattern

Suitable measures were required to assess the key components. Possible tools were highlighted in the literature, and reviewed for their validity, reliability, and suitability to answer the study's aim and objectives. The MRC framework (2010) states '*best available methods should still be used to yield useful results*' (p 8), therefore justification for the tools chosen for this methodology is now discussed.

#### **4.3.3iii) Justification for Self report Quality of Life (QOL) and dysphagia symptom tool**

In order to generate an outcome measure to explore perception of swallowing skills and quality of life in COPD, the use of pre-validated tools was investigated. Health related quality of life questionnaires (HRQOL), and disease specific questionnaires are most commonly used by the medical profession to gain an insight into the service user's perception of their difficulties. Generic HRQOL are applicable to different diseases and therefore able to measure changes between disease states. The most frequently used HRQOL questionnaires in COPD are the Medical Outcome Study, Short Form 36 (MOS-SF36) (Mahler & Mackowiak, 1995; Wyrwich, Tierney, Babu, & Kroenke, et al., 2005; Nguyen, Donesky-Cuenco, & Carrieri-Kohlman, 2008); Sickness Impact Profile (SIP) (Bergner, Bobbit, Carter, & Gilson, 1981); Nottingham Health Profile (NHP) (van Schayck, Dompeling, Rutten, & Folgering, et al., 1995; Ramirez- Velez, 2007); and Quality Well Being (QWB) (Kaplan, Atkins, & Timms, 1984). Disease specific questionnaires focusing on respiratory disease have also been developed, with the most frequently used tools being Chronic Respiratory Disease Questionnaire (CRDQ) (Nguyen, Donesky-Cuenco, & Carrieri-Kohlman, 2008); St. George Respiratory Questionnaire (SGRQ) (Sant'Anna, Stelmach, Feltrin, & Filho, et al., 2003); and The Quality of Life for Respiratory Illness Questionnaire (QLRIQ) (Maille, Koning, & Kaptein, 1994). Although there are numerous HRQOL and disease specific questionnaires valid to investigate quality of life in COPD population, the questions are too general for the purposes of this study. Generic HRQOL and disease specific (COPD) tools

provide general measures of holistic quality of life, or general functioning, and ask one to two questions about general nutrition status(Gupta & Kant, 2009). Furthermore, they do not explore specific swallowing difficulties in detail, or the impact any swallowing difficulties may have on quality of life. Thus a quality of life tool was required to analyse the *dysphagia specific* quality of life; that is, questions regarding the impact on quality of life as a result of swallowing.

There are two acknowledged oropharyngeal dysphagia disease specific quality of life tools published in the literature; the M.D. Anderson Dysphagia Inventory (MDADI) (Chen, Frankowski, Bishop-Leone, & Herbert, et al., 2001) and the Swallowing Quality of Life (SWAL-QOL) (McHorney, Robbins, Lomax, & Rosenbek, et al., 2002). Whilst both tools are affordable, non invasive, quick to administer and reportedly indicate any dysphagic symptoms before in depth formal assessment, there are two main differences which differentiate the tools in terms of suitability for the study detailed in this thesis. The MDADI was designed to assess swallowing related quality of life secondary to head and neck cancer, whilst the SWAL-QOL was developed using a general dysphagic population (including COPD subjects). Secondly, The SWAL-QOL contains more in depth questioning on quality of life as well as including symptom related domain; useful for the objectives set out within the study detailed in this thesis. Therefore the SWAL-QOL questionnaire was selected for use in this study as it was developed with a heterogeneous population; including COPD subjects. It also incorporates psychosocial sections seen in HRQOL tools and disease



specific QOL tools. Therefore the SWAL-QOL will now be discussed in detail, and its relevance to this study.

#### *Development of SWAL-QOL Tool*

The SWAL-QOL; or Swallowing Quality of Life is a disease specific (dysphagia) quality of life measure that integrates clinical dysphagia-specific physiological outcomes and psychosocial issues as perceived by the patient. It was published by McHorney and Robbins et al (2002) to be used as a research tool in clinical practice, and also to investigate effectiveness of intervention strategies. The tool was developed over three phases; focus groups with service users and carers; pretesting and item revision; and field testing to assess validity and reliability. For the purposes of this thesis, only the last phase will be discussed in detail.

The SWAL-QOL questionnaire is a 44 item self report questionnaire. The items are divided into ten quality of life sections ('Burden', 'Food Selection', 'Eating Duration', 'Eating Desire', 'Fear', 'Sleep', 'Communication', 'Mental Health', 'Fatigue', 'Social Functioning') and one pathophysiological section ('Symptoms'). Each item answer is in the form of a Likert scale which is equally weighted. In order to assess validity, relevant questions were compared to the Medical Outcomes Study (MOS).

Sampling included both historical and prospective design. Inclusion criteria was a diagnosis of oropharyngeal dysphagia as seen in videofluoroscopy, was in 'stable' dysphagia status according to the Speech and Language Pathologist and the service user, and was within three months of being assessed by videofluoroscopy. Dysphagia 'stability' was determined by a

'three item Diet Assessment Form' conducted by the Speech and Language Pathologist (food texture, liquid consistency and percentage of oral nutrition).

Exclusion criteria were no informed consent, non English speaking, inadequate reading or writing for the task, or had an active oesophageal dysphagia. A mail out/mail back technique was enrolled for people diagnosed with oropharyngeal dysphagia. There was a 70% return rate (n=386), with a majority of white male (approx 80%) of average age of 66 years (+/- 13 years). The majority of 'first diagnosis' was Head and Neck Cancer (28.2%), with COPD being 6% of sample. A healthy control group was recruited which consisted of 40 males and females with an average age of 72 years. The healthy control group completed only six sections; 'Food Selection', 'Eating Desire', 'Fear', 'Communication', 'Fatigue' and 'Sleep'. They were not given 'Mental Health', 'Social Functioning', 'Burden' or 'Eating Duration'; as the phrase 'swallowing problem' was part of the item stem which was deemed unsuitable for 'non-dysphagics' to answer.

Responses to the questionnaire from the normal and dysphagia group were analysed for validity and reliability. Reliability measures tested scale, test-retest and intraclass reliability. Cronbach  $\alpha$  coefficient to test internal consistency of scale reliability showed seven scales had an  $\alpha > 0.90$ . Only the 'Fear' section had an  $\alpha = 0.79$ , lower than the standard of  $\alpha > 0.80$  expected. Intraclass correlation was reported between 0.59- 0.91, with three sections under the standard of 0.75 expected. Validity measures tested convergent, Factor structure and clinical validity. Convergent validity was tested using scale to scale correlations ( $r = 0.19-0.74$ ) and against MOS scale ( $r = 0.50-0.56$ ). The 'Symptoms' section was analysed for internal consistency. 'Known

groups validity' was used for clinical validity to distinguish between groups (disease and healthy) and severity. Results from 'between groups' showed statistically significant differences ( $p < 0.01$ ) for all items.

#### *Use of SWAL-QOL in other studies*

The SWAL-QOL has been used in eight independent articles. Three articles validated the tool in a language other than English (Mandarin, French and Dutch) either in multiple disease states compared with the EuroQOL (Bogaart, 2009), or a specific disease state (Khaldoun, Woisard, & Verin, 2009) compared against UW-QOL (Lam and Lai, 2010). Four articles used the SWAL-QOL as an outcome measure to assess dysphagia related quality of life pre and post cancer related treatment/care (Genden, Okay, Stepp, & Rezaee, 2003; Roe, Leslie, & Drinnan, 2007; Banderira, Axevedo, Vartanian, & Nishimoto, et al., 2008; Greenblatt, Sippel, Levenson, & Frydman, et al., 2009). Lastly, McKinstry and Tranter et al (2009) used the SWAL-QOL to measure outcomes after dysphagia assessment and education within a Pulmonary Rehabilitation setting as discussed in chapter two.

The use of a disease specific QOL tool (rather than a generic QOL tool) increases the internal validity of the research. Although the SWAL-QOL is still in its infancy, it has evidence to support its validity and reliability to be used as a research tool for dysphagia specific assessment. As well as providing information on the perception of QOL for patients with COPD, the research within this thesis may also provide evidence for using the SWAL-QOL within a British COPD population.

The SWAL-QOL does not have a summary or total score at the end of the questionnaire. McHorney and Robbins et al (2002) noted interpretation problems used on other quality of life questionnaires and therefore scores are calculated at the end of each section. This also allows for the researcher/clinician to use sections as required. Multiple questions per section also increases validity and improves reliability to be used in small sample research projects.

#### *Use of SWAL-QOL in this study*

Minor modifications were made to the SWAL-QOL secondary to results from field testing the SWAL-QOL on a COPD population, as will be discussed later in section 4.4.

#### **4.3.3iv)      *Justification for Biomechanical swallow analysis tool***

'Bedside assessment' is the most common assessment used in outpatients and inpatients to assess swallowing difficulties. However bedside assessment has been reported to fail to identify up to 50% of pharyngeal stage dysphagia; even with the most experienced clinician (Splaingard, Hutchins, & Chaudhuri, 1988). Instrumental examination has been documented as providing more information than bedside evaluation (Langmore, 2003). For the purposes of this study, instrumental measures were required to record and simultaneously measure oral and pharyngeal swallow, alongside respiratory-swallow pattern analysis. Therefore bedside

assessment did not suit the requirements of this study. Instrumental assessments of the swallow found within the literature were the Swallow Provocation Test, SEMG, Fibreoptic Endoscopic Evaluation of Swallowing (FEES) and videofluoroscopy which are now discussed.

### *Swallowing Provocation Test (SPT)*

In a series of letters to the editors of differing journal articles and within a fully published study, Teramoto and colleagues describe an evaluation designed to detect aspiration at bedside for elderly patients (Teramoto, Matsuse, & Fukuchi, 1999; Teramoto & Fukuchi, 2000; Teramoto, Kume, & Ouchi, 2002; Teramoto, Yamamoto, Yamaguchi, & Ouchi, 2004; Teramoto, Ishii, Yamamoto, & Yamaguchi, et al., 2005). The Swallowing Provocation Test (SPT) and Simple SPT (S-SPT) were evaluated on stroke subjects and report having a high specificity and sensitivity rating (above 80%). Teramoto and Fukuchi (2000) and Terada and Muro et al (2010) are the only known studies that provide a detailed methodological design of performing the SPT. The procedure requires the subject to be supine whilst a small bolus is injected directly into the pharynx via a nasal catheter; either as two stages (SPT) as employed by Teramoto and Fukuchi (2000) and Terada and Muro et al (2010) (0.4ml and 2.0ml injections) or one stage (S-SPT) seen in Kobayashi and Kubo et al (2007) (bolus volume not reported) and Matsuda and Teramoto et al (2004) (1ml). The injection is timed to occur at end expiration with the subject blind to the timing of the bolus arrival. Whilst this ensures accurate bolus measurement entering the pharynx, it excludes the oral preparatory and oral stage as discussed in chapter two; increasing the

difficultly for the subject to successfully prepare the bolus before entering the pharynx (Langmore, Terpenning, Schok, & Chen, et al., 1998; Harding, 2002). The position of the catheter was not clearly detailed in any of the studies, however, positioning may result in the 'trigger' position also being missed out. Teramoto and Fukuchi et al (2000) reports that the injection is timed to correspond with end exhalation phase. However as discussed in chapter three, this places the subject at increased risk of aspiration as they would need to inhale immediately after the bolus was injected; increasing the potential for the bolus to be inhaled.

The research teams classified a normal swallow reflex response as 'less than three seconds'. It is widely acknowledged swallow initiation as almost instantaneous (Logemann, 1988), with a normal pharyngeal stage of approximately 750msec-1sec (Logemann, Kahrilas, Cheng, & Pauloski, et al., 1992; Love & Webb, 1996). Teramoto and Ishii et al highlight their misunderstandings of the nature of oropharyngeal dysphagia further in their letter to the editor in 2005. They define findings of gastro-oesophageal reflux as a pharyngeal swallowing disorder, quoting figures of oropharyngeal dysphagia which also include incidence of gastro- oesophageal reflux; thus making it difficult to draw conclusions on swallowing difficulties exclusively due to true oropharyngeal dysphagia.

In my opinion, and those expressed as responses to Teramoto and Kume et al's 2002 letter to the editor (Mokhlesi, 2002; Morice, 2005), the use of The Swallow Provocation Test to detect aspiration, and the evidence which supports it should be viewed with caution. Furthermore, it is acknowledged

that visual analysis of the swallow provides the most valid method of assessing aspiration (Langmore, Terpenning, Schork, & Chen, et al., 1998).

### *Surface Electromyography (SEMG)*

Surface electromyography (SEMG) uses basic electrodes attached to the surface of the skin to identify muscle activity. When placed submentally, the electrodes show activation of the anterior belly of the digastric, mylohyoid and geniohyoid muscles; with electrodes placed above the thyroid cartilage showing activity from the thyrohyoid muscles (Reimers-Neils, Logemann, & Larson, 1994). SEMG then gauges the vertical excursion of the submental and infrahyoid muscles to indicate a swallow has occurred. In a study of five healthy adults using this technique, Reimers-Neils and Logemann et al (1994) found submental muscle activity initiated 85% of swallows observed; whilst infrahyoid muscle activity terminated 72% of swallows.

This technique has been acknowledged to be a potentially useful adjunct to traditional bedside evaluations (Gupta, Reddy, & Canilang, 1996). It is cost effective, less invasive and easier to administer at bedside. However SEMG assessment excludes the oral preparatory and oral stages of the swallow, and is difficult to differentiate between true swallow activity and mastication movements or laryngeal bobbing. Furthermore, the assessor must assume pharyngeal dysfunction without visual confirmation; and unable to comment on the physiology of the nature of the dysphagia (Martin-Harris, Brodsky, Price, & Michel, et al., 2003). As with SPT discussed earlier, the study in this thesis requires objective measures to visually confirm the oral and pharyngeal stage of the swallow and the nature of the respiratory-swallow

pattern. Therefore SPT and SEMG were discounted as potential methodologies for this study.

### *Fibreoptic Endoscopic Evaluation of Swallow (FEES)*

Fibreoptic endoscopic evaluation of swallow (FEES) uses a nasendoscope to view the nasopharyngeal and laryngeal anatomical structures (Langmore, 2003). It shows the anatomy and swallow events pre and post the pharyngeal stage, however it is unable to assess the oral stage of the swallow, and creates a 'white out' phase during swallow apnoea; thereby not visualising function *during* the swallow (Logemann, Rademaker, Pauloski, & Ohmae, et al., 1998). This technique is considered a valid tool for assessing saliva management, and detecting any penetration and aspiration of a bolus or pharyngeal residue; with the latter reported as greater severity during FEES when compared with videofluoroscopic assessment (Kelly, Leslie, Beale, Payten, & Drinnan, 2006). The FEES equipment is portable and able to be conducted at bedside, and should include a multidisciplinary team. This includes a Speech and Language Therapist competent in conducting the evaluation (Kelly, Hydes, McLaughlin, & Wallace, 2007). As discussed in the previous sections, the research objectives of the study detailed in this thesis require visual assessment of the oral and pharyngeal stages during the swallow simultaneously with respiratory-pattern assessment and recording to later analyse inhalation/exhalation patterns surrounding the swallow.

Additionally, FEES equipment was not available to the research team at the time of data collection, nor was any of the research team trained in using this



technique. Therefore FEES was considered unsuitable for the study in this thesis.

### *Videofluoroscopy*

Videofluoroscopy (VF) is currently the predominate method for assessing oropharyngeal dysphagia, and visualise and analyse swallows (Martin-Harris, Brodsky, Michel, & Ford, Walters, et al., 2005; Swigert, 2007; Frowen, Cotton, & Perry, 2008). Videofluoroscopy is conducted in the radiology suite, and provides visualisation of oral and pharyngeal stages of the swallow; identifying any underlying abnormality in the biomechanics of the swallow as well as visualising any penetration and/or aspiration of the bolus. It takes approximately 15 minutes, with an estimated total x-ray dose 1.22 mSv per session (Crawley, Savage, & Oakley, 2004). This is equivalent to approximately 14 months natural background radiation. The Health Protection Agency Radiation Protection Division describe a 'few year's natural background radiation' as 'Low Risk', with 1:10,000 to 1:1,000 lifetime additional risk of cancer (Health Protection Agency, accessed online 2006). Patients are unlikely to identify any health detriment from their participation in the study. The potential radiation detriment resulting from this study was therefore deemed appropriate for the purposes of the study detailed in this thesis.

The use of videofluoroscopy allows the professional (researcher or clinician) to assess the biomechanical swallow process. The disadvantage is that the radiology suite does not provide a 'natural environment'. For example, videofluoroscopy assesses each swallow in 'a moment in time' within the

confines of a radiological suite. Videofluoroscopy is able to provide information on the anatomical structures and physiology, but unable to identify any sensory changes. There is little research in exploring the impact that the technology has on changing the performance of the patient, or interfering with the overall process. For example the patient may not like the taste of a trial bolus and therefore alters the movement and duration of the oral stage. Additionally, there is little evidence on the degree of error of recordings. Furthermore, videofluoroscopes vary in age and clarity, but no known studies have explored the relationship between clarity of the image and missed penetration/aspiration.

Both FEES and VF aim to identify the nature of biomechanical dysphagia, however videofluoroscopy allows visualisation of the oral stage and pharyngeal stage physiology, and therefore was chosen as the 'best available' tool to assess the biomechanical swallow in this study, with its limitations being recognised.

#### **4.3.3v)        *Justification for Respiratory-Swallow Pattern analysis tool***

This study required unobtrusive measurements of the respiratory phase surrounding the swallow to investigate the impact of an altered respiratory-swallow pattern on swallowing ability during stable and exacerbation phases of COPD adults; concurrently with videofluoroscopy assessment. The two main techniques to assess respiration are via direct airflow (oral or nasal) or indirectly called respiratory effort, which measures lung inflation (chest wall or abdomen excursion). A review of techniques to record respiration during

swallowing found measuring the respiratory-swallow pattern by indirect methods alone inadequate due to artefactual movement in the readings. (Tarrant, Ellis, Flack, & Selley, 1997). This review concluded nasal airflow combined with chest excursion provides the most accurate readings for swallowing related research. Intranasal pressure measurement combined with plethysmography has been used in other respiratory-swallow pattern studies, as outlined in chapter three (Dozier, Harris, Brodsky, & Michel, et al., 2006; Kelly, Huckabee, Jones, & Carroll, 2007; Cvejic, Harding, Churchward, & Turton, et al., 2011). The nasal transducer measures exhalation by increased pressure due to flowing air, and inhalation by decreased pressure. Chest excursion is measured through two bands worn across the chest where combined signals give measures of tidal volume. The use of both nasal and chest plethysmography decreases the possibility of lost data due to mouth breathing, and also corroborates the direct and indirect measures. The equipment recording the respiration phase data needed to be portable, compact and non invasive for the subject and to the radiology equipment. The Limited Polysomnogram (LPSG) was selected as it is non invasive and portable. For the purposes of this study, the LPSG was used to record respiratory traces before, during and after each swallow. The event marker on the LPSG was used to ensure the LPSG and videofluoroscopy were synchronised when recording the onset of the oral and pharyngeal stage of the swallow; for later analysis.

Whilst the LPSG is acknowledged as 'gold standard' practice in the assessment of sleep apnoea, there are no known publications documenting the LPSG machine to be used concurrently with videofluoroscopy. However

the principles of what it measures have been widely measured in combination with swallow in patients with COPD (Shaker, Ren, Townsend, & Dodds, et al., 1992; Gross, Atwood, Ross, & Olszewski, et al., 2009; Gross, Atwood Jnr, Grayhack, & Shaiman, 2003; Cvejic, Harding, Churchward, & Turton, et al., 2011).

#### **4.4 Feasibility and Piloting**

Feasibility and piloting was originally part of the modelling phase in the MRC (2000) framework, and was revised in 2010 to become a separate stage.

This stage includes preparatory work on areas such as testing procedures for their acceptability and validity; and may be paper based or qualitative testing, such as the use of preliminary surveys. Each of the key components are now discussed within this stage.

##### **4.4.1 Self report dysphagia symptoms and quality of life (QOL)**

Feasibility testing of the SWAL-QOL was conducted in order to evaluate the suitability of using the questionnaire on a British COPD population; not previously diagnosed with oropharyngeal dysphagia, as this does not appear to be previously researched; by the author of the SWAL-QOL, or within independent studies in the literature. Feasibility testing also allowed for a non intrusive prevalence estimate before embarking on the larger study; as sample size estimations were not available from the literature. Permission was gained from the author of the SWAL-QOL to use in this study (see Appendix 1).

#### **4.4.1i) Aims of Feasibility Testing**

1. To evaluate 'proof of principle' before combining with more in-depth study.
2. To test suitability of SWAL-QOL in a British COPD population, not previously diagnosed with oropharyngeal dysphagia

#### **4.4.1ii) Sample size**

Information was not available from the literature on the likely sample size required to estimate prevalence of swallowing difficulties in COPD. Therefore an estimate of expected proportion using a sample size of 35 was trialled (Julious, 2005), and this allowed an assumed prevalence of 10%. Initial sample size also allowed for a predicted return rate of questionnaires.

#### **4.4.1iii) Ethics and Clinical Governance**

Ethics and Clinical Governance approval was gained from the North Sheffield Research and Ethics Committee and Sheffield Research and Development in February 2005 (REC Reference number 05/Q2308/7) and April 2005 (STH Reference number STH13949) respectively (Appendix 2). As the population studied were not known to the researcher, ethics and clinical governance approval was granted on the stipulation I became involved only after written consent from participants was granted.

#### **4.4.1iv) Method**

Mail out/Mail in cross sectional study.

#### **4.4.1v) Recruitment**

Sheffield Teaching Hospital (STH) Information Technology Department randomly selected 200 names from the 1 389 patients who were discharged from STH with a diagnosis of COPD in 2004. Cross matching was deemed necessary to ensure accurate identification of potential participants before initial contact, thus a COPD Specialist Nurse cross matched names with the COPD Supported Early Discharge Scheme computerised database to confirm a diagnosis of COPD.

The respiratory consultants (in charge of the potential participant's care) agreed to approach their clients via letter, inviting them to participate in the research project. The respiratory consultant mailed a participant pack (Appendix 3) to each of the selected COPD candidates, which contained:

- A personalised letter signed by the respiratory consultant to invite the person to participate in a research project.
- A client information letter describing the research project and what participating will involve
- Self report questionnaire, the SWAL-QOL. Participants were encouraged to complete the comments section with the SWAL-QOL.
- Contact numbers attached if they need assistance with completing or sending the pack, or for requesting further information.

- A consent form to sign for the questionnaire; use of their professional notes and informing their GP
- A franked self-addressed envelope for returning the completed survey and consent form to the respiratory secretary.

A second posting of the participant packs occurred after 14 days if there was no response. On confirmation of returned questionnaires and written consent, medical notes and questionnaires were reviewed against the inclusion/exclusion criteria and for missing data.

Each returned pack was allocated a code and identifying information was removed and filed separately. The database of names was kept separate from the survey and consent forms, and filed in a lockable cabinet at the researcher's workplace. Identifying information was destroyed on completion of the field test.

#### **4.4.1vi)      *Inclusion/Exclusion criteria***

Inclusion criteria were a primary diagnosis of COPD, admitted to STH under a Respiratory Consultant in 2004, and known to the COPD Supported Early Discharge scheme.

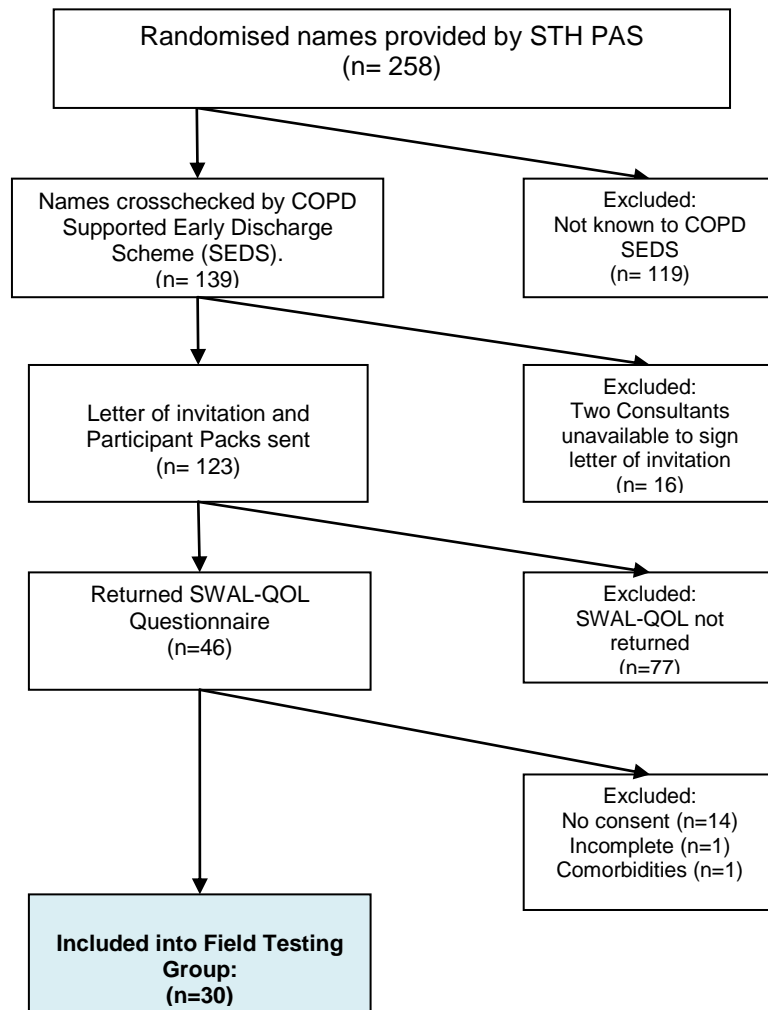
Exclusion criteria were co-morbidities known to cause oropharyngeal dysphagia (neurological or oncological), not known to the STH Respiratory Consultant or the COPD Supported Early Discharge Scheme, or failure to consent.

#### **4.4.1vii) Results**

Although 200 names were requested from the STH database, 299 names were supplied with 41 names being repeated. The COPD Supported Early Discharge Scheme Specialist Nurse matched 139 names that had accessed the Supported Early Discharge Scheme in 2004 and therefore had a confirmed diagnosis of COPD. Two respiratory consultants were unavailable to sign letters of invitation and send participant packs, resulting in 16 names being excluded. Participant packs were mailed to 123 people by seven respiratory consultants, with 46 (37%) surveys returned via the respiratory medicine secretary. From the returned surveys, 16 were excluded due to non consent (n=14), incomplete data (n=1) or co-morbidities (obtained from the medical notes) causing dysphagic symptoms (n=1). Information on the characteristics of the respondents was not available for all 30 participants included in the research group due to missing data in the questionnaire and medical notes. None of the research participants had a dysphagia assessment previously. Figure 6 shows a flowchart, illustrating the steps of the selection process and reasons for exclusion.



**Figure 6: Flowchart of selection of SWAL-QOL field test research group.**



### *Characteristics of Respondents*

Biographical information of respondents; as summarised in table 9, revealed a median age of 75 years (35-90 years), and 42% respondents were male. Median BMI (n=23) was 23.4 (14- 37). A BMI of 20 or less was found in 22% of the sample.

Of the COPD respondents classified into severity by their respiratory consultant (n=10), 40% were coded as mild and 60% coded as moderate COPD, with none of the respondents were classified as severe COPD.

Median hospital admissions due to chest related illness was one admission within the last six months (0-6 admissions).

Self imposed modification of food was reported by seven (24%) respondents, in which they excluded harder to eat textures such as fried foods, toast and boiled rice. All respondents continued with normal drinks, and did not self impose thicker drinks such as tomato juice, yoghurt drinks to aid safety of the swallow (see section 2.6).

**Table 9: Summary of biodemographics of field test research group.**

<b>Biographical Information</b>	<b>N</b>	<b>Descriptives</b>	<b>Range (min-max)</b>
Age (Median)	30	75 years	35 - 90
Gender Ratio Male:Female	30	13:17	
COPD Severity	10	40% Mild 60% Moderate	
Hospital Admissions in last 6 months (Median)	28	1.0	0 - 6
Description of current intake Food Drinks	30	24% self imposed modified diet 100% Normal fluids	
Body Mass Index (BMI) (Median) (normal range 20-25)	23	23.4	14.6- 37.1
Ethnic Origin	30	97% White British 3% Black Caribbean	
Marital Status	30	47% Married 10% Single 37% Widowed 6% Divorced	

#### **4.4.1viii) Analysis of SWAL-QOL**

Analysis of the SWAL-QOL was divided in order to answer the aims of the field test. Firstly, proof of principle was explored by analysing each section against normative data provided in the development of the questionnaire. Secondly, qualitative responses were gathered to further explore the suitability of using the SWAL-QOL within a British COPD population.

##### *Proof of Principle*

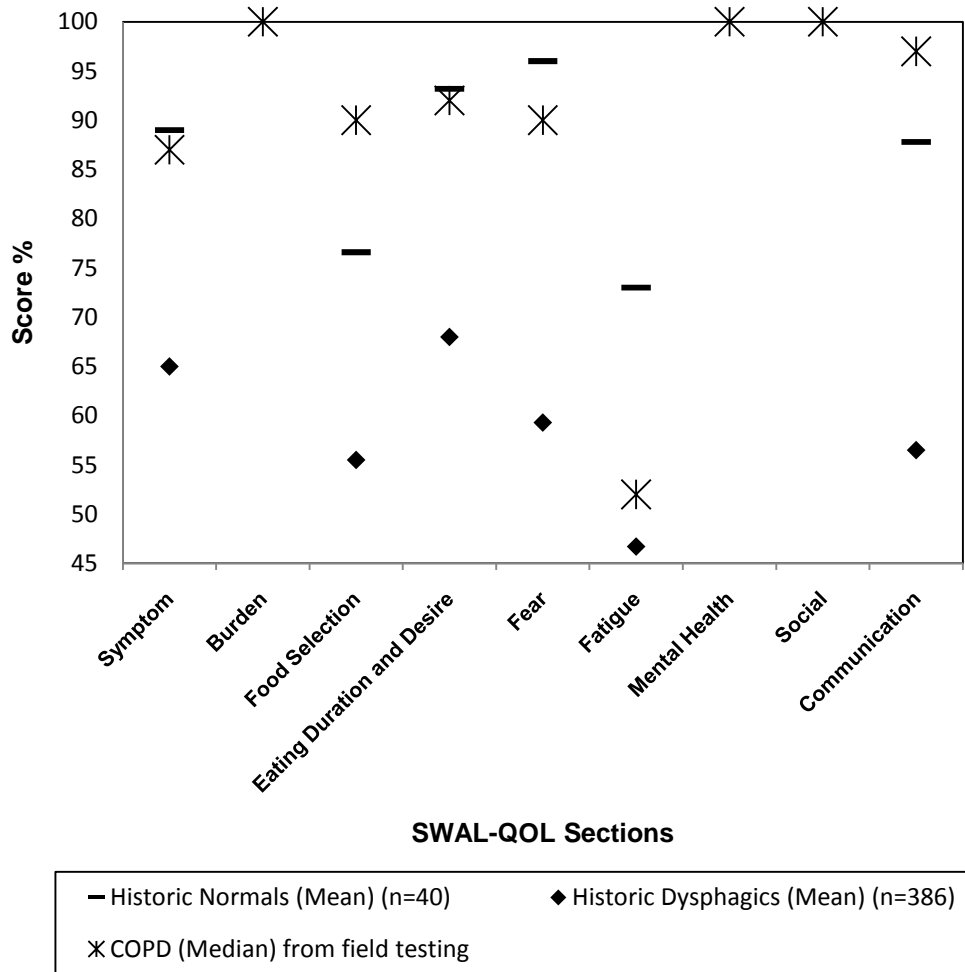
The first aim of the field test was to determine whether people with COPD perceive symptoms of dysphagia which negatively impacts on their quality of life. Descriptives of the 30 questionnaires included in the study are summarised in table 10.

**Table 10: Descriptives of COPD SWAL-QOL field test scores by domain**

<b>SWAL QOL Domain (Score range)</b>	<b>N</b>	<b>Median</b>	<b>Range (min-max)</b>
Symptom (14-70)	26	61	28-70
Burden (2-10)	30	10	2-10
Food Selection (2-10)	30	9	2-10
Eating Duration and Desire (5-25)	29	23	5-25
Fear (4-20)	29	18	7-20
Fatigue (5-25)	26	13	5-25
Mental Health (5-25)	30	25	7-25
Social (5-25)	28	25	5-25
Communication (2-10)	30	10	8-10

In order to investigate variation from a normal SWAL-QOL response and compare with answers from a dysphagic population, COPD results were compared with the reported historical normals and historical known dysphagics used for the development of the SWAL-QOL (McHorney, Robbins, Lomax, & Rosenbek, et al., 2002). This was achieved by converting each SWAL-QOL section Likert scale into a total scale score and then linearly converting into a percentage; as conducted in McHorney and Robbins et al's (2002) study and shown in figure 7. A score of 100% indicates no perceived difficulty, and the lower the score the more perceived difficulty. Not all of the historical data was reported; therefore the sections Burden, Mental Health and Social have no comparative data. All COPD data (except the domains Communication and Food Selection) fell between the historical normal and historical dysphagia data.

Figure 7: COPD SWAL-QOL field test domains compared with historical controls (McHorney and Robbins et al, 2002).



*Suitability*

The second aim of the feasibility test was to explore the suitability of using the SWAL-QOL within a British population, not previously diagnosed with dysphagia. Invitation letters included a general request to add any comments throughout the questionnaire, or in the space provided at the back. All of the 30 respondents included in the study made at least one comment about the study. Comments could be divided into two main themes; style of questioning and time taken to complete.

- Style of questioning:* The highest number of comments from included respondents (n=27) regarded the item stem. At the beginning of each section, the question asked '*how often.....as a result of your swallowing problem*'. Some respondents (n=17) wrote at the top of the questionnaire that they did not have a swallowing problem. Of these respondents, five discontinued scoring some sections. However this was contradicted later in the questionnaire within the additional comments section, where statements were written such as '*I don't have a swallowing problem but...*

  - '*I choke on my saliva....*' (n=7)
  - '*I can't eat hard foods*' (n=5)
  - '*I can't swallow dry foods....I chew and then.... spit them out*' (n=7)
  - '*I cough on drinks*' (n=11).
- Time taken to complete:* The second highest number of comments (n=22) pertained to length of the questionnaire. McHorney and Robbins et al (2002) suggested the questionnaire should take approximately 14 minutes to complete. Of the 22 comments, only one reported the time, stating it took 30 minutes to complete, whilst another reported '*being bored half way through*'.

Rather than reduce the number of questions in each domain; which would affect the validity of scale, whole domains were omitted that were deemed as either not addressing the aim and objectives of the study detailed in this thesis, or difficult for patients with COPD to answer. The Fatigue domain was

omitted from the final questionnaire, as eighteen subjects in field testing commented it was difficult to distinguish questions as a result of swallowing as opposed to their normal COPD symptoms. The Communication domain was also omitted, as this was not an aim for the study detailed in this thesis. This left six QOL domains and one symptom domain within the final questionnaire to be used in the study detailed in this thesis.

#### **4.4.1ix)      *Limitations of the field testing***

The most notable limitation of the field testing of the SWAL-QOL was the method of selecting the sample. Due to ethics and clinical governance stipulations, I was unable to access databases or medical notes before written consent from the participant was granted. Therefore I was required to access names via a Specialist COPD Nurse volunteering her time for the project, and a database that had confirmed diagnoses of COPD. The Supported Early Discharge Scheme used specific criteria for inclusion into the scheme which were; no medical complications, no radiological consolidation, and oxygen saturations greater than 90% on air. These criteria excluded clients who needed to stay in hospital for longer due to medical complications and severe pneumonia, and therefore would be classified as 'too unwell' for the scheme. By using this database, 119 names provided from the original STH database were excluded from this feasibility testing; which would have included the more severe COPD client group. Therefore the finding of the feasibility testing is likely to underestimate the prevalence of the burden of dysphagia in the hospital population of COPD patients overall.

The design of the research included personalised letters of invitation to the client by the known respiratory consultant, and franked, self addressed envelopes to enhance the response rate. However, the response rate still only achieved 37%. This was further reduced to 24% when questionnaires were excluded for non consent, missing data and co-morbidities. Low response rate may have been influenced by a number of factors. It may be due to general difficulties recruiting participants using a questionnaire, as patients who are unwell are less likely to participate. As this is an older population with mobility and respiratory difficulties, they may have had difficulties in completing or sending the survey. However the potential to assist the participants was hindered by the ethics stipulation of only becoming involved when signed consent was received via the respiratory department.

#### **4.4.1x)        *Conclusions of field testing***

The SWAL-QOL proved to be a useful tool to use for a British COPD population and produced coherent answers. Field Testing revealed 82% of respondents perceived some symptoms of oropharyngeal dysphagia, indicating further testing in this population was warranted.

Comments from the respondents led to two modifications to the SWAL-QOL. Firstly, as the sample population had not been previously diagnosed with dysphagia, the stem item question for each section was changed from '*how often.....as a result of your swallowing problem*', to '*as a result of your swallowing*'. Secondly, to reduce time spent on completing the questionnaire,



only sections considered relevant to the study were retained to use in the larger study.

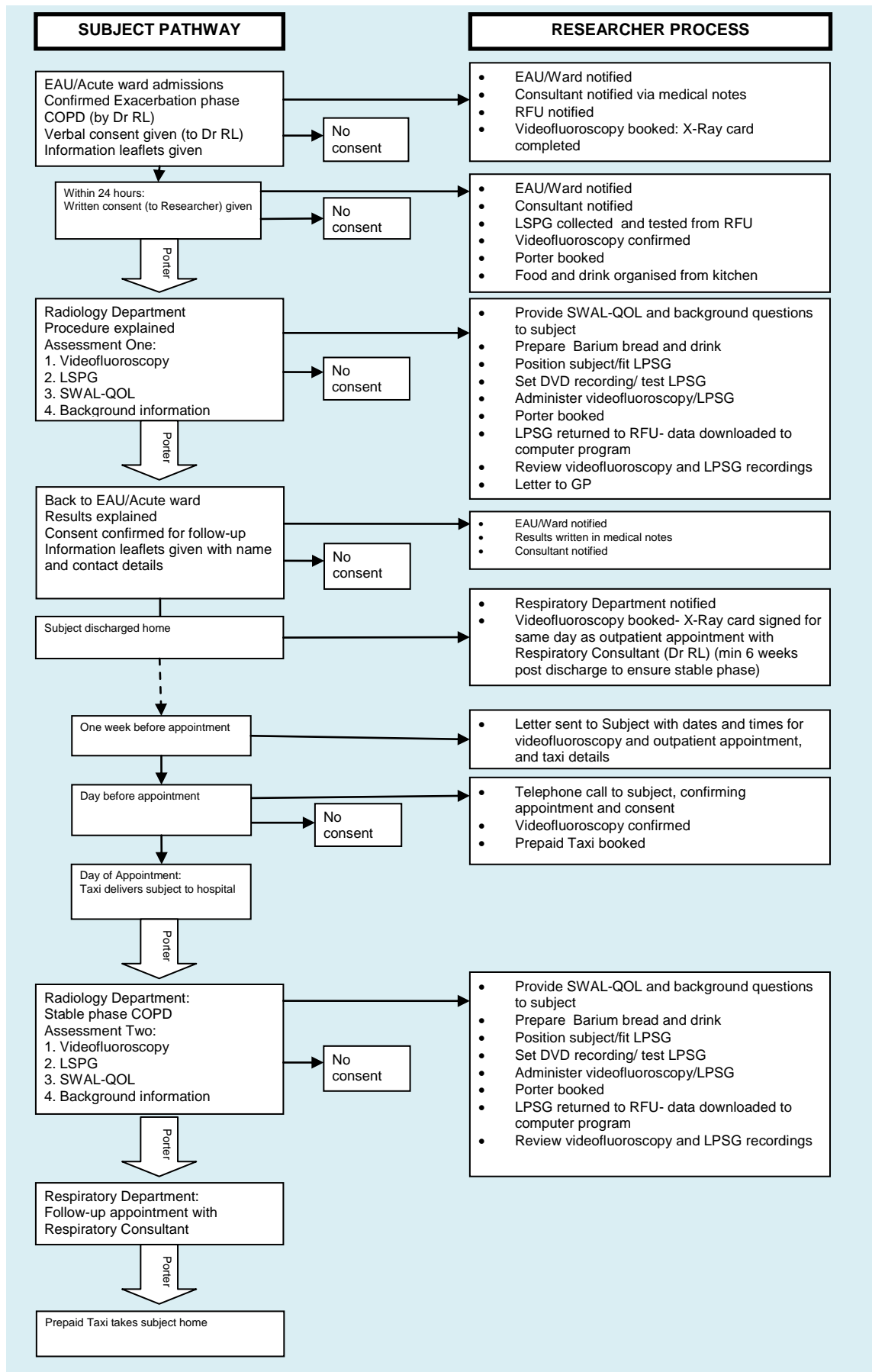
#### **4.4.2 Biomechanical swallow analysis**

The second key component requiring analysis is the biomechanical swallow. The Speech and Language Therapy Department in Sheffield Teaching Hospitals operates a weekly videofluoroscopy clinic to examine the biomechanics of swallowing in referred patients. Feasibility of using this as a tool for research purposes has already been established within the literature (discussed in chapters two and three) and in current clinical practice. I am one of the Speech and Language Therapists currently providing this service in the hospital, and therefore further feasibility testing for videofluoroscopy to be used as a tool for this study was not required. However, as the participants have not been referred for the service and are attending solely for the purposes of the research, feasibility testing was required to document patient flow through the research process, and issues such as cost implications and staffing issues as shown in figures 8 and 9.

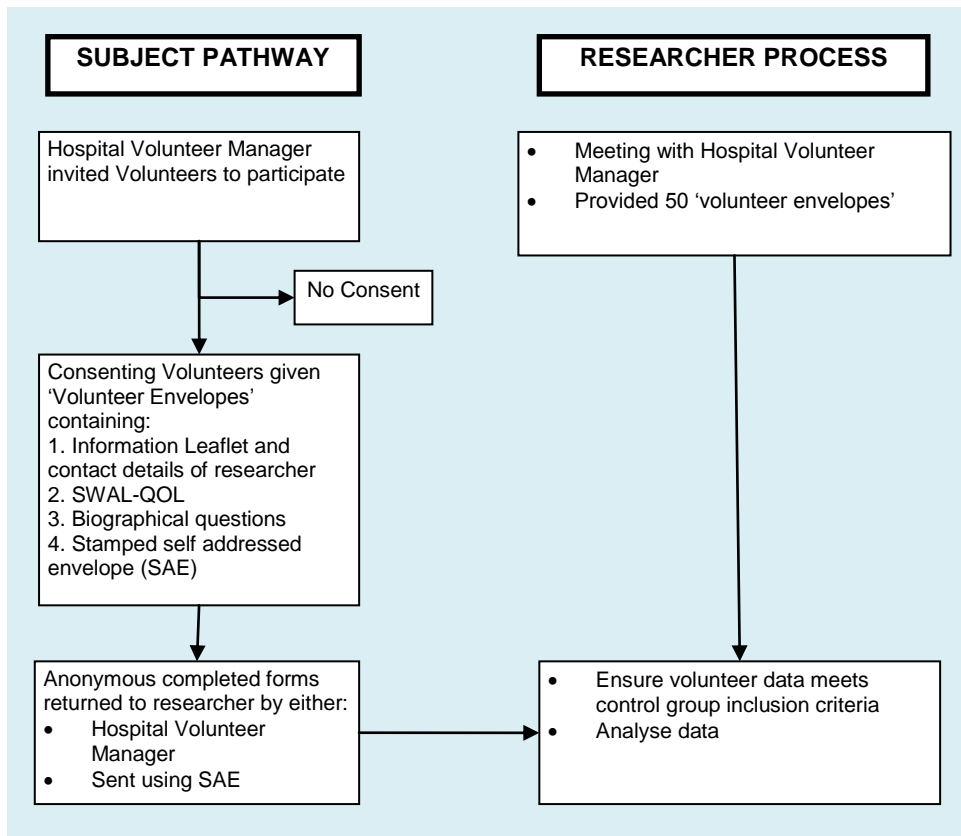
Agreement was granted from the STH Radiology and Speech and Language Therapy Departments to allocate two sessions per week for the sole purpose of this research. Each videofluoroscopy assessment was charged at £250 per session, paid with grants received (see Appendix 13). The subject's GP and relevant Staff at STH were consulted and agreed to the research pathway. Staff members consulted were from Speech and Language Therapy Department (such as Therapists, Assistants and Secretaries),

Emergency Admissions Unit (EAU) and acute wards (such as admitting Consultants, Nurses), Radiological Department (such as expert Radiographer, Receptionists and Nurses), Respiratory Outpatient Department (such as Respiratory Function Unit (RFU) Specialists, Nurses, Receptionists, Consultant), and other hospital staff (such as Porters, front desk Receptionists, taxi desk Receptionist, kitchen staff and the Hospital Volunteer Manager).

**Figure 8: Pathway for research subject and corresponding researcher process**



**Figure 9: Pathway for control subjects and corresponding researcher process.**



#### **4.4.3 Respiratory-Swallow Pattern analysis**

The final key component for feasibility and modelling was assessment and analysis of the respiratory-swallow pattern. The preparatory work required for this component consisted of testing the Limited Polysomnogram (LPSG) for its acceptability and validity within the design of the study detailed in this thesis. This was achieved by evaluating the accuracy of the respiratory traces on four volunteer staff members before ethics approval and recruitment phase of the study. These 'practise sessions' within the Respiratory Functions Unit at the Royal Hallamshire Hospital given by two respiratory physiologists also provided training on how to place the straps on the subject, ensuring battery checking and calibration occurs before starting

the assessment, pressing the event marker for each oral and pharyngeal stage of the swallow, and downloading the information from the hand held machine onto the computer programme for later analysis. Data from the resting respiration, saliva swallows and bolus swallows from the four volunteer staff members were then interpreted for clinical validity. The respiratory traces for twenty swallows were analysed; with the duration of each swallow's respiratory trace elongated to visualise when inhalation or exhalation occurred more easily. Each respiratory-swallow pattern showed a clear rise when inhalation occurred and decline for exhalation for the 'effort' of chest excursion (chest straps); and a clear decline when inhalation occurred and rise when exhalation occurred for airflow measures (nasal cannulae). These respiratory traces surrounding a clear swallow apnoea, represented as a plateau on the respiratory trace; showing no detected chest excursion or airflow. Event markers successfully indicated the initiation of either the oral or pharyngeal stage of the swallow, providing further confirmation of when the phase of the swallow occurred with reference to the respiratory trace. The LPSG was therefore deemed suitable for the purposes of the study detailed in this thesis.

## **4.5 Evaluation**

The revised MRC (2010) guidelines emphasize the importance of choosing the right study design to suit the aims and objectives of the research.

However it also stresses the importance of randomisation and clinical trials.

In the case of this research, a full- scale randomised study is unjustified as proof of principle evidence is still required, as shown previously in the theoretical stage. Chapter five details the methods undertaken to demonstrate the prevalence of key components within patients with COPD; with chapter six reporting the results and chapter seven discussing outcomes of the evaluation stage alongside other stages of the MRC framework.

### *Summary of use of MRC Framework in this thesis*

The revised MRC Framework for Development and Evaluation of Complex Interventions (2010) allows for a general model for the study detailed in this thesis to follow. Although the framework tends to focus on randomised controlled clinical trials, it has recently highlighted the importance of proof of principle studies requiring alternative study designs. This research thesis focuses the development, feasibility and evaluation stages to gain evidence to support the aim of the study.

The limited research exploring dysphagia in COPD has been documented between grades B and D (discussed in section 2.8.1) (O'Kane & Groher, 2009). Identification of the nature of a disorder within a disease (such as oropharyngeal dysphagia with COPD) has been shown more appropriately

with cross sectional study methodology (Sackett, Rosenberg, Gray, & Haynes, et al., 1996).

#### **4.6 Ethical considerations**

Assessing the same research subject during the stable and exacerbation phase reduced confounding variables to determine the effect of different phases of the disease. The study detailed in this thesis would have benefited from using a case control research design; including controls for each objective as seen in Cvejic and Harding et al (2011). However ethical stipulations for the study in this thesis required the control group to complete only objective one of the study (SWAL-QOL).

Interventions were not withheld for this study, as, generally speaking, COPD patients are not recognised as being at risk of aspiration and hence not assessed. It is more likely therefore that participation in the study will increase recognition of problems and lead to additional treatment rather than the converse. One purpose of this study was to obtain true prevalence, therefore raising awareness and providing appropriate referral criteria.

## **4.7 Limitations**

The study detailed in this thesis was limited by the ability of the subject to be adequately mobile to attend the videofluoroscopy clinic session. If subjects were deemed medically too unwell to be able to attend videofluoroscopy, this automatically excluded the severe end of the COPD population. Follow-up during the stable phase was reduced due to subjects not reaching a 'stable' state of their disease during the data collection period of time. Four participants required multiple hospitalisations during this time and were considered too unwell to continue, and are discussed in more detail in chapter seven.

Recruitment was required to be within 48 hours before the allocated videofluoroscopy timeslots to ensure maximum exacerbative phase assessment. Although this arrangement was reviewed, it reduced potential recruitment to fall within two days per week; and within the hospital containing the videofluoroscopy unit. Whilst potentially limiting total recruitment this strategy allows maximum sensitivity for the detection of differences between exacerbation and stable phases of COPD.



#### **4.8 Summary of chapter**

The three key components identified as active ingredients in this study; patient perception of swallowing impairment and swallowing related quality of life, biomechanical swallow and respiratory-swallow pattern, have been discussed within the stages of the MRC framework. Although the content of the study is new and innovative, the measures justified in this chapter to be used for obtaining the research aim and objectives have long been acknowledged as suitable means for research; with videofluoroscopy considered to be a 'gold standard' technique. Measures were considered 'best available that would yield useful results' (Medical Research Council, 2010).

# **Chapter Five**

## **Methods**

## **Chapter Five: Methods**

### **5.1 Introduction**

The 'Evaluation stage' of the MRC Framework; as discussed in chapter five, describes choosing a research design to suit the research question. This chapter details the relevant methods employed to explore the objectives of this study.

### **5.2 Ethics and Clinical Governance**

Ethical approval was gained from the North Sheffield Local Research Ethics Committee (REC Reference number 07/Q2308/32), and Sheffield Teaching Hospitals NHS Foundation Trust Research and Development Department (Reference Number STH14598) in May 2007 (Appendix 4).

The application to the Ethics Committee originally included identical assessments for the normal healthy control group and the research group. However the Ethics Committee did not approve inclusion of the normal healthy control subjects in the videofluoroscopy and respiratory analysis for this study, but allowed them to complete the questionnaire. The Ethics Committee further stipulated that I was required to recruit normal healthy controls indirectly. As the control group was intended to be recruited from hospital volunteers, their line manager agreed to provide the invitation letter and participation pack once consented. As potential research subjects were also not known to Speech and Language Therapy prior to the study, the Ethics Committee also stipulated consent must be taken by the respiratory consultant before I approached the research subject with further information on the study.

### 5.3 Study Design

This study used a prospective, repeated measures observational design; with a cross sectional control stage. Table 11 summarises the key elements of the research design by study objective, including measures used within each objective.

**Table 11: Study design by research objective.**

Objective	Objective 1	Objective 2	Objective 3
Measure	SWAL-QOL(ab)	Videofluoroscopy + SWAL-QOL(ab) Symptom section	LPSG + Videofluoroscopy
<b>Normal Healthy Control Group</b>	√	X	X
<b>COPD</b>	<b>Exacerbation Phase</b>	√	√
	<b>Stable Phase</b>	√	√

SWAL-QOL(ab)= abridged version of SWAL-QOL

### 5.4 Sample Size

There was no previously published research at the time of protocol development to base a power calculation to estimate sample size in order to gain statistical significance. Feasibility testing discussed in chapter four revealed 82% (n=30) of COPD subjects perceived some level of dysphagic symptoms. Therefore the sample size determined for this study of 12 per group was justified on feasibility and precision around the estimates (Julious, 2005). It was judged that this should be sufficient to have reasonable

estimates of means and confidence intervals, and allow estimates to be used in future larger studies.

## **5.5 Recruitment and Consent**

### **5.5.1 Research Group**

Recruitment into the research group was conducted during admission to the Royal Hallamshire Hospital, Sheffield Teaching Hospitals (STH), Sheffield U.K., and presenting with acute exacerbation of COPD. Potential subjects were identified by a respiratory consultant (Dr R.L) in the Emergency Admissions Unit (EAU) or on the ward within 24 hours of admission. Once each subject met the inclusion criteria (detailed later) and consented for the study, I approached the subject and provided a detailed explanation of what the study involved. A letter of invitation and information leaflets were provided (see Appendix 5), and the potential subject was given time to read the leaflets and discuss with family. I returned within 24 hours to gain written consent and ensure they were medically appropriate for the assessment. Consent was gained at the start of the investigation for the entire assessment procedure; however confirmation of consent was gained before each videofluoroscopy. The subject remained under the active care of Dr R.L. throughout the study. Once consented, the subject's General Practitioner (GP) was notified of the subject's inclusion and details of the study; and requested the GP confirm the subject's suitability for videofluoroscopy, and provide current medication lists and number of antibiotic treatments within the last six months (see Appendix 6).

### **5.5.2 Control Group**

Volunteers from the Sheffield Teaching Hospital Volunteers organisation were invited to participate as part of the control group of this study. Due to Ethic Committee requirements, recruitment was conducted via the Volunteer Hospital Manager, and information packs (Appendix 7) were distributed during an unrelated social event. Potential subjects were asked to complete the questionnaire *‘if they did not have a past medical history of smoking, neurological condition, and/or head and neck surgery’*.

## **5.6 Inclusion Criteria**

Inclusion and exclusion criteria are discussed by research and control group. The research group is further divided by exacerbation and stable phase. Criteria used for this study is summarised in table 12.

### **5.6.1 Research Group**

General inclusion criteria for research group subjects were a confirmed primary diagnosis of COPD and under an STH Respiratory Consultant’s active care (Dr R.L.).

#### **5.6.1i) Exacerbation Phase**

Potential COPD subjects were included in the exacerbation phase of the study if their condition met with the general inclusion criteria as judged by Dr R. L., and had two out of three of:

- increased sputum,
- increased breathlessness and fever,
- required treatment with oral steroids and/or antibiotics following assessment in hospital.

### **5.6.1ii) Stable Phase**

COPD subjects were included in the stable phase of the study if their condition was deemed 'clinically stale'; that is no change in daily symptoms or medication use for six weeks. This was assessed by Dr R.L. before commencement of the second assessment phase of the study.

### **5.6.2 Control Group**

Subjects were included into the normal healthy control group if considered fit and healthy with no co-morbidities causing dysphagia. Consent was implicit with returning a completed SWAL-QOL questionnaire. At the time of handing out the questionnaires, they were asked to complete the questionnaire if *they did not have* a history of neurological conditions such as stroke or had a history of smoking. The questionnaire also included a section on background information with specific questions on past medical history and smoking status to ensure control subjects met the inclusion criteria (see Appendix 8).

## **5.7 Exclusion criteria**

### **5.7.1 Research Group**

Subjects were excluded if they were:

- non consenting
- cognitively impaired (acute or chronic)
- deemed to have a co-morbidity causing dysphagia (e.g. stroke, neurodegenerative conditions such as multiple sclerosis, motor neuron disease, Parkinson's disease), or previous head and neck cancers incorporating the oral cavity or pharynx.
- not known to Respiratory Consultant (Dr R.L.)
- unable to tolerate videofluoroscopy procedure

Subjects were also excluded during the study if their condition became immediately life threatening; required ventilatory support or supplemental oxygen that could not be adequately delivered by nasal cannulae.

### **5.7.2 Control Group**

Subjects were excluded if consent was not gained, questionnaires not returned, or if biographical information included co-morbidities that may cause dysphagia, a history of smoking, or they documented any relevant co-morbidity in the 'other' section in the biographical section.



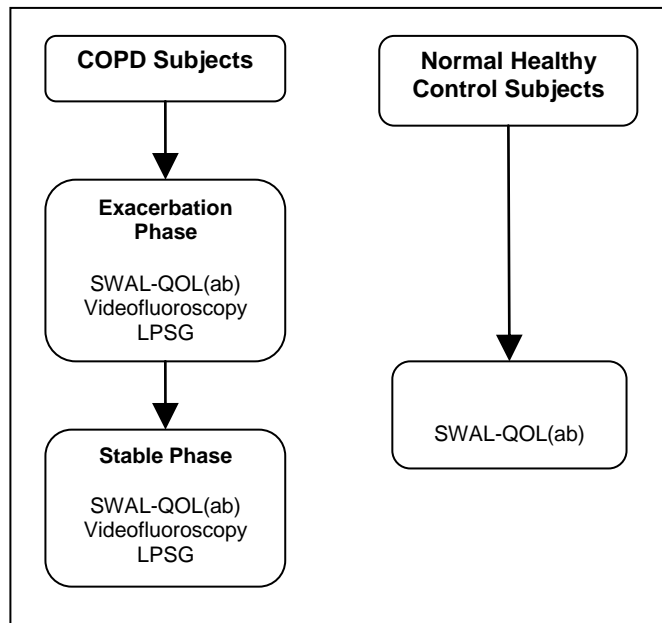
**Table 12: Summary of inclusion and exclusion criteria.**

	INCLUSION CRITERIA	EXCLUSION CRITERIA
<b>COPD Subjects</b>	<ul style="list-style-type: none"> <li>• Consent given</li> <li>• Confirmed diagnosis of COPD</li> <li>• Under care of Respiratory Consultant Dr R.L.</li> <li>• Meets Exacerbation/Stable criteria</li> </ul>	<ul style="list-style-type: none"> <li>• No consent</li> <li>• Decreased cognitive ability</li> <li>• Co-morbidities causing oropharyngeal dysphagia</li> <li>• Unable to tolerate Videofluoroscopy procedure</li> <li>• Deteriorated medical status</li> </ul>
<b>Normal Healthy Control Subjects</b>	<ul style="list-style-type: none"> <li>• Consent given</li> <li>• Considered fit and healthy</li> </ul>	<ul style="list-style-type: none"> <li>• No consent</li> <li>• Questionnaire not returned</li> <li>• History of smoking</li> <li>• Co-morbidities causing oropharyngeal dysphagia</li> </ul>

## 5.8 Assessment Procedure

This section details the assessments conducted for the research and control group and is summarised in figure 10.

**Figure 10: Subject flowchart through assessment procedure.**

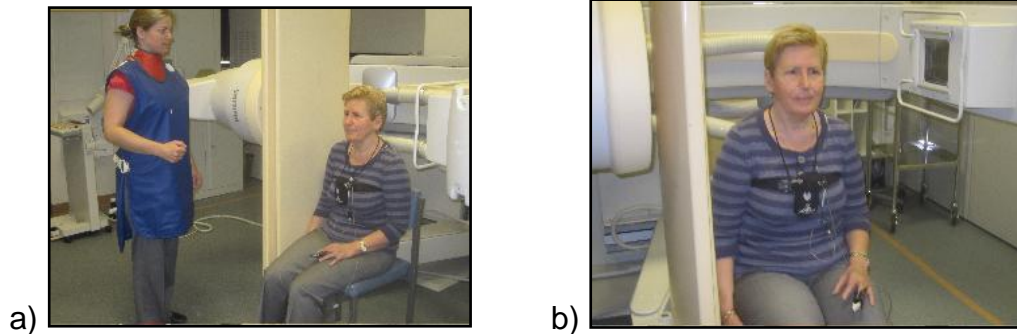


### **5.8.1 Research Group**

The assessment procedure for both the exacerbative and stable phase assessments was identical for the research group. During each session, subjects completed the abridged SWAL-QOL (Appendix 9). Severity of COPD was further described by level of dyspnoea via the Dyspnoea Visual Analogue Scale (VAS) and Modified Borg Scale (see Appendix 10) in the radiology waiting area before entering the videofluoroscopy suite. Once in the radiology suite, the Limited Polysomnogram (LPSG) was positioned; respiratory strap around the chest, above the subject's shirt/dress (for chest excursion) and nasal prongs (for respiratory flow)

The subject was positioned in a sitting position, lateral to the radiology cone. I stood alongside the volunteer (using a lead apron and thyroid shield) for reassurance, to pass the volunteer each trial bolus, and to press the event marker button to record each oral and pharyngeal stage on the LPSG output for later analysis (as discussed in section 4.4.3). Figure 11a) and b) show an example set up (not actual subject) in the radiology suite. In these photos, the LPSG machine is attached to the front of the chest excursion strap, however, during actual assessment, I held the LPSG machine in order to press the event marker button to coincide with oral and pharyngeal stages of the swallow on videofluoroscopy. The LPSG machine was calibrated before each session to ensure accurate readings, and the respiration traces were continuous throughout the videofluoroscopy period.

**Figure 11: Example set up of a) Speech therapist positioning and b) subject ready for videofluoroscopy and LPSG trial.**



Videofluoroscopy conformed to standard procedures as set out by Logemann (1993) and Ionising Radiation (Medical Exposure) Regulations (IRMER) (Department of Health, 2007). The radiological image was consistently set to include a lateral view of the subject's lips, tongue and alveolar ridge anteriorly; cervical spine posteriorly; nasopharynx and the upper one third of the trachea, to the level of C6-C7. E-Z-HD™ Barium Sulphate was used for all procedures and was mixed with water to form a liquid suspension, before adding to water for drink trials, or thick puree consistency to add on bread for solid trials. The videofluoroscopy started recording when the bolus reached the lips, and continued to observe any follow-up swallows. The image was recorded at 30 frames per second on a Maxwell DVD for later analysis. The recordings were labelled with subject identification numbers to ensure anonymity.

Each subject was required to swallow six 10 ml barium water units (three units before and after the bread trials), considered equivalent to the consistency of 'thin fluids', and three 1/8 barium coated white sliced bread units. Ten ml bolus size was chosen to discourage piecemeal deglutition (Perlman & He, 2006) and ensure wider upper oesophageal sphincter

opening (Logemann, Pauloski, Rademaker, & Kahrilas, 2002). The fluids were presented via a small medicine cup per bolus trial and 1/8 sliced white bread with barium coating per trial. Subjects were instructed to drink or eat normally when ready to reduce effects of command on the swallow (Daniels, Schroeder, DeGeorge, & Rosenbek, 2006).

Sessions occurred at the same time of day (midday) for each assessment to increase sensitivity of the results. This aimed to reduce any diurnal complications such as fatigue or changes in thirst or hunger. Subjects were seated during assessment, to relax and assess in a 'normal' posture for mealtime.

Each session lasted approximately 30 minutes to complete the SWAL-QOL<sub>(ab)</sub> questionnaire, videofluoroscopy and respiratory assessment. Biographical and medical history were documented from each subjects' medical notes. Current medication and number of antibiotic treatments were gathered from their General Practitioner.

### **5.8.2 Control Group**

The control group was recruited from the Sheffield Teaching Hospitals volunteer service by their Line Manager using the inclusion and exclusion criteria described previously. Each potential subject was given a pack which included a letter of invitation, information sheets on the study, SWAL-QOL<sub>(ab)</sub> questionnaire and a self addressed envelope. Completed SWAL-QOL<sub>(ab)</sub> questionnaires were returned anonymously through internal hospital post, franked self addressed envelope or via the Volunteer Manager.

Due to Ethics Committee restrictions, the control group were not approached by anyone related to the study; nor underwent videofluoroscopic, respiratory or medical note investigations.

## **5.9 Data Collection**

### **5.9.1 Research Group**

Data was collected from three main sources to meet the aim and objectives for this study during exacerbation and stable phase of COPD from the research group:

- self report answers from abridged SWAL QOL questionnaire
- videofluoroscopy assessment for objective biomechanical analysis of swallow
- respiratory assessment (LPSG) for respiratory-swallow pattern analysis

General information to describe the research subjects' respiratory status ;dyspnoea visual analogue scale and Modified Borg scale was completed before each videofluoroscopy assessment. All data was coded to ensure anonymity and destroyed once data analysis was completed.

### **5.9.2 Control Group**

Data was collected from answers from completed and returned SWAL-QOL<sub>(ab)</sub> questionnaires.

## **5.10 Data Analysis**

All data was analysed using descriptive and quantitative methods, using a statistical package (SPSS for Windows, version 14). The data was duplicated onto the package to highlight any inputting errors, to be corrected before analysis was initiated. I completed all of the analysis with supervision and advice provided by the University of Sheffield, School of Health and Related Research (SchARR) statistical support (Prof M.C. and Dr G.Y.).

As the data was not normally distributed, non parametric tested was used. Mann Whitney U Tests were used to investigate the difference between two independent data sets (Normal Healthy Controls versus Stable COPD), and Wilcoxon Signed Rank Tests were used to investigate two related sets of data (Stable versus Exacerbation COPD).

### **5.10.1 Swallowing related Quality of Life (QOL)**

Each SWAL-QOL<sub>(ab)</sub> total scale score was converted into a percentage, and compared between subjects; against normal healthy scores, and within subjects; by phase of COPD. The results in this section provided information for objective one of the study. Two important questions to be answered in this section are:

- Is there a perceived difference of dysphagia symptoms and swallowing related quality of life between 'normal healthy' and by phase of COPD?
- Is there a perceived difference of dysphagia symptoms and swallowing related quality of life between stable and exacerbation phases of COPD?

If normal healthy swallows differ from stable phase swallows, and stable phase swallows differ from exacerbation phase swallows, then logic leads to believe exacerbation phase swallows differ from normal healthy swallows.

### **5.10.2 Biomechanical Analysis**

Videofluoroscopy recordings scored for one primary event (overall dysphagia) and three secondary events (penetration, aspiration, spontaneous compensatory strategies), to meet objectives two and 2a of the study. Videofluoroscopies were scored using an analysis sheet, with penetration and aspiration also rated using Rosenbek and Robbins et al's (1996) scale (see Appendix 11). Videofluoroscopy data was scored dichotomously. Whilst it is acknowledged that this approach reduces the richness of data, information in this preliminary stage of investigation was required to be condensed for the purposes of addressing the main objectives set out in the study detailed in this thesis and provide information on prevalence. Thus, three important questions to be answered by this section are:

- Are people with COPD dysphagic, compared with normative data found within the literature?
- If so, what is the nature of the dysphagia?
- If so, is there a difference found between stable and exacerbation phases of COPD?

### **5.10.2i) Overall Dysphagic**

A swallow was considered *overall dysphagic* if either of the oral or pharyngeal stages were shown to be disordered on videofluoroscopy for food and/or drink. Types of dysphagic characteristics were documented in chapter two.

### **5.10.2ii) Penetration**

A swallow was scored as penetrated if a food or drink bolus entered the airway above or to the level of the vocal cords; before, during or after the swallow was initiated, as discussed in chapter two. Evidence of penetration was scored using the Rosenbek and Robbins et al (1996) penetration-aspiration scale; where a score of three to five (indicating increased depth and amount of penetrated bolus) would indicate a dysphagic characteristic as discussed previously in section 2.3.3.

### **5.10.2iii) Aspiration**

A swallow was scored as aspirated if a food or drink bolus entered the airway, and continued past the true vocal cords towards the lungs with or without the presence of a reflexive cough; before, during or after the swallow was initiated, as discussed in chapter two. This would score between six and eight using the Rosenbek and Robbins et al (1996) penetration- aspiration scale, and either score would be considered dysphagic as discussed previously in section 2.4.3.



#### **5.10.2iv) Spontaneous Compensatory Strategies**

The swallow was coded as using spontaneous compensatory strategies if the swallow physiology contained movements or postural changes; considered as additional or altered from the known normal swallow physiology. A swallow was coded as using a spontaneous compensatory strategy if:

- more than three swallows was used to clear a 10ml water bolus or 1/8 slice of bread from the oral cavity
- Chin tuck during the swallow
- Head tilt to either side to aid flow of bolus in oral cavity
- Head turn to either side to direct bolus flow towards opposite side of pharynx
- Early laryngeal elevation and closure, before initiation of pharyngeal stage
- Extended breath holding pre or post swallow
- Multiple swallows during breath hold

#### **5.10.3 Respiration-Swallow Pattern Analysis**

Respiratory-Swallow patterns were recorded simultaneously with videofluoroscopy using a Limited Polysomnogram (LPSG). Recordings were later transferred to the Respiratory Functions Unit computer, coded using identification numbers, and analysed using the Stardust program. Relevant data was then transferred onto SPSS and analysed to meet objectives three of the study. Two important questions answered in section are:

- What is the most common respiratory-swallow pattern used in COPD?
- Does the respiratory-swallow pattern alter during exacerbative phase COPD?
- Is there a difference between food and drink swallows?

### **5.10.3i) Swallow Apnoea**

Swallow apnoea duration was measured by the length in time of zero effort in chest excursion, and zero flow from nasal cannulae LPSG readings during the swallow.

### **5.10.3ii) Respiration-Swallow Pattern**

The LPSG recorded resting respiration, and changes in respiration before, during and after the swallow. Airflow was measured by identifying the direction of the respiratory/effort traces before and after each swallow apnoea as discussed in section 4.4.3. The event markers recorded on the readings delineated the onset of the oral and pharyngeal stage of each swallow, allowing analysis of respiratory status and oxygen saturation before, during and after the swallow, and recorded on a respiratory phase scoring sheet (see Appendix 12). This allowed for cross checking videofluoroscopy and respiratory data to ensure accurate timing of readings.

### **5.10.4 Correlational data analysis**

Data from the primary event 'Overall Dysphagic' from biomechanical analysis was compared to the SWAL-QOL<sub>(ab)</sub> symptom section and inhalation post swallow respiratory-swallow pattern to meet objectives 2b and 3a respectively. Two important questions answered in these sections are:

- Are perceptions of swallow symptoms more likely occur with biomechanical objective ratings of 'overall dysphagic'?
- Are 'overall dysphagic' characteristics more likely to occur as a result of using inhalation post swallow?

## **5.11 Reliability**

### **5.11.1 SWAL-QOL<sub>(ab)</sub>**

Scores for the SWAL-QOL<sub>(ab)</sub> were inputted twice into the SPSS package to highlight any inputting errors, which were corrected before statistical analysis was carried out.

### **5.11.2 Biomechanical analysis**

All of the videofluoroscopy data was analysed by the researcher (SLT 1). Five videofluoroscopy recordings were viewed by three independent experienced Speech and Language Therapists (SLT 2- 4) with an average of five years experience; who were blinded to the study.

### **5.11.3 Respiratory-swallow pattern analysis**

Training was provided by two respiratory function unit physiologists (C.B. and A.P.) in using the LPSG machine, and downloading and interpreting data. The first ten swallows were analysed by me and the two physiologists, until 100% agreement was obtained. Thereafter, at least one of the physiologists reviewed a further 30% of swallows, ensuring 100% agreement with my analysis.

## **5.12 Analysis ‘Per Subject’ versus ‘Percentage of Swallows Per Subject’**

Videofluoroscopy and respiration-swallow pattern data was analysed *per subject*, and *by percentage of swallows per subject*. Reporting results *per subject* provided an estimate of prevalence within the research group;

however it reports only the majority of events, as only dysphagic events and respiratory-swallow patterns occurring 50% or more of the time are included by this technique. Therefore clinically relevant information from each subject who showed greater variability; resulting in dysphagic events or respiratory-swallow pattern occurring less than 49% of the time, was not being reported. This is overcome by recording *by percentage of swallows per subject*. This provides clinically relevant information on the variability utilised by each subject, and allows for more clinically significant information when investigating swallowing and respiratory-swallow pattern.

### **5.13 Summary**

The study detailed in this thesis used a prospective, repeated measures observational design; incorporating a cross sectional control phase.

Measures were analysed using descriptive and quantitative methods, suitable to meet the aim and objectives of the study. Findings from the study are reported in the next chapter.

# **Chapter Six**

## **Results**

## **Chapter Six: Results**

### **6.1 Introduction**

This chapter presents the results from the study detailed in this thesis.

General descriptives and demographical information of the sample population are provided initially, followed by further statistical analysis reported by study objective.

### **6.2 General Descriptives**

#### **6.2.1 Research pathway**

Recruitment for the study occurred between May 2007 and March 2008.

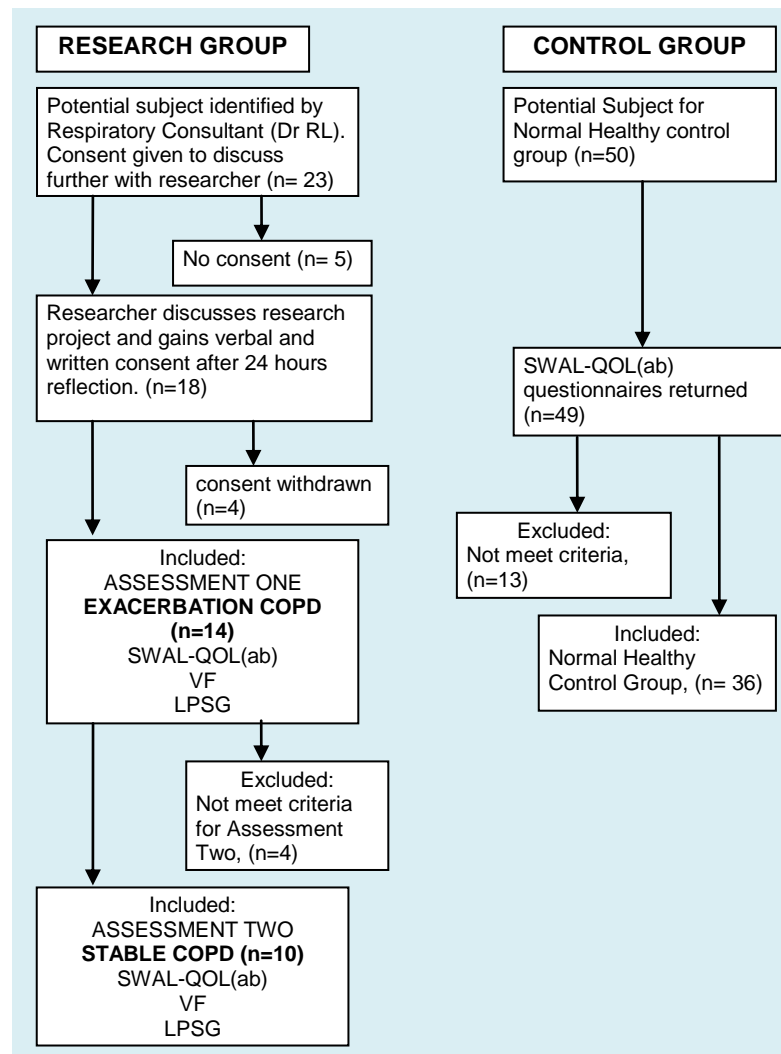
COPD subjects were considered as potential candidates for the study if they were admitted to the Royal Hallamshire Hospital (RHH), Sheffield on Wednesdays and Thursdays each week. This time period was used to ensure subjects were within 48 hours of exacerbation phase before videofluoroscopy assessment was conducted as allocated sessions were on Fridays. Allocated videofluoroscopy times were increased in September 2007 to include Thursday sessions, thereby allowing recruitment to extend to Tuesdays to Thursdays.

During the recruitment period, 4 764 people with COPD were discharged from any of the Sheffield Teaching Hospitals, with 1 165 people being discharged from The Royal Hallamshire Hospital (RHH). Of those who were discharged from RHH, 138 patients were coded as 'acute exacerbation of COPD', ranging between three and 13 discharges a month during the data collection phase. Of the 138 patients admitted to RHH presenting with an

acute exacerbation of known COPD, 39 patients were admitted into hospital within the allocated timeframe; with 23 potential subjects meeting the inclusion criteria. Of the 23 patients, five potential subjects did not consent at the first stage, and three agreed to discuss the research further, however did not consent to the research. Therefore fifteen subjects were initially consented; with one subject withdrawing consent midway through the exacerbation phase assessment and therefore was not included within the final analysis. Thus 14 subjects completed 'Assessment One' of the study, with ten subjects meeting the criteria to be followed up in stable phase to complete 'Assessment Two'.

Fifty participant packs were handed to Hospital Volunteers, and 49 (98%) were returned. Of those returned, 13 did not meet the inclusion criteria; therefore 36 normal healthy volunteers were included in the study as the control group. The flow diagram (figure 12) summarises the steps of the research pathway for COPD and normal control subjects recruited. Each step shows the number of subjects included (or excluded).

**Figure 12: Flow diagram of number of subjects considered at each stage of the research process.**



The SWAL-QOL<sub>(ab)</sub> questionnaire was given to normal subjects (control group) (n=50) by their manager (Sheffield Teaching Hospitals NHS Trust Volunteers Manager) and requested to return completed questionnaires anonymously via a stamped, self addressed envelope provided. A total of 49 questionnaires were returned, however 13 were excluded as they did not meet the inclusion criteria (Stroke n= 4, Smoker n= 8, Parkinson’s disease n= 1). Therefore a total of 36 questionnaires (10 males) for the normal healthy age match controls were analysed.



Once consent procedures were completed, COPD subjects (research group) were given the SWAL-QOL<sub>(ab)</sub> questionnaire to complete immediately before each videofluoroscopy assessment. The SWAL-QOL<sub>(ab)</sub> was either given to them to complete on their own, or help was given with reading/scribing if requested.

A total of fifteen COPD subjects were recruited during exacerbation phase. One subject consented to the study and completed the SWAL-QOL<sub>(ab)</sub> questionnaire during an exacerbative phase, however withdrew consent before completing videofluoroscopy and respiratory analysis. Therefore the completed SWAL-QOL<sub>(ab)</sub> was not included in the results. Four (4/14) of the COPD subjects were not considered medically stable within the allocated research period, therefore could not be followed up for the stable phase stage for the purposes of this study. Thus ten subjects (10/14) met the criteria to be followed up during a stable phase.

### **6.2.2 Demographics**

General biographical information as summarised in table13, show median ages for the normal control group approximates the median age of COPD subjects. Information was gathered from all recruited subjects unless otherwise stated; the sample size indicated in each box, or the diagonal line showing information for that event was not applicable.

Table 13 also details diagnostic information on COPD in subjects including severity of COPD, and median FEV<sub>1</sub>/FVC % ratio, dyspnoea visual analogue (VAS) (Wewers & Lowe, 1990) and the Modified Borg Scale (MBS) (Burdon,

Jumiper, Killian, Hargrave, & Campbell, 1982). Recruited COPD subjects were classified as moderate and severe for both phases of the condition. The four COPD subjects not included in stable phase data were classified as moderate (n=1) and severe (n=3). Taking FEV<sub>1</sub> and FEV<sub>1</sub>/FVC % ratings is not considered reliable during exacerbation phase (National Clinical Guideline Centre, 2010), therefore this was not included as part of the demographic information.

Information of the number of hospital admissions for each subject was taken from medical notes at the Royal Hallamshire Hospital before the exacerbation phase assessment. None of the subjects included in the follow-up stable phase assessment were admitted to hospital between assessments. The four COPD subjects not included in the stable phase data were admitted to hospital before exacerbation phase assessments between one and three times within the previous six months, and had multiple admissions between assessments (Md= 3).

The number of courses of antibiotics for chest related illness was provided either by self report for the normal control group, or by General Practitioner for the COPD group (n=9). Antibiotic use was documented for the six months previous to exacerbation phase assessment.

**Table 13: General biodemographic information of research subjects.**

	<b>Normal Healthy Control</b>	<b>Stable Phase COPD</b>	<b>Exacerbation Phase COPD</b>
Total number of subjects (Male: Female ratio)	36 (11:25)	10 (4:6)	14 (6:8)
Age Median (min-max)	68.5 (58-87)	71 (65-91)	71 (62-91)
BMI Median (min-max)	23.97 (21-30) (n=34)	24 (18-29)	21 (17-28)
Severity of COPD subjects ratio Mild: Moderate: Severe		0:8:2	0:9:5
FEV <sub>1</sub> median (min-max)		0.87 (0.48- 1.14)	
FEV <sub>1</sub> /FVC % median (min-max)		37.22 (29- 45)	
Modified Borg Scale (MBS) median (min-max)		2.0 (0.5- 5.0)	6.0 (1.0- 9.0)
Visual Analogue Scale (VAS) median (min-max)		2.41 (1.30- 3.90)	6.32 (2.00- 9.50)
Number of hospital admissions in last 6 months Median (min-max)	0 (n=30)	0 (n=10)	1.43 (0-3) (n=13)
Number of courses of antibiotics for chest related illness in last 6 months Median (min-max)	0 (0-2) (n=25)		4 (1-6) (n=9)
Self Imposed Modified Diet	0% Food  0% Drink	29% Food  0% Drink	71% Food  0% Drink

### **6.3 Rater reliability**

Inter or intra rater reliability was conducted on the three measures of assessment. The SWAL-QOL<sub>(ab)</sub> used intrarater reliability as discussed earlier to gain 100% accuracy. Interrater reliability was used for LPSG recording to ensure 100% between myself and at least one respiratory physiologist. Videofluoroscopy used interrater reliability and the results are now discussed.

#### **6.3.1 Videofluoroscopy**

Reliability testing of interpretation of videofluoroscopy recordings was conducted on 20% of data (5/24). Table 14 shows interrater reliability from three experienced speech and language therapists (SLT 2-4) rating five videofluoroscopies (VF) during four events, and compared to my ratings (SLT 1). A score of yes relates to a subject scoring more than 50% within in each event for six drink trials and three food trials. There was a 75% and 100% agreement for objective one (PHAG) for food and drink respectively, and 50-100% agreement for secondary objectives: penetration (PEN), aspiration (ASP) and use of spontaneous compensatory manoeuvres (MAN).

**Table 14: Percentages of 'total agreement' for interrater reliability of swallow events observed during videofluoroscopy.**

	EVENT	SLT1		SLT2		SLT3		SLT4		TOTAL AGREEMENT %	
		DRINK	FOOD	DRINK	FOOD	DRINK	FOOD	DRINK	FOOD	DRINK	FOOD
VF1	PHAG	YES	YES	YES	NO	YES	NO	YES	NO	100	75
	PEN	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	ASP	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	MAN	YES	NO	YES	NO	YES	NO	NO	NO	75	100
VF2	PHAG	YES	YES	YES	YES	YES	YES	YES	NO	100	75
	PEN	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	ASP	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	MAN	YES	YES	YES	YES	YES	YES	YES	NO	100	75
VF3	PHAG	YES	YES	YES	YES	YES	YES	YES	YES	100	100
	PEN	YES	NO	YES	NO	YES	NO	YES	NO	100	100
	ASP	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	MAN	YES	NO	YES	NO	YES	NO	YES	NO	100	100
VF4	PHAG	YES	YES	YES	YES	YES	YES	NO	NO	75	75
	PEN	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	ASP	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	MAN	NO	NO	YES	YES	YES	YES	NO	NO	50	50
VF5	PHAG	YES	NO	YES	NO	YES	NO	YES	YES	100	75
	PEN	YES	NO	YES	NO	YES	NO	NO	NO	75	75
	ASP	NO	NO	NO	NO	NO	NO	NO	NO	100	100
	MAN	NO	NO	YES	YES	YES	NO	NO	YES	50	50

PHAG= Overall Dysphagic  
 PEN= Penetration observed  
 ASP= Aspiration observed  
 MAN= Spontaneous compensatory manoeuvres observed

## 6.4 Objective One

Objective one of this study aimed to:

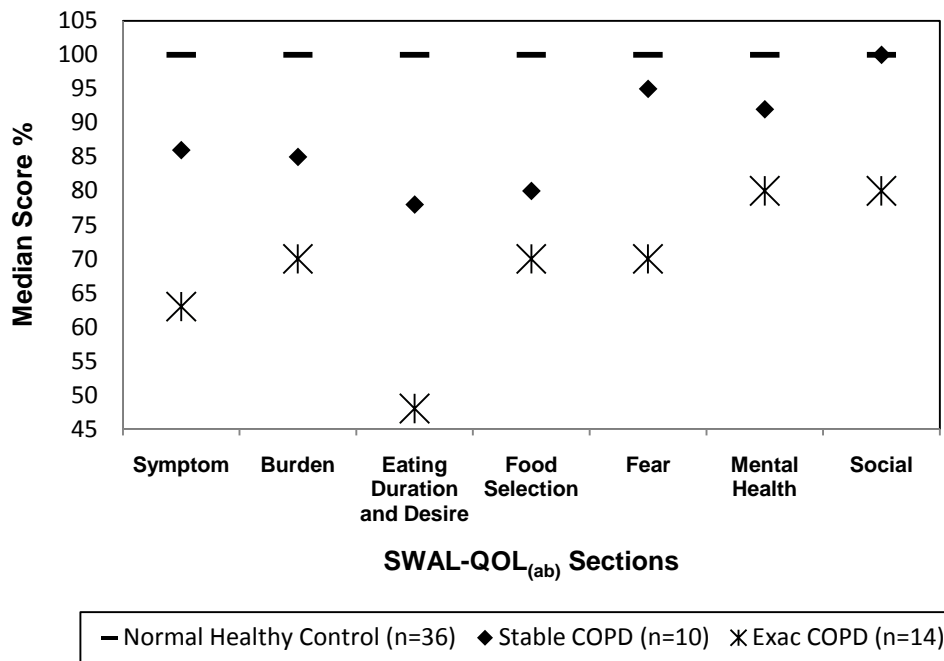
*Compare perception of dysphagic symptoms and swallowing related quality of life between Normal Controls, and by phase of COPD*

This was achieved using the abridged SWAL-QOL (SWAL-QOL<sub>(ab)</sub>). To compare the mean scores of the SWAL-QOL<sub>(ab)</sub> domains between and within research groups, the total median scores of each SWAL-QOL<sub>(ab)</sub> domain were converted into a percentage to allow an overview of the data, as shown in figure 13. The normal healthy control group (black bar) indicated having the highest scores and reported no dysphagic symptoms or impact on quality of

life for all domains assessed; further confirmation that the SWAL-QOL is appropriate for the local population.

All domains for COPD subjects in stable phase (diamond) showed lowered scores (compared to normal controls), except for the 'Social' domain which equalled the normal healthy control scores. All domains for the COPD subjects in exacerbation phase (asterisk) showed the lowest scores; hence the most dysphagic symptoms and greatest impact on swallowing related quality of life.

Figure 13: Median percentage scores for SWAL-QOL (ab) domains



The SWAL-QOL<sub>(ab)</sub> can be divided into two sections; perception of physiologic dysphagic symptoms as assessed by the 'symptoms' domain, and the associated impact on quality of life as assessed by the remaining six domains. The results for the two sections are now discussed.

#### **6.4.1 Perception of oropharyngeal symptoms**

This section explores issues relating to perceived oral and pharyngeal function of the swallow by phase of COPD; measured using the 'Symptoms' domain of the SWAL-QOL<sub>(ab)</sub>. Results were compared with the normal control group and by phase of COPD. Table 15 reports descriptive statistics for scores on the Symptom domain of the SWAL-QOL<sub>(ab)</sub> for each group.

The SWAL-QOL<sub>(ab)</sub> Likert scale is inversely related to symptoms of dysphagia. Fourteen questions in the Symptom domain investigate physical difficulties with swallowing. A maximum score of 70 relates to no dysphagic symptoms perceived by the scorer, a score of 56 and above indicates infrequent or no signs of dysphagia and a score lower than 56 would show evidence of perceived difficulties with swallowing. The minimum score for this domain is 14, which indicates the most severe symptoms of dysphagia.

There were 30% (n=3) of COPD subjects during stable phase, and 71% (n=10) during exacerbation phase who scored 56 or lower in this domain, with no normal healthy control group subject scoring lower than 56. The normal control group (n=36) showed a median score of 70 with a very small range (3), therefore rating their swallow as having no dysphagic symptoms. The median score for COPD subjects during stable phase indicated no dysphagic symptoms; however there was a larger variation when compared to normal controls. COPD subjects during exacerbation phase reported more frequent physiological swallowing difficulties; again there was a further increase in the range of scores.

**Table 15: Descriptive statistics for SWAL-QOL (ab) 'Symptom' domain.**

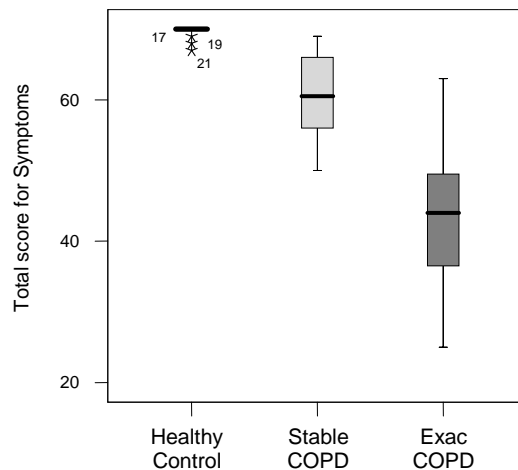
<b>Total score for Symptoms section</b>	<b>N</b>	<b>Median<sup>†</sup></b>	<b>Range (min-max)</b>
Normal Healthy	36	70	67-70
Stable COPD	10	60.50	50-69
Exac COPD	14	44.00	25-63
Total	60		

<sup>†</sup> Scores within normal limits = 56-70

Further analysis using a box and whisker plot (figure 14), show the distribution of the scores in more detail. The interquartile range (box) shows the middle 50% of the total scores, with the median represented as a black bar within the interquartile range. The whiskers (line above and below each interquartile range) show the remaining data within 1.5 box-lengths from the edge of the box, and extreme outliers (more than three box-lengths from the edge of the box) represented as an asterisk with the subject identification number (Pallant, 2007). The normal control group show three close outliers (asterisks). The phases of COPD show a relatively large interquartile range relative to the outliers (whiskers), and they are slightly skewed; Stable COPD positively and Exacerbation COPD negatively skewed. The skewness reveals that the data is not normally distributed.



Figure 14: Box and whisker plot summary of SWAL-QOL(ab) 'Symptoms' domain.



COPD subjects generally scored 'symptoms' of dysphagia differently within each phase of their condition and from the normal control group which required further exploration. Non parametric testing was used as the box and whisker plots show that ratio between the upper and lower quartile was greater than two, revealing that the data is not normally distributed (Machin, Campbell, & Walters, 2010). Furthermore, as advised by a statistician (Prof M.C.), calculations of the mean and median revealed a difference of greater than 1% for the majority of data points; providing further evidence of asymmetry. Mann Whitney U tests were used for testing the two independent sets of data (Normal control group versus Stable COPD), and Wilcoxon Signed Rank Tests were used to the test the two related sets; Stable COPD versus Exacerbation COPD (as this was the repeated measures design discussed in chapter five). The results of non parametric testing are now discussed.

#### 6.4.1i) Normal Healthy Control vs. Stable COPD

Quantitative analysis on the Symptom section of the SWAL-QOL<sub>(ab)</sub> using the Mann Whitney U Test investigated the difference between the normal healthy control group and the stable COPD group, as shown in table 16.

Table 16: Mann Whitney U Test: Normal- Stable COPD for SWAL-QOL(ab) 'Symptoms' domain.

Total score for Symptoms	Normal Control - Stable COPD
Mann-Whitney U	3.00
Z	-5.935
Asymp. Sig. (2-tailed)	.000*

\* Significant at p<0.05

A statistically significant difference was found between Normal Controls (Md= 70, n=36) and Stable COPDs (Md= 60.50, n=10) subjects, U= 3.00, z= -5.935, p=0.00. The Stable COPD subjects in this study were statistically more likely to perceive more physiologic dysphagic symptoms than normal healthy controls.

#### 6.4.1ii) Exacerbation COPD vs. Stable COPD

Quantitative analysis using the Wilcoxon Signed Rank Test investigated the difference between Stable and Exacerbation phase COPD, as shown in table 17.

Table 17: Wilcoxon Signed Rank Test: Stable COPD-Exac COPD for SWAL-QOL(ab) 'Symptom' domain

Total score for Symptoms	Stable COPD- Exac COPD
Median Difference	-2.501 <sup>a</sup>
Z	0.012*
Asymp. Sig. (2-tailed)	

a. based on positive ranks

\* Significant at p<0.05

A statistically significant difference was found between scores of Stable COPD and Exacerbation COPD for the Symptoms domain,  $z = -2.501$ , ( $p < 0.05$ ). The COPD group in this study were statistically more likely to report more physiologic dysphagic symptoms in exacerbation phase than during stable phase.

#### **6.4.2 Perception of swallowing related quality of life**

This section in objective one explored the impact that any physiological dysphagic symptoms may have on quality of life (QOL). Six domains of quality of life were assessed; Burden, Eating duration and desire, Food selection, Fear, Mental Health and Social in normal controls and by phase of COPD. Table 18 shows descriptive statistics for the six QOL domains; including the minimum and maximum achievable score, and median and range for each of the groups. Sample size is the same for each domain and is therefore documented in the Burden category only. Scores within normal limits (WNL) indicate no swallowing related quality of life changes within each domain. The median for the normal control group resulted in the maximum achievable score for each category, with minimal variation. Both phases of COPD scored lower than the normal control group, with exacerbation phase scoring the lowest in each domain, also with the largest range.

**Table 18: Descriptive analysis of six SWAL-QOL<sub>(ab)</sub> domains.**

Total score for SWAL-QOL <sub>(ab)</sub> Domains		Median	Range (min-max)
<b>Burden</b> (Min score= 2, Max score= 10) (WNL= 9-10)	Normal Control (n= 36)	10	8-10
	Stable COPD (n=10)	8.5	4-10
	Exac COPD (n=14)	7	2-10
<b>Eating duration and desire</b> (Min score=5, Max score=25) (WNL= 23-25)	Normal Control	25	24-25
	Stable COPD	19.5	16-23
	Exac COPD	12	5-25
<b>Food selection</b> (Min score=2, Max score=10) (WNL= 8-10)	Normal Control	10	8-10
	Stable COPD	8	6-10
	Exac COPD	7	2-10
<b>Fear</b> (Min score=4, Max score=20) (WNL= 18-20)	Normal Control	20	20-20
	Stable COPD	19	13-20
	Exac COPD	14	8-20
<b>Mental Health</b> (Min score=5, Max score=25) (WNL= 23-25)	Normal Control	25	25-25
	Stable COPD	23	13-25
	Exac COPD	20	9-25
<b>Social</b> (Min score=5, Max score=25) (WNL= 20-25)	Normal Control	25	25-25
	Stable COPD	25	17-25
	Exac COPD	20	5-25

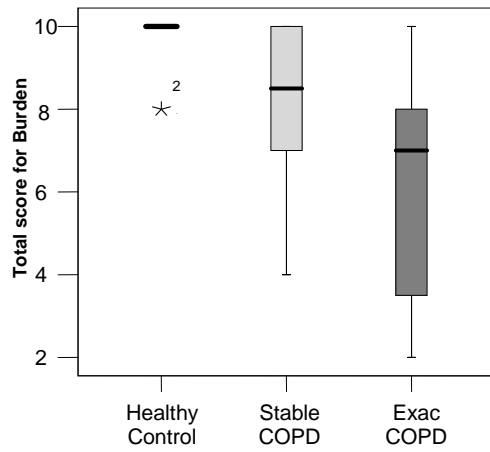
WNL= Within Normal Limits for each domain

Figure 15 also shows the differences between the groups, quantitatively highlighting the variability of the data between the normal control group and the phases of COPD using box and whisker plots for each of the six domains.

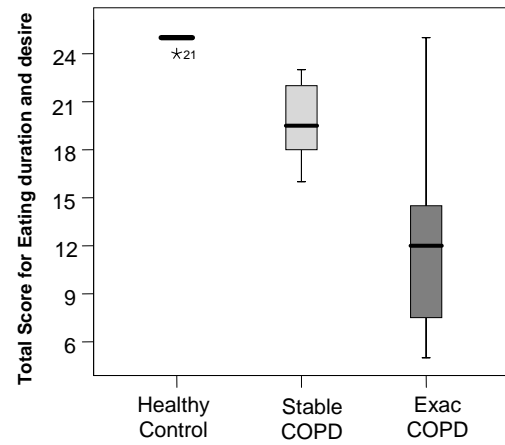
The COPD data show a large interquartile range with symmetry shown only with Burden (Stable phase) and Fear (Exacerbation phase COPD). Eating duration and desire (Exacerbation phase COPD) is positively skewed, and the remaining domains are negatively skewed. The level of skewness reveals the data is not normally distributed.

Figure 15: Box and Whisker Plot by SWAL-QOL(ab) domains

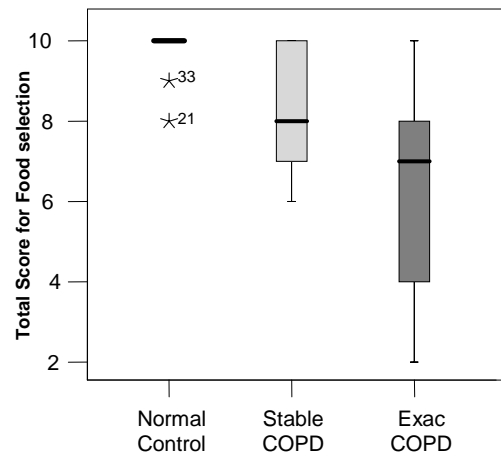
a) Burden



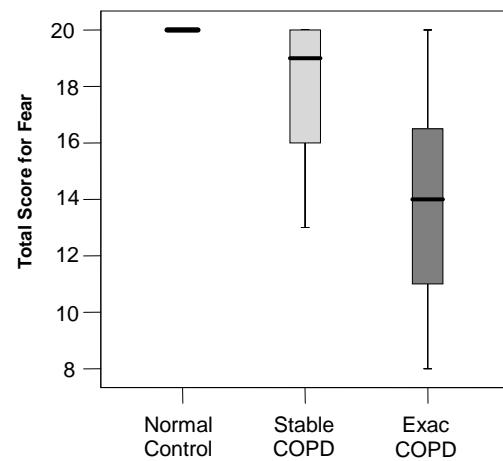
b) Eating duration and desire



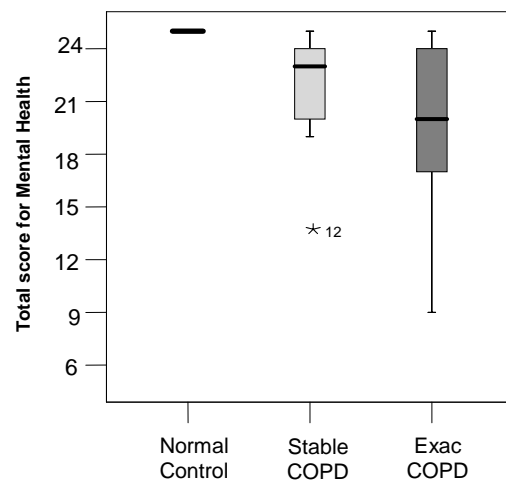
c) Food Selection



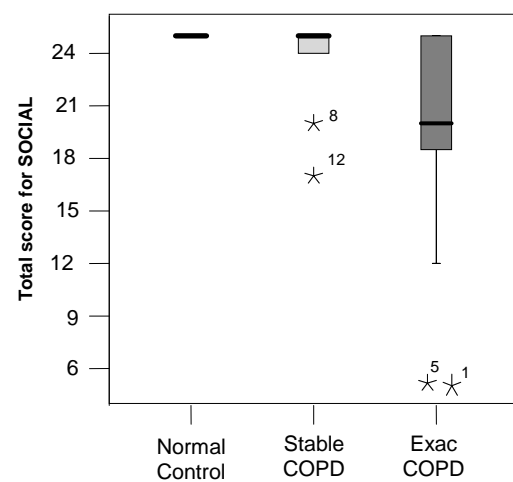
d) Fear



e) Mental Health



f) Social



As with the physiologic dysphagia symptom measures discussed previously, the data required further analysis, and therefore non parametric tests were used. Results are now discussed.

**6.4.2i) Normal Healthy Control vs. Stable COPD**

A Mann Whitney U test was used to test if any significant differences occurred between the Normal Control group and Stable COPD in ratings of swallowing related quality of life, as shown in table 19.

**Table 19: Mann Whitney U Test: Normal-Stable COPD SWAL-QOL(ab) QOL domains.**

Test Statistics(b)

Total Score SWAL-QOL <sub>(ab)</sub> for Healthy Control-Stable COPD						
	Burden	Eating duration and desire	Food selection	Fear	Mental Health	Social
<b>Mann Whitney U</b>	58.50	0.00	77.50	108.00	36.00	112.00
<b>Z</b>	-4.90	-6.41	-4.135	-3.276	-5.807	-3.353
<b>Asymp. Sig (2-tailed)</b>	<b>p&lt;0.0001*</b>	<b>p&lt;0.001*</b>	<b>p&lt;0.001*</b>	<b>p&lt;0.001*</b>	<b>p&lt;0.001*</b>	<b>p&lt;0.001*</b>

\* Significant at p<0.05

A statistically significant difference was found in all domains of swallowing related quality of life (p<0.05). Stable COPD subjects in this study were more likely to rate their swallowing as negatively impacting their quality of life, more than the normal control group.

#### 6.4.2ii) Exacerbation COPD vs. Stable COPD

A Wilcoxon Signed Rank Test was used to investigate any difference between COPD subjects during stable and exacerbation phase scores for ratings of swallowing related quality of life, as shown in table 20.

**Table 20: Wilcoxon Signed Rank Test: Exac COPD-Stable COPD SWAL-QOL<sub>(ab)</sub> QOL domains.**

Total Score SWAL-QOL <sub>(ab)</sub> for Exac COPD-Stable COPD						
	Burden	Eating duration and desire	Food selection	Fear	Mental Health	Social
<b>Z</b>	-1.725 <sup>a</sup>	-2.312	-1.841 <sup>a</sup>	-2.023 <sup>a</sup>	-0.957 <sup>a</sup>	-1.225 <sup>a</sup>
<b>Asymp. Sig (2-tailed)</b>	0.084	<b>0.021*</b>	0.066	<b>0.043*</b>	0.339	0.221

<sup>a</sup> Based on positive ranks

\* Significant at  $p < 0.05$

A statistically significant difference was found between Stable and Exacerbation phase of COPD for two domains; Eating duration and desire ( $p = 0.021$ ), and Fear ( $p = 0.043$ ). The COPD group in this study were more likely to rate their quality of life lower in exacerbation phase than during stable phase of their condition for questions relating to Eating duration and desire and Fear.

## 6.5 Objective Two

Objective two of this study contained one primary and two secondary objectives. This objective aimed to:

*Investigate the prevalence of oropharyngeal biomechanical dysphagia by phase of COPD.*

- a) *Explore the nature of the oropharyngeal dysphagia by phase of COPD.*
- b) *Compare the perception of dysphagia symptoms with the biomechanical analysis by phase of COPD.*

This was achieved using videofluoroscopic analysis. Videofluoroscopy measures were assessed within the same subjects during stable phase and exacerbation phase of their condition. Fourteen COPD subjects were assessed during exacerbation phase with ten subjects being suitable for follow-up in stable phase. Table 21 indicates the median times and exposure for videofluoroscopy.

**Table 21: Median Videofluoroscopy durations and radiation exposure**

	<b>Stable COPD</b>	<b>Exacerbation COPD</b>
Number of subjects	10	14
VF Time in minutes median (min-max)	3.18 (1.80-4.00)	4.26 (2.70-7.00)
VF Exposure in mGy/cm <sup>2</sup> median (min-max)	3476.33 (2034- 4979)	4373.29 (2520- 7321)



### *Number of Swallows Analysed*

Subjects were given six water trials and three food trials. A total of 131 drink swallows (56 in stable and 75 in exacerbation phase) and 72 food swallows (30 in stable and 42 in exacerbation phase) were able to be analysed from videofluoroscopy.

Data was lost due to not meeting stable criteria (n= 4), withdrawal of consent (n=1), recording equipment not working correctly (13 drink swallows). Most volunteers used the required number of swallows for drink (93% stable and 89% exacerbation phase) and food (100% for both stable and exacerbation).

Videofluoroscopic measures were analysed *per subject* in order to provide a descriptive overview of the results, and as a *percentage of swallows per subject* for further quantitative analysis as discussed previously in chapter five.

#### **6.5.1 Prevalence of dysphagia**

The primary aim of objective two was to estimate prevalence of oropharyngeal biomechanical dysphagia in subjects with COPD. Subjects were coded as 'overall' dysphagic if either of the oral or pharyngeal stages of the swallow were shown to be disordered on videofluoroscopy for food and/or drink; with definitions of dysphagia discussed in chapters two and five. Types of dysphagic characteristics observed for *one or more swallows* by COPD subjects were:

- reduced oral control of bolus (including reduced anterior-posterior movement, reduced bolus cohesiveness, reduced chewing, reduced tongue strength) during stable phase food (n=5) and drink trials (n=4), and during exacerbation phase food (n= 9) and drink trials (n=4).
- reduced 'base of tongue' strength during stable phase food (n= 4) and drink trials (n= 6), and during exacerbation phase food (n= 7) and drink trials (n=11).
- delayed initiation of swallow during stable phase food (n= 2) and drink trials (n=7), and during exacerbation phase food (n= 3) and drink trials (n=10).
- reduced laryngeal elevation and closure during stable phase food (n= 0) and drink trials (n= 6), and during exacerbation food (n= 3) and drink trials (n=7).
- reduced pharyngeal constriction during stable phase food (n= 0) and drink trials (n=1), and during exacerbation phase food (n= 2) and drink trials (n=1).

These dysphagic characteristics precipitate events coded within the secondary objectives (penetration, aspiration and spontaneous manoeuvres). Table 22 highlights the difference in reporting objectives as *50% or more of trials* versus *one or more trials* for each objective, and the implications discussed further in section 7.3.2i. From table 22, there is a clear increase in number of subjects considered dysphagic during exacerbation phase.

**Table 22: Number of subjects dysphagic by phase of COPD.**

		Primary Objective		Secondary Objectives					
		Overall Dysphagic		Penetration (Mode Rosenbek score)		Aspiration (Mode Rosenbek score)		Spontaneous Manoeuvres	
		For 50% or more of trials	For one or more of trials	For 50% or more of trials	For one or more of trials	For 50% or more of trials	For one or more of trials	For 50% or more of trials	For one or more of trials
<b>Stable COPD (n=10)</b>	FOOD	20%	50%	0%	10% (2)	0%	0%	20%	40%
	DRINK	70%	70%	10% (2)	40% (2)	0%	20% (8)	50%	80%
<b>Exacerbation COPD (n=14)</b>	FOOD	64%	86%	14% (3)	29% (3)	0%	7% (7)	43%	86%
	DRINK	100%	100%	50% (3)	86% (4)	21% (8)	57% (8)	79%	100%

### **6.5.1i) Percentage of swallows**

Further analysis using quantitative measures was explored using 'percentage of swallows' per subject. Table 23 summarises relevant descriptive statistics for the percentage of drink and food swallows considered dysphagic in either stable or exacerbation phase COPD. Median scores reveal a higher percentage of swallows are classified as dysphagic in exacerbation phase for food and drink trials. All trials showed a large range of scores.

**Table 23: Percentage of swallows considered dysphagic.**

Percentage of Swallows Considered 'Overall' Dysphagic		N	Number of swallows analysed	Median %	Range % (Min-Max)
<b>DRINK</b>	Stable Phase	10	56	83.00	0-100
	Exacerbation Phase	14	75	93.00	67-100
<b>Total</b>		24	131		
<b>FOOD</b>	Stable Phase	10	30	16.50	0-100
	Exacerbation Phase	14	42	67.00	0-100
<b>Total</b>		24	72		

A Wilcoxon Signed Rank Test revealed a statistically significant difference between stable and exacerbation phase of COPD for percentage of swallows considered dysphagic for drinks,  $Z = -2.103$ , ( $p=0.035$ ) and food,  $Z = -1.995$  ( $p=0.046$ ) as shown in table 24.

**Table 24: Wilcoxon Signed Rank Test: Exac COPD-Stable COPD for percentage of swallows considered dysphagic.**

Percentage of Swallows Considered Dysphagic	DRINK	FOOD
<b>Exacerbation- Stable</b>		
Z	-2.103(a)	-1.995(a)
Asymp. Sig. (2-tailed)	<b>0.035*</b>	<b>0.046*</b>

a Wilcoxon Signed Ranks Test

\* Significant at  $p < 0.05$

COPD subjects in this study had significantly more swallows rated as dysphagic during exacerbation phase of their condition; compared to stable phase, for food and drink trials.

## 6.5.2 Nature of dysphagia

Biomechanical analysis of the swallow using videofluoroscopy enables a detailed investigation of dysphagic events. For the purposes of this thesis, three clinically significant events (penetration of the bolus, aspiration of the bolus, and spontaneous manoeuvres) were recorded and analysed as secondary objectives in objective two.

### 6.5.2i) Penetration of bolus

Penetration was defined as the bolus entering the airway to the level of the vocal cords, as discussed in chapter two. Descriptive statistics for food and drink swallows shown to penetrate in COPD subjects during stable and exacerbation phase for food and drink trials are summarised in table 25. A median 'percentage of swallows' penetrated revealed little or no penetration of a bolus during food or drink trials, with an increase in penetration seen during exacerbation phase for drink trials.

Table 25: Percentage of swallows penetrated by phase of COPD.

Percentage of Swallows Penetrated	N	Number of swallows analysed	Median (%)	Range (Min-Max) (%)	
<b>DRINK</b>	Stable Phase	10	56	0.00	0-50
	Exacerbation Phase	14	75	41.50	0-83
<b>Total</b>	24	131			
<b>FOOD</b>	Stable Phase	10	30	0.00	0-33
	Exacerbation Phase	14	42	0.00	0-67
<b>Total</b>	24	72			

Further analysis on penetration scores using a Wilcoxon Signed Rank Test revealed a statistically significant difference between stable and exacerbation phase of COPD for penetration during drink swallows,  $Z = -2.15$ , ( $p = 0.031$ ), but not for food swallows,  $Z = -1.30$ , ( $p > 0.05$ ) as shown in table 26. COPD subjects in this study were more likely to penetrate on drink trials during Exacerbation phase; compared to Stable phase of their condition.

**Table 26: Wilcoxon Signed Rank Test: Exac COPD-Stable COPD Percentage of swallows penetrated**

Percentage of Swallows Penetrated	DRINK	FOOD
<b>Exacerbation-Stable</b>		
Z	-2.153(a)	-1.300(a)
Asymp. Sig. (2-tailed)	<b>0.031*</b>	0.194

(a) Based on negative ranks.

\* Significant at  $p < 0.05$

### **6.5.2ii) Aspiration of the bolus**

Aspiration of the bolus was defined as entering the airway and passing through the vocal cords, as discussed in chapter two. Descriptive statistics for swallows shown to aspirate food or drink trials during stable or exacerbation phase of COPD are shown in table 27. As seen with analysis of penetration of trials, a median 'percentage of swallows' aspirated revealed little or no aspiration of a bolus during food or drink trials, with an increase in aspiration seen during exacerbation phase for drink trials. All of the aspirated swallows were rated as trace aspiration, or equivalent to less than or equal to 1% of bolus total. Of the swallows coded as aspirated, all were scored as silent (i.e. no cough reflex was elicited).

**Table 27: Descriptives of percentage of swallows aspirated by phase of COPD.**

Percentage of Swallows Aspirated		N	Number of swallows	Median %	Range (Min-Max) (%)
<b>DRINK</b>	<b>Stable Phase</b>	10	56	0.00	0-17
	<b>Exacerbation Phase</b>	14	75	17.00	0-83
<b>Total</b>		24	131		
<b>FOOD</b>	<b>Stable Phase</b>	10	30	0.00	0-0
	<b>Exacerbation Phase</b>	14	42	0.00	0-33
<b>Total</b>		24	72		

Further analysis of aspiration scores using a Wilcoxon Signed Rank Test revealed no statistically significant difference between stable or exacerbation phase COPD for aspiration on drink swallows,  $Z = -1.70$ , ( $p > 0.05$ ) or food swallows,  $Z = -1.00$  ( $p > 0.05$ ), as shown in table 28.

**Table 28: Wilcoxon Signed Ranks Test: Exac COPD-Stable COPD: Percentage of swallows aspirated**

Percentage of Swallows Aspirated	DRINK	FOOD
<b>Exacerbation-Stable</b>		
Z	-1.703(a)	-1.000(a)
Asymp. Sig. (2-tailed)	0.089	0.317

(a) Based on negative ranks.

A COPD subject in this study was statistically no more likely to aspirate on food or drinks during either phase of their condition. However it is notable that all aspirations seen during the study took place with drinks in exacerbation phase and this may be a type 2 statistical error due to the modest sample size. This will be discussed further in section 7.3.2ii.

### 6.5.2iii) *Spontaneous Manoeuvres*

The third event scored for this study was the subject's use of spontaneous manoeuvres during videofluoroscopy. Descriptive statistics for the percentage of spontaneous manoeuvres used during food and drink swallows in either stable or exacerbation phase COPD are shown in table 29. Types of spontaneous manoeuvres observed in COPD subjects were:

- breath holding pre swallow during stable phase food (n=2) and drink trials (n=3) and exacerbation phase food (n=3) and drink (n=7) trials
- laryngeal elevation holding post swallow during stable phase drink trials (n= 2) and during exacerbation phase food (n=3) and drink trials (n=3)
- more than three clearing swallows during stable phase food (n=3) and drink trials (n=7) and during exacerbation food (n= 10) and drink trials (n=12)
- head tilt during exacerbation phase food (n=1) and drink trials (n=1)
- chin tuck during exacerbation drink trials (n=1)

**Table 29: Descriptives of percentage of swallows using spontaneous manoeuvres by phase of COPD.**

Percentage of Swallows using Spontaneous Manoeuvres		N	Number of swallows	Median (%)	Range (Min-Max) (%)
DRINK	Stable Phase	10	56	50.00	0-100
	Exacerbation phase	14	75	58.50	17-100
	Total	24	131		
FOOD	Stable Phase	10	30	0.00	0-100
	Exacerbation Phase	14	42	41.50	0-100
	Total	24	72		

Further analysis on spontaneous manoeuvres using a Wilcoxon Signed Rank Test revealed no statistically significant difference between stable or



exacerbation phase for using spontaneous manoeuvres with drink swallows,  $Z = -1.404$ , ( $p > 0.05$ ). However food swallows did reach statistical significance,  $Z = -2.013$  ( $p = 0.044$ ) as shown in table 30.

**Table 30: Wilcoxon Signed Rank Test: Exac COPD-Stable COPD: Percentage of swallows using spontaneous manoeuvres.**

Percentage of Swallows Using Spontaneous Manoeuvres	DRINK	FOOD
<b>Exacerbation-Stable</b>		
Z	-1.404(a)	-2.013(a)
Asymp. Sig. (2-tailed)	.160	<b>0.044*</b>

a Based on negative ranks.

\* Statistically significant at  $P > 0.05$

A COPD subject in this study was more likely to use spontaneous manoeuvres during exacerbation phase for food swallows than in stable phase of the condition.

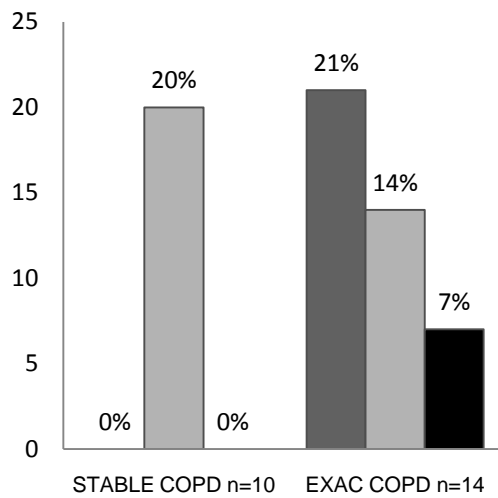
### 6.5.3 Perception reports vs. biomechanical analysis

The event coded as 'considered dysphagic' from videofluoroscopy and the SWAL-QOL<sub>(ab)</sub> 'Symptom' domain from objective one analysis can be further divided to show symptoms for oral stage and pharyngeal stage dysphagia.

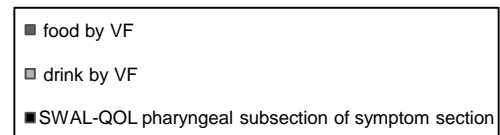
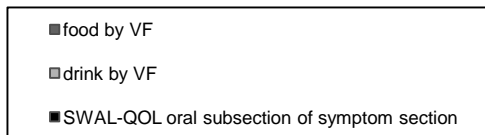
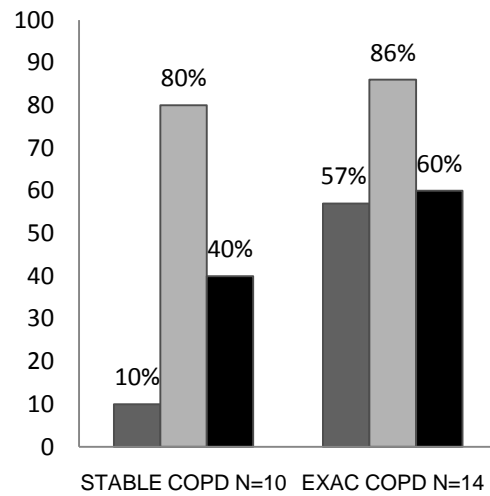
This enables a general overview comparing the number of subjects perceiving swallowing difficulty with objective detection of dysphagia as shown in figure 16a) oral stage symptoms and 16b) pharyngeal stage symptoms. Oral stage food scores for stable phase COPD appear to be the only rating similar in SWAL-QOL<sub>(ab)</sub> and videofluoroscopy analysis.

**Figure 16: Perception vs Biomechanical analysis: Percentage of subjects considered dysphagic**

a) oral stage



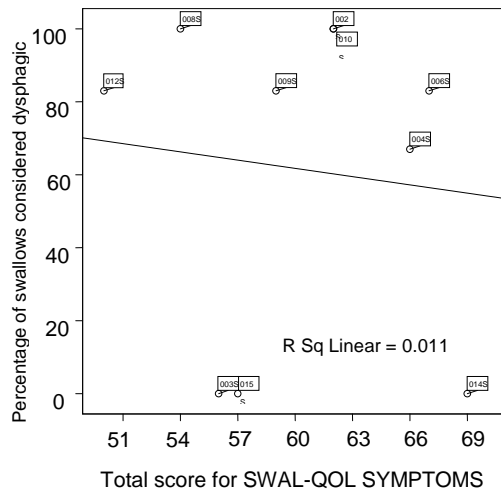
b) pharyngeal stage



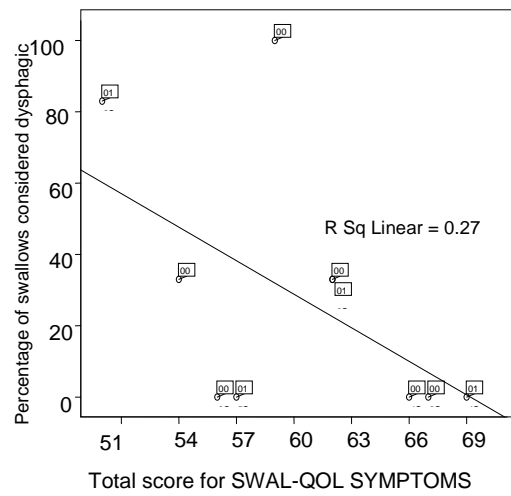
To analyse this theory further, scatterplots and non parametric testing was used to quantify the strength of the relationship (Pallant, 2007). Food and drink were separated and rated by phase of COPD. A negative Spearman's Rho correlation coefficient was expected, due to the inverse scores on the SWAL-QOL<sub>(ab)</sub>. Figure 17 shows four scatterplots for *Percentage of swallows considered dysphagic* and *SWAL-QOL Symptoms domain* in either stable or exacerbation phase of COPD during drink and food trials.

**Figure 17: Scatterplots Symptoms domain vs overall dysphagic score by phase of COPD for food and drink swallows.**

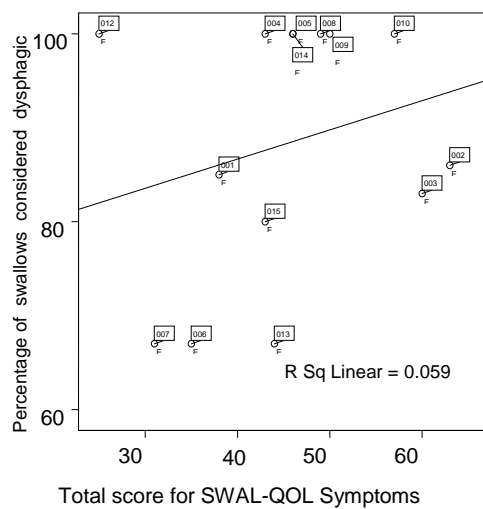
a) Drink swallows Stable COPD



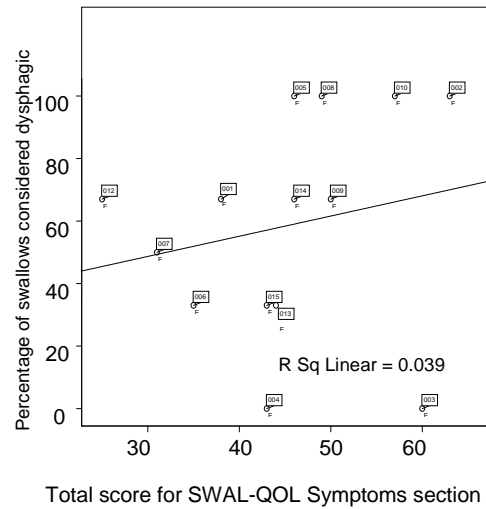
b) Food swallows Stable COPD



c) Drink swallows EXAC COPD



d) Food swallows EXAC COPD



The scatterplots and Spearman's Rho coefficients in table 31 reveal scores for stable phase food and drink swallows produced the expected negative relationship.

**Table 31: Spearman's Rho coefficient for percentage of swallows considered dysphagic v SWAL-QOL Symptom domain score by phase of COPD.**

Phase of COPD			Spearman's Rho	Total score for SWAL-QOL SYMPTOMS
<b>Stable Phase</b>	<b>DRINK</b>	Percentage of drink swallows considered dysphagic	Correlation Coefficient	<b>-.145</b>
			Sig. (2-tailed)	.689
			Number of swallows	48
	<b>FOOD</b>	Percentage of food swallows considered dysphagic	Correlation Coefficient	<b>-.480</b>
			Sig. (2-tailed)	.160
			Number of swallows	26
<b>Exacerbation Phase</b>	<b>DRINK</b>	Percentage of drink swallows considered dysphagic	Correlation Coefficient	.317
			Sig. (2-tailed)	.270
			Number of swallows	62
	<b>FOOD</b>	Percentage of food swallows considered dysphagic	Correlation Coefficient	.357
			Sig. (2-tailed)	.210
			Number of swallows	31

Drink trials during stable phase COPD suggested a small relationship between ratings on 'considered dysphagic' and the SWAL-QOL Symptoms domain; with scores on the Symptom domain helping to explain 20% of the variance on scores for 'overall dysphagic' using videofluoroscopy. However the significance level shows that this relationship is highly uncertain ( $r = -0.145$ ,  $p > 0.05$ ). Food swallows in stable phase suggested a medium strength relationship; with the Symptom domain helping to explain 23% of the variance on scores for 'overall dysphagic' using videofluoroscopy. However this did not reach statistical significance and therefore shows this relationship is also highly uncertain ( $r = -0.480$ ,  $p > 0.05$ ). Statistical significance may not have been reached due to the modest sample size.

Spearman's Rho correlational coefficient scores in exacerbation phase for food and drink did not produce the expected negative relationship, but indicated a medium strength relationship for drink ( $r= 0.317$ ) and food ( $r= 0.357$ ). Neither drink nor food trials reached statistical significance showing this relationship is highly uncertain.

## 6.6 Objective Three

The final objective for this study explored the respiratory-swallow pattern in COPD. It aimed to:

*Investigate the nature of the respiratory-swallow pattern by phase of COPD.*

a) *Compare the respiratory-swallow pattern with the biomechanical analysis by phase of COPD.*

The respiratory-swallow pattern was measured simultaneously with videofluoroscopy to record respiratory status throughout the swallowing process, using a Limited Polysomnogram (LPSG). Readings from chest excursions provided the most accurate information regarding respiratory status before; at the time of; and after a swallow. Airflow readings provided by the nasal cannulae proved inconsistent (possible reasons explored in chapter seven). This information, synchronised with videofluoroscopic events enabled measurements to be taken for swallow apnoea duration and the respiratory-swallow patterns; inhalation-swallow apnoea-inhalation (INH/INH); exhalation-swallow apnoea-inhalation (EXH/INH); or inhalation-swallow apnoea- exhalation (INH/EXH); and exhalation-swallow apnoea- exhalation (EXH/EXH) (Martin-Harris, 2008).

Descriptive analysis of swallow apnoea durations; as shown in table 32, show exacerbation phase had the largest range of duration for food (3.17sec) and drink (1.95) swallows than during stable phase.

**Table 32: Descriptives of swallow apnoea duration by phase of COPD.**

Swallow Apnoea Duration		N	Number of swallows	Median Sec	Range (Min-Max) Sec
DRINK	Stable Phase	9	48	1.630	0.960-2.000
	Exacerbation Phase	14	62	1.585	0.850- 2.800
Total		24	110		
FOOD	Stable Phase	9	26	1.170	1.000- 2.700
	Exacerbation Phase	14	31	1.500	0.830- 4.000
Total		24	57		

Results of the respiratory-swallow pattern are presented descriptively *per subject*, and further quantitative analysis was completed using *percentage swallows per subject*; as described in the methodology chapter and conducted for objective two, which are now discussed.

### 6.6.1 Nature of respiratory-swallow pattern

The predominate respiratory-swallow pattern used by the COPD subjects in this study was Exhalation-(swallow apnoea)-Inhalation (EXH/INH) for food and drink trials in Stable phase; whereas Inhalation-(swallow apnoea)-Inhalation (INH/INH) equalled the EXH/INH pattern during drink trials in Exacerbation phase when reporting COPD subjects using a respiratory-

swallow pattern for 50% or more of trials. Table 33 summarises subjects using respiratory-swallow patterns for 50% or more of trials and also for one or more of trials; where greater variation in the use of respiratory-swallow patterns within subjects can be seen, as discussed previously for prevalence of dysphagia.

**Table 33: Number of subjects using a Respiratory-Swallow pattern by phase of COPD.**

		INH/INH		EXH/INH		INH/EXH		EXH/EXH	
		For 50% or more of trials	For one or more of trials	For 50% or more of trials	For one or more of trials	For 50% or more of trials	For one or more of trials	For 50% or more of trials	For one or more of trials
<b>Stable COPD (n=10)</b>	FOOD	10%	30%	40%	90%	10%	50%	0%	20%
	DRINK	0%	50%	70%	90%	30%	80%	0%	20%
<b>Exacerbation COPD (n=14)</b>	FOOD	29%	43%	57%	79%	7%	71%	0%	0%
	DRINK	43%	64%	43%	64%	21%	100%	0%	14%

### **6.6.1i) Percentage of swallows**

To analyse the variability within subjects; and therefore include all clinically relevant data, respiratory-swallow pattern was further analysed using *percentage of swallows* per subject. Table 34 summarises descriptive statistics for the median percentage of swallows used by subjects for each of the four respiratory-swallow patterns by phase of COPD for food and drink trials. This table highlights the variability of respiratory-swallow patterns used within this COPD sample, more specifically the increased use of INH/INH pattern during Exacerbation phase for food and drink swallows, not seen when assessing *per subject*.

**Table 34: Percentage of swallows using respiratory-swallow patterns by phase of COPD.**

Phase of COPD		DRINK MEDIAN%	FOOD MEDIAN%
Stable Phase	INH/INH (mid INH)	14.8	13.30
	EXH/INH (end EXH)	50.80	60.20
	EXH/EXH (mid EXH)	3.4	6.60
	INH/EXH (end INH)	31.00	19.90
<b>TOTAL</b>		<b>100%</b>	<b>100%</b>
Exacerbation Phase	INH/INH (mid INH)	30.43	23.86
	EXH/INH (end EXH)	29.86	49.57
	EXH/EXH (mid EXH)	3.36	0.00
	INH/EXH (end INH)	36.36	26.57
<b>TOTAL</b>		<b>100%</b>	<b>100%</b>

The two respiratory-swallow patterns using inhalation post swallow (INH/INH and EXH/INH) were further analysed as these were reported to be the least likely respiratory phases to be observed within normal and normal age swallows; as reported within the literature (see chapter three). A Wilcoxon Signed Rank Test revealed no statistically significant difference in use of inhalation post swallow when a subject was in either stable or exacerbation phase of COPD with drink swallows,  $Z = -0.654$ , ( $p > 0.05$ ) or food swallows,  $Z = -0.137$  ( $p > 0.05$ ) as shown in table 35.

**Table 35: Wilcoxon Signed Rank Test: Exac COPD-Stable COPD: Percentage of inhalation post swallow.**



Percentage of swallows using Inhalation post swallow	DRINK	FOOD
Exacerbation-Stable		
Z	-0.654(b)	-0.137(a)
Asymp. Sig. (2-tailed)	0.513	0.891

(a) Based on negative ranks.

(b) Based on positive ranks.

A COPD subject in this study was no more likely to use inhalation post swallow for food or drink swallows during stable or exacerbation phase of their condition.

### 6.6.2 Respiratory swallow pattern analysis vs. biomechanical analysis

The secondary objective aimed to compare the respiratory-swallow pattern and biomechanical swallow analysis from objective two. A Spearman's Rho correlational coefficient was used to analyse the relationship between percentage of swallows considered dysphagic and percentage of swallows using inhalation post swallow; for food and drink trials by phase of COPD, as shown in table 36. A positive correlation was expected, indicating the higher the use of inhalation post swallow, the higher percentage of swallows considered dysphagic.

**Table 36: Spearman’s Rho Correlation of percentage swallows considered dysphagic vs. Percentage of swallows using inhalation post swallow by phase of COPD.**

Phase of COPD			Spearman’s Rho	Total score for INHALATION POST SWALLOW	
<b>Stable Phase</b>	<b>DRINK</b>	Percentage of drink swallows considered dysphagic	Correlation Coefficient	0.268	
			Sig. (2-tailed)	0.454	
				Number of swallows	48
	<b>FOOD</b>	Percentage of food swallows considered dysphagic	Correlation Coefficient	0.165	
			Sig. (2-tailed)	0.649	
				Number of swallows	26
<b>Exacerbation Phase</b>	<b>DRINK</b>	Percentage of drink swallows considered dysphagic	Correlation Coefficient	<b>-0.590*</b>	
			Sig. (2-tailed)	0.026	
				Number of swallows	62
	<b>FOOD</b>	Percentage of food swallows considered dysphagic	Correlation Coefficient	-0.008	
			Sig. (2-tailed)	0.978	
				Number of swallows	31

\* Significant at 0.05 level (2 tailed)

A small strength relationship was indicated for stable phase drink and food swallows; with inhalation post swallow helping to explain only 7% of dysphagia in drink swallows and 3% in food swallows. However both significance levels show that the relationships are highly uncertain; ( $r= 0.268$ ,  $p>0.05$ ) and ( $r= 0.165$ ,  $p>0.05$ ) respectively.

Analysis of the respiratory-swallow pattern during exacerbation phase revealed unexpected results. There was a large, negative correlation for drink swallows during exacerbation phase, which also reached statistical significance ( $r= - 0.590$ ,  $p=0.026$ ). This is explored further in chapter seven.

## **6.7 Summary of Results**

This study aimed to investigate the nature and extent of oropharyngeal dysphagia in COPD. Clinically appropriate measures were chosen to investigate the perception of swallowing difficulties and associated impact on quality of life, prevalence of biomechanical dysphagia and nature of respiratory-swallow pattern. Secondary objectives explored the nature of the biomechanical dysphagia findings, and the relationship between perception of swallowing skills with biomechanical measures and biomechanical measures with respiratory-swallow pattern analysis. Results using this method do not appear to have been documented in the literature previously by phase of COPD, and are summarised in table 37.

Findings revealed COPD subjects in this study have statistically lower perceived swallowing skills than normal healthy age matched peers; negatively impacting on their quality of life. Findings also revealed a statistically significant deterioration in perception and objectively measured swallowing ability during exacerbation phase when compared with stable phase. Although not all findings reached statistical significance, the results of the study detailed in this thesis may provide clinically important information; as highlighted by interest generated through awards and conference presentations (see Appendix 13), and is explored further in the next chapter.

Table 37: Summary of findings by objective.

OBJECTIVE	OUTCOME
<p><b>ONE</b></p>	<p><b><i>COPD subjects in this study were statistically more likely to:</i></b></p> <ul style="list-style-type: none"> <li>• Perceive their swallowing ability lower than normal healthy controls (p&lt;0.01).</li> <li>• Perceive their swallowing ability lower during exacerbation phase than stable phase of their condition (p=0.012).</li> <li>• Perceive their swallowing related quality of life lower than normal healthy controls (p&lt;0.01 for all domains)</li> <li>• Perceive their swallowing related quality of life lower during exacerbation phase than stable phase of their condition (Eating duration and desire, p=0.021, Fear, p=0.043).</li> </ul>
<p><b>TWO</b></p>	<p><b><i>For 50% or more of trials:</i></b></p> <ul style="list-style-type: none"> <li>• 70% of COPD subjects during stable phase were considered dysphagic on drink swallows, increasing to 100% during exacerbation phase.</li> <li>• 20% of COPD subjects during stable phase were considered dysphagic on food swallows, increasing to 64% during exacerbation phase.</li> <li>• No subject aspirated drink or food trials for more than 50% of trials during stable phase; however 21% of subjects aspirated drink trials during exacerbation phase.</li> </ul> <p><b><i>COPD subjects in this study showed statistically more swallows during exacerbation phase:</i></b></p> <ul style="list-style-type: none"> <li>• As 'overall' dysphagic for food (p=0.046) and drink (p=0.035)</li> <li>• As penetrated for drink swallows (p=0.031)</li> <li>• As using spontaneous manoeuvres for food swallows (p=0.044)</li> </ul>
<p><b>THREE</b></p>	<p>A non statistically significant difference, but clinically relevant finding was seen as <b><i>COPD subjects in this study used inhalation post swallow for 50% or more of trials during stable phase:</i></b></p> <ul style="list-style-type: none"> <li>• For 74% of food and 66% of drink swallows</li> </ul> <p><b><i>And during exacerbation phase:</i></b></p> <ul style="list-style-type: none"> <li>• For 74% of food and 61% of drink swallows.</li> </ul>

# **Chapter Seven**

## **Discussion**

## **Chapter Seven: Discussion**

### **7.1 Introduction**

People with Chronic Obstructive Pulmonary Disease (COPD) frequently report difficulty with eating and drinking. However there has been a dearth of previous research interest which has resulted in a limited evidence base regarding true prevalence or the nature of oropharyngeal dysphagia in this population; and how oropharyngeal dysphagia contributes to the onset, frequency or severity of exacerbations. Furthermore, the impact of swallowing related quality of life as experienced by people with COPD is also under researched. The study detailed in this thesis aimed to address this lack of evidence and inform statistical power required for future longitudinal studies in patients with COPD. This was achieved by using an innovative research design, incorporating triangulation methodology to assess the extent and nature of oropharyngeal dysphagia by phase of COPD.

This chapter discusses the statistically and clinically significant findings within the study detailed in this thesis (reported in chapter six), and compares this new information with current knowledge within the literature. Additionally, this chapter considers the clinical implications of the findings, the limitations of this study and highlights areas requiring further exploration.

## **7.2 Literature**

The literature review provided in chapters two and three revealed the normal and normal age swallow has been previously well documented (Logemann, 1988; Martin-Harris, Brodsky, Michel, & Lee, et al., 2007). Similarly, aberrations to the swallow pattern have also been well documented in neurological and non neurological aetiologies such as stroke and head and neck cancer (Leslie, 2010). However, a review revealed paucity in the evidence base regarding the prevalence and nature of oropharyngeal characteristics in patients with COPD; a progressive pulmonary disease. Nevertheless, the strong evidence base for normal swallow patterns combined with the limited literature investigating COPD swallows was used to inform the methodological design of this study and compared to findings within this study.

Subsequent to protocol development and data collection within this study, four studies (Gross, Atwood, Ross, & Olszewski, et al., 2009; McKinstry, Tranter, & Sweeney, 2009; Terada, Muro, Ohara, & Kudo, et al., 2010; Cvejic, Harding, Churchward, & Turton, et al., 2011), one systematic review (O'Kane & Groher, 2009) and editorial (Singh, 2011) were published, pertinent to this study's design and findings. Although these articles were not published in time to inform research design, they were reviewed in the relevant chapters of this thesis and are included within the discussion alongside this study's findings.

### **7.3 Research Findings**

The study detailed in this thesis added new information regarding the extent and nature of oropharyngeal dysphagia in patients with COPD to the body of knowledge, using an innovative and highly replicable research design. A repeated measures design was enlisted to assess COPD subjects in exacerbation phase and followed up in stable phase which focused on three main objectives; perception of swallow and swallow related quality of life, biomechanical swallow and respiratory-swallow pattern. Secondary objectives explored the interaction between these three assessment measures. Findings are now discussed alongside evidence within the literature.

#### **7.3.1 Objective one: Perception of swallow and swallow related quality of life.**

Objective one aimed to compare perception of physiological dysphagic symptoms and swallowing related quality of life between normal healthy controls and by phase of COPD. This was measured using the pre validated SWAL-QOL<sub>(ab)</sub> (McHorney, Robbins, Lomax, & Rosenbek, et al., 2002).

##### ***7.3.1i) Perceived oropharyngeal dysphagia symptoms***

The 'symptom' domain in the SWAL-QOL<sub>(ab)</sub> measured common physiological signs and symptoms related to oropharyngeal dysphagia; such as 'coughing on food/drink', 'food getting stuck in the throat' or 'problems chewing'. This domain was inversely related to symptoms; the lower the



score the higher the perceived difficulty, with a score of 56 or lower indicating a frequent occurrence of perceived difficulty. There were 30% of COPD subjects in this study during stable phase (n=3), and 71% during exacerbation phase (n=10) who scored 56 or lower in this domain, with none of the normal healthy control group subjects scoring lower than 56 (n= 36). Non parametric testing revealed COPD subjects in this study perceived their physiological swallowing ability as significantly lower than the normal healthy control group ( $p<0.001$ ); with a significant deterioration during exacerbation when compared to stable phase ( $p=0.012$ ).

To date, there is no known published study that has used the SWAL-QOL with COPD subjects to estimate true prevalence (as reported by patient experience) or evaluate changes by phase of COPD. McHorney and Robbins et al (2002) developed the SWAL-QOL using populations previously diagnosed as dysphagic, and reported the questionnaire was not considered a screening tool. However in a study by Ding and Logemann (2008), correlations between videofluoroscopy ratings and patient self perceptions of swallowing difficulties were high for patients with respiratory diseases (Cramer's  $V= 0.864$ ,  $p<0.001$ ). Furthermore, the SWAL-QOL has been used in other studies with populations not previously diagnosed (or documented) as dysphagic (Genden, Okay, Stepp, & Rezaee, 2003; Lovell, Wong, Low, & Ngo, et al., 2005; Roe, Leslie, & Drinnan, 2007; Bandeira, Azevedo, Vartanian, & Nishimoto, et al., 2008; Greenblatt, Sippel, Levenson, & Frydman, et al., 2009; Leow, Huckabee, Anderson, & Beckert, 2010); as used in this study and discussed in chapter three. Of these studies only Roe and Leslie et al (2007) documented an estimated prevalence (64%, n=11)

from their 'non head and neck cancer' research group receiving palliative care; which is lower than the estimated prevalence found for COPD subjects in the study detailed in this thesis during exacerbation phase, as assessed by the SWAL-QOL 'symptom' domain (71%, n=14).

The majority of studies using the SWAL-QOL documented significant differences in group scores when compared against a normal control group or post intervention within a disease group. Leow et al (2010) and McHorney and Robbins et al (2002) (during development of the SWAL-QOL) are the only known studies to compare disease groups against normal healthy controls. Both studies reported normal control mean scores on the 'symptom' domain of 63/70 (mean age= 73 years) and 62/70 (mean age= 73 years) respectively. Surprisingly, the normal healthy control group in this study recorded a median score of 70/70 for the 'symptom' domain, with three close outliers (see section 6.4.1). Evidence within the literature investigating normal swallowing patterns (discussed in chapter two) may highlight reasons for the differences seen between the study detailed in this thesis and control groups reported by Leow and Huckabee et al (2010) and McHorney and Robbins et al (2002). As Logemann (1990) suggests, age is a factor in changes in swallowing pattern; with the median age of 69 years within the study in this thesis which is younger than Leow and Huckabee et al (2010) and McHorney and Robbins et al's (2002) control groups. Gender differences have also been shown in Logemann and Pauloski et al (2002); with the study in this thesis recruiting 69% of women, compared to Leow and Huckabee et al (2010) and McHorney and Robbins et al (2002) recruiting equal numbers of men and women. The study detailed in this thesis used a more rigorous

criteria for the control group to exclude any previous history of smoking; compared to Leow and Huckabee et al (2010) who included subjects who had stopped smoking for five or more years prior to data gathering. A history of 'never smoked' was important within this study's recruitment criteria, to ensure the normal control group did not contain any potentially undiagnosed cases of COPD. Additionally, McHorney and Robbins et al (2002) included recruitment within residential homes with an undisclosed medical history, and therefore may have not have been as 'healthy' as controls recruited for the study in this thesis. Nevertheless, scores over 56/70 were considered within normal limits for this study, thereby categorising all control groups (for this study and within the literature) within the normal range.

Results from COPD subjects in this study also reflect similar findings found in the literature who also used the SWAL-QOL to investigate a specific disease group. Most studies evaluating symptoms of oropharyngeal dysphagia using the SWAL-QOL were with oncological related diseases (Genden, Okay, Stepp, & Rezaee, 2003; Lovell, Wong, Low, & Ngo, et al., 2005; Roe, Leslie, & Drinnan, 2007; Bandeira, Azevedo, Vartanian, & Nishimoto, et al., 2008; Greenblatt, Sippel, Levenson, & Frydman, et al., 2009; Khaldoun, Woisard, & Verin, 2009). Only three of these studies documented 'symptom' domain mean scores for their subjects post surgery; with Banderia and Azevedo et al (2008) and Greenblatt and Sippel et al (2009) reporting scores above 56/70 and Khaldoun and Woisard et al (2009) who reported a mean score of 39/70. Interestingly, the Greenblatt and Sippel et al (2009) study also recorded a pre-surgical symptom mean score which was above 56/70, thereby placing pre-surgical patients within the normal range for this domain. Lower scores in

the Khaldoun and Woisard et al (2009) study may reflect subjects recruited with pharyngeal cancer, as the SWAL-QOL symptom domain is predominated with pharyngeal symptom questions compared to oral symptoms. However this study's findings of COPD subjects during stable phase were similar to Banderia and Azevedo et al (2008) and Greenblatt and Sippel et al's (2009) (pre and post surgery) findings within oral and thyroid cancer surgical subjects respectively, and also findings during feasibility testing for the study in this thesis (Md score 58/70); discussed in section 4.4.1. As the feasibility testing was a mailout/mail in design, respondents came from the community setting (respondents' homes) and therefore more likely to be stable during completion of the questionnaire.

In studies using the SWAL-QOL with disease states other than oncology and with a previous diagnosis of oropharyngeal dysphagia, Leow and Huckabee et al (2010) investigated perceived symptoms in Parkinson's disease (PD), and found a mean score of 49/70 for the 'symptom' domain within the later stage PD group. Similarly, Khaldoun and Woisard et al (2009) reported a mean score of 48/70 for stroke patients with long term oropharyngeal dysphagia. Another finding published after this study's data gathering phase was in McKinstry and Tranter et al (2009), who explored rehabilitation outcomes in chronic respiratory disease subjects previously diagnosed with oropharyngeal dysphagia. Subjects recorded a 'pre intervention symptom domain' mean score of 49/70. However as discussed in section 2.8.5iii, COPD was a majority subgroup of the research sample with 78% of McKinstry and Tranter et al's (2009) subjects diagnosed with COPD. They also do not state inclusion/exclusion criteria or comorbidities, nor do they

state the COPD subject's phase of COPD at the time of assessing pre intervention scores. Nevertheless, all previous studies evaluating known dysphagic populations report scores on the 'symptoms' domain of the SWAL-QOL similar to findings for COPD subjects in the study detailed in this thesis during exacerbation phase; who have not been previously diagnosed with oropharyngeal dysphagia.

### **7.3.1ii) *Perceived swallowing related quality of life***

Six domains of the SWAL-QOL<sub>(ab)</sub> measured swallowing related quality of life; Burden, Eating duration and desire, Food selection, Fear, Mental Health and Social. Non parametric testing revealed COPD subjects in this study perceived their swallowing related quality of life as significantly lower in all six domains when compared with the normal healthy control group (all domains  $p > 0.001$ ), and showed a significant deterioration in two domains during exacerbation phase when compared to stable phase; Eating duration and desire ( $p = 0.021$ ) and Fear ( $p = 0.043$ ). These results suggest COPD subjects in this study take longer to eat a meal, have a reduced appetite, and have increased fear regarding choking on food/drink; significantly more than the normal control group, and significantly more during exacerbations. The remaining quality of life domains evaluated using the SWAL-QOL<sub>(ab)</sub> revealed COPD subjects rated swallowing as being a greater burden in life, had greater difficulty choosing food and drink they feel they could swallow safely, showed greater levels of frustration and anxiety around mealtimes, and

reported a negative impact on social situations significantly more than the normal control group in this study.

Of other studies using the SWAL-QOL, only three documented scores for the quality of life domains (Bandeira, Azevedo, Vartanian, & Nishimoto, et al., 2008; Greenblatt, Sippel, Levenson, & Frydman, et al., 2009; McKinstry, Tranter, & Sweeney, 2009). As with the symptom domain analysis described earlier, swallowing related quality of life mean scores within the literature, and during feasibility testing showed similar findings to median scores during stable phase COPD in the study detailed in this thesis. However McKinstry and Tranter et al's (2009) findings for 'pre intervention' COPD subjects varied; with two scores similar to this study's stable phase COPD findings (Food selection and Eating duration and desire), two scores similar to this study's exacerbation phase COPD findings (Burden and Social), and two scores not matching either phase within the study detailed in this thesis (Fear and Mental Health). This may be due to mixed medical aetiologies, co-morbidities and/or phase of COPD. However, as discussed previously, McKinstry et al's lack of detail regarding recruitment criteria and phase of disease during testing makes it difficult to compare findings. Nevertheless, findings from this study show perceived swallowing difficulties impact patients with COPD. Interestingly, these findings were also captured in patient reports described during case history and clinical suspicion; discussed in chapter one and during feasibility testing (chapter four).

### **7.3.1iii) Further considerations**

The SWAL-QOL is still a relatively new tool, and disease specific clinical validity and clinical significance of scores have yet to be explored. The SWAL-QOL has been validated to be used as a research tool for small samples to evaluate outcomes of intervention, therefore assessing changes in domain scores within subjects. However what has not been established is the threshold of a clinically meaningful change- is a difference of one point meaningful within a clinical situation? Differences in scores between phases of COPD were found to be statistically significant in the findings detailed in this thesis; however further research is also required to ascertain the clinical significance of these differences; which are also addressed in subsequent objectives in this study.

McHorney and Robbins et al (2002) developed the SWAL-QOL using multiple medical conditions; which included 6% of subjects with a primary condition coded as 'obstructive respiratory disease' (n= 23). However results were reported as a group mean and therefore unable to quantify the number of COPD subjects and mean scores that were included within this subgroup. COPD specific SWAL-QOL findings within McKinstry and Tranter et al's (2009) study are inconsistent with findings within the study in this thesis as discussed earlier. This variability of findings may be due to phase of the condition, as addressed within this study; however severity may also effect outcome. In the study detailed in this thesis, recruits were rated as moderate to severe COPD. Whereas during feasibility testing for this thesis, and documented within the McKinstry and Tranter et al (2009) study, recruits were coded as mild to moderate COPD; reflecting the higher scores (and

therefore less dysphagic and swallowing related quality of life issues) shown for the symptom and associated quality of life domains. Additionally, three of the four subjects that did not complete the stable phase of the study in this thesis were coded as severe COPD and rated within the most dysphagic symptoms and associated quality of life. These results highlight the need for further research to ascertain the impact of severity of COPD on oropharyngeal dysphagia.

Feedback during feasibility testing for this thesis revealed responders had difficulty differentiating general COPD symptoms and those caused by swallowing difficulties (n=18). As a result, the domain evaluating fatigue was removed as all questions in this domain proved difficult to differentiate and had the most negative comments; reporting the greatest confusion. However the 'Fear' domain had only one potentially confusing question and was therefore retained due to the potential relevance to the research aim.

However subjects may still have had difficulty differentiating general 'COPD symptoms' from 'swallowing symptoms' when answering the question '*I worry about getting pneumonia*' within this domain. Similarly, subjects with (understandably) limited knowledge into their swallowing skills may have found questions in the 'symptoms' domain; such as '*frequency of coughing*', or '*Having to clear your throat*', difficult to separate from general COPD symptoms. Small, mostly non significant changes between pre and post intervention scores in McKinstry and Tranter et al's (2009) study may also illustrate this point, as once educated on swallowing symptoms, COPD subjects may have increased their awareness and therefore had been better equipped to answer the questions more accurately. Further research may be



required to investigate the sensitivity of the SWAL-QOL within a COPD population.

COPD subjects in this study who self modified their diet may also have had a positive impact on SWAL-QOL scores. Subjects who excluded harder to eat consistencies from their diet (29% in stable phase and 71% during exacerbation phase of COPD) may have reported fewer symptoms resulting in a perceived higher quality of life than those who continued with eating all consistencies, but with increased difficulty during exacerbations. Similarly, levels of personal control and self efficacy (as discussed in section 1.4.2iv) may also have contributed to how subjects perceived their swallowing related quality of life, as diagnosis and severity does not explain the variance in quality of life ratings. However this was beyond the scope of the study detailed in this thesis.

### **7.3.2 Objective Two: Biomechanical swallow characteristics**

The second objective for this study investigated prevalence of biomechanical dysphagia by phase of COPD. Additional secondary objectives explored the nature of the oropharyngeal dysphagia observed, and also compared perception of dysphagic symptoms discussed in section 7.2.1i) with objective biomechanical analysis. This was achieved using the videofluoroscopy assessment, and the 'symptoms' domain scores from the SWAL-QOL. The normal healthy control group did not complete this part of the study as it did not receive Ethic Committee's approval, discussed previously in section 5.2.

### **7.3.2i) Prevalence of oropharyngeal dysphagia in COPD**

Data from videofluoroscopy recordings was translated into four main outcomes for food and drink trials; overall dysphagia diagnosis, penetration of the bolus, aspiration of the bolus and use of spontaneous compensatory manoeuvres. More COPD subjects in this study were considered dysphagic on 50% or more of trials during an exacerbation phase (n=14) for food (64%) and drink (100%) trials, than for food (20%) and drink trials (70%) during stable phase (n=10) as shown in table 22 in chapter six. Non parametric testing was completed using percentage of swallows per subject. This allowed documentation of *all* swallows assessed and highlighted the variability within subjects in order to gain a greater clinical understanding of the nature of oropharyngeal dysphagia in COPD. This study found COPD subjects exhibited a significant deterioration in their swallowing ability, with more dysphagic swallows during exacerbation phase than during stable phase for food (p= 0.046) and drink (p= 0.035) trials.

These findings broadly concur with Coelho (1987) and Good-Fratturelli and Curlee et al (2000) who estimated prevalence of dysphagia in COPD as 71% and 85% respectively; with both noting increased dysphagic characteristics with drink swallows more than solid trials. However as discussed in chapter two, both samples were selected from a pre-existing dysphagia caseload with co-morbidities that may account for dysphagia. When comparing with a well documented disease group, findings in the study detailed in this thesis during stable phase COPD were similar to estimated prevalence of between 30% and 65% for assessment within seven days of acute stroke (Smithard, O'Neill, Park, & Morris, et al., 1996; Wade & Langton Hewer, 1997; Mann,

Hankey, & Cameron, 2000; Pownall, 2009). It is noteworthy that estimated prevalence for drink trials for either phase of COPD in the study detailed in this thesis exceeded estimates of prevalence during the most acute stage of stroke.

### **7.3.2ii) Secondary Objectives**

Swallows may be considered dysphagic if they differ from the acknowledged normal patterns, yet they can still be considered functional, or predict no medical sequelae (such as aspiration pneumonia) from assessment. This next sections endeavoured to explore dysphagic characteristics within the COPD research group further by analysing three key elements of the biomechanical swallow process; penetration, aspiration and use of spontaneous compensatory manoeuvres. Additionally, this objective compared perception of swallow using the 'symptoms' domain of the SWAL-QOL with objective biomechanical measures.

#### *Penetration*

COPD subjects in this study were found to penetrate *on one or more* swallows for 10% of food and 40% of drink trials during stable phase (n=10), and 29% of food and 86% of drink trials during exacerbation (n=14). This concurs with previous findings within the COPD literature (Good-Fratturelli, Curlee, & Holle, 2000; Mahoney, Foo, Goudge, & Scott, et al., 2004; Carney, Sheppard, & Laframboise, 2005). However the findings within the literature

vary by bolus number, type and size, and phase of COPD proving difficult to compare findings with substantial rigor. Current evidence suggests the occurrence of laryngeal penetration increases with age within normal healthy populations (Daniels, Corey, & Hadskey, 2004; McCullough, Rosenbek, Wertz, & Suiter, et al., 2007; Allen, White, Leonard, & Belafsky, 2010). This suggests penetration documented within the study detailed in this thesis, and shown within the literature for COPD is considered within normal limits. However, the study detailed in this thesis is the first known study to explore differences between phases in COPD subjects not previously diagnosed with dysphagia, and revealed a significant increase in rates of penetration of drink trials during exacerbation phase ( $p=0.031$ ). Furthermore, subjects observed to penetrate food and drink reported within the study in this thesis were coded as three (enters the laryngeal vestibule with visible residue remaining) with increased frequency during exacerbation phase. These findings highlight an increased risk of dysphagia when COPD patients become medically unstable, as predicted within other disease states previously diagnosed with dysphagia (Logemann, Pauloski, Rademaker, & Kahrilas, 2002). However a larger sample is required to confirm these preliminary findings.

## *Aspiration*

This is the first known study to compare oropharyngeal aspiration by phase of COPD subjects not previously diagnosed with dysphagia in order to estimate prevalence. Although findings did not reach statistical significance, trace aspiration was noted more during exacerbation phase for drinks and food trials. Rates of aspiration for COPD subjects in this study during *one or more* swallows for food (7%) and drink (57%) trials during exacerbation (n=14); when compared to food (0%) and drink (20%) trials during stable phase (n=10), may provide clinically significant information. Additionally, findings within this study were also similar to the literature for COPD subjects with known dysphagia exploring rates of aspiration. COPD subjects in this study generally concurred with the prevalence of aspiration occurring more during liquid than solids trials (Good-Fratturelli, Curlee, & Holle, 2000; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002). Good-Fratturelli and Curlee et al (2000) reported a large proportion of their sample (42%) aspirated. Whereas Carney and Sheppard et al (2005) was the only study to overtly recruit exacerbation phase subjects, and revealed aspiration during drink trials (10/21) on videofluoroscopy. Both Good-Fratturelli and Curlee et al's (2000) and Carney and Sheppard et al's (2005) study revealed lower rates of aspiration in a known dysphagic population than findings in the study detailed in this thesis for drink trials during exacerbation phase.

Consequently, findings within the study detailed in this thesis may provide clinically significant information regarding the importance of strong pulmonary defences but the findings require further exploration given the modest number of subjects included.

Whether oropharyngeal aspiration within a normal healthy population is considered normal (Beal, Chesson, Garcia, & Caldito, et al., 2004; Butler, Stuart, & Kemp, 2009) or abnormal (Robbins, Hamilton, & Lof, 1992; Allen, White, Leonard, & Belafsky, 2010), the normal healthy population are considered to be more mobile and exhibit strong pulmonary defences to combat aspiration should it occur (Gleeson, Egli, & Maxwell, 1997; Langmore, 1991; Langmore, Terpenning, Schork, & Chen, et al., 1998). This is in direct contrast to patients with COPD who, by the very nature of their disease, have deteriorating lung function alongside reduced mobility and lowered pulmonary defence mechanisms (Donaldson & Wedzicha, 2006). Perhaps trace aspiration; considered insignificant and a normal occurrence in some studies alongside normal lungs defences and mobility, may need to be viewed as more detrimental within a population with reduced lung function. To understand the importance of aspiration for patients with COPD, further longitudinal research should endeavour to explore the health outcomes of unmanaged dysphagia; comparing groups of COPD patients with and without oropharyngeal aspiration (trace or otherwise), rather than exclusively comparing with findings from normal healthy controls.

### *Spontaneous Compensatory Manoeuvres*

Spontaneous manoeuvres for one or more swallows were used by COPD subjects in this study during 40% of food and 80% of drink trials during stable phase (n=10), and 86% of food and 100% of drink trials during exacerbation phase (n=14). Furthermore, non parametric testing revealed COPD subjects

in this study used significantly more spontaneous compensatory manoeuvres for food trials during exacerbation phase than during stable phase ( $p=0.044$ ). Yet findings for both consistencies (regardless of phase of COPD) may provide clinically significant information when compared with normative information documented within the literature. Descriptive analysis revealed COPD subjects in this study provided additional airway protection by spontaneously using compensatory manoeuvres. As discussed in chapter two, normal healthy adults irrespective of age do not appear to use spontaneous compensatory manoeuvres during swallowing (Leslie, Drinnan, Ford, & Wilson, 2005; Perlman & He, 2006). Therefore the use of spontaneous manoeuvres as seen in this study may reflect an underlying oropharyngeal dysphagia and a subconscious effort to compensate for difficulties; more so (with or without success) during exacerbation phase within this study.

Teaching compensatory manoeuvres can be part of a Speech and Language Therapy intervention plan when a patient has oropharyngeal dysphagia, as discussed in section 2.6. However none of the COPD subjects in this study had received swallowing advice or were taught compensatory manoeuvres prior to recruitment. Therefore they all spontaneously developed strategies in order to feel safer when eating and drinking. Interestingly, some of the techniques observed are recognised manoeuvres taught by Speech and Language Therapists to improve the efficiency and safety of the swallow (Logemann, 1998). Previous studies in the literature have also revealed that patients with progressive and degenerative diseases naturally develop functional compensations or tolerances to swallowing difficulties (Logemann,

1999; Hadjikoutis, Pickersgill, Dawson, & Wiles, 2000). With this in mind, the use of spontaneous manoeuvres may have positively influenced the amount of penetration and aspiration observed in the study detailed in this thesis as discussed earlier. By spontaneously using compensatory manoeuvres, COPD subjects in the study detailed in this thesis may have successfully avoided aspirating a bolus, and/or produced a swallow that was coded as dysphagic (by using a manoeuvre) but functional. This may be further highlighted by the relatively high proportion of subjects considered dysphagic compared with a lower proportion observed to penetrate or aspirate. Additionally, the increased proportion of penetration and aspiration seen during exacerbation phase may indicate that spontaneous manoeuvres may not be as effective during exacerbations for COPD subjects in this study. The findings emerging from this preliminary study confirm that larger scale studies on the use and effectiveness of spontaneous compensatory manoeuvres by phase of COPD is merited.

#### *Perception of swallow verses videofluoroscopy*

The 'symptom' domain on the SWAL-QOL was compared with the 'overall dysphagic' score from videofluoroscopy (both discussed earlier) to investigate whether patient perception of physiological swallow correlated with objective biomechanical measurement. A negative relationship was expected; the lower the score on the symptom domain, the higher the percentage for the 'overall dysphagia' section. Findings revealed a small to moderate relationship which was not statistically significant between stable



food ( $r = -0.480$ ,  $p > 0.05$ ) and drink swallows ( $r = -0.145$ ,  $p > 0.05$ ), however exacerbation phase trials did not produce the expected negative relationship.

McHorney and Martin-Harris et al (2006) suggest the SWAL-QOL provides a relative independence of dysphagia specific QOL and biomechanical function and results should provide 'varied but complimentary information about the patient'. This is certainly true regarding the QOL domains as these areas explore the perceived impact of swallowing on the patient; acknowledged within the literature to differ from objective measures (Wilson & Cleary, 1995). However, information on the 'symptoms' domain clearly state questions pertaining to oral and pharyngeal physiological dysphagic symptoms, questions also found in dysphagia specific functioning questionnaires for head and neck cancer (Chen, Frankowski, Bishop-Leone, & Herbert, et al., 2001) and therefore should correspond to more objective measures. Interestingly, McHorney and Martin-Harris et al (2006) explored the relationship between the SWAL-QOL and videofluoroscopic assessment with known dysphagics, but excluded correlational analysis from the findings between the symptom domain and videofluoroscopy results without explanation. Furthermore, videofluoroscopies were historical measurements from outpatient clinics and SWAL-QOL was completed up to three months post videofluoroscopy using a mail out/mail in system; hence videofluoroscopy may have been completed during an acute phase, and SWAL-QOL completed during stable dysphagia. It is noted that McHorney and Martin-Harris et al (2006) used penetration/aspiration rates to correlate with the quality of life domain. As discussed earlier, symptoms of swallowing difficulties are not always associated with pathophysiological markers of

dysphagia, therefore using a true representation of the swallow; such as an 'overall dysphagic' rating as used in this study which includes more dysphagic characteristics than just penetration/aspiration rates, may provide more relevant information. However the study detailed in this thesis recruited a small sample and larger longitudinal studies are required to confirm these preliminary findings.

### **7.3.3 Objective Three: Respiratory-swallow pattern**

The final objective of this study aimed to investigate the respiratory-swallow pattern used in stable and exacerbation phases of COPD, and to explore the relationship between the respiratory-swallow pattern and biomechanical assessment. This was achieved by simultaneously assessing respiration surrounding the swallow during videofluoroscopy analysis using a Limited Polysomnogram (LPSG), and the 'overall dysphagic' score obtained in objective two. The normal healthy control group did not complete this part of the study as it did not receive Ethic Committee's approval, as discussed previously.

#### ***7.3.3i) Respiratory-swallow pattern***

Data from LPSG readings were translated into four main respiratory-swallow patterns; inhalation-swallow-inhalation (INH/INH), exhalation-swallow-inhalation (EXH/INH), inhalation-swallow-exhalation (INH/EXH) or exhalation-swallow-exhalation (EXH/EXH). This study was interested in the

variation of pattern within subjects and the use of inhalation post swallow (either INH/INH or EXH/INH patterns) increasing the risk of aspiration; as predicted by Martin-Harris and Brodsky et al (2003). Descriptive analysis revealed the COPD subjects in this study used inhalation post swallow for one or more swallows for 100% of food and drink trials during stable phase, and 93% and 100% for food and drink trials respectively during exacerbation phase. Non parametric testing revealed a non-statistically significant difference for COPD subjects in this study, suggesting they were *no more likely* to use inhalation post swallow during stable or exacerbation phase.

Although findings did not reach statistical significance, descriptive analysis may provide clinically significant information. COPD subjects in this study revealed an altered respiratory-swallow pattern from the well documented normal pattern within the literature discussed in chapter three; which acknowledges exhalation *post swallow* as the predominant pattern used by normal healthy adults (Selley, Flack, Ellis, & Brooks, 1989; Smith, Wolcove, Colacone, & Kreisman, 1989; Shaker, Ren, Townsend, & Dodds, et al., 1992; Martin, Shaker, & Dodds, 1994; Paydarfar, Gilbert, Poppel, & Nassab, 1995; Preiksaitis, Mayrand, Robins, & Diamant, 1992; Klahn & Perlman, 1999; Gross, Atwood Jnr, Grayhack, & Shaiman, 2003; Martin-Harris, Brodsky, Michel, & Ford, et al., 2005). The (non statistically significant) altered respiratory-swallow pattern found in the study detailed in this thesis cannot be accounted for by increasing age, as the majority of studies suggest age does not alter this pattern (Zamir, Ren, Hogan, & Shaker, 1996; Hiss, Treole, & Stuart, 2001; Hirst, Ford, Gibson, & Wilson, 2002;

Charbonneau, Lund, & McFarland, 2005; Leslie, Drinnan, Ford, & Wilson, 2005; Kelly, Huckabee, Jones, & Carroll, 2007).

The high proportion of the preferred aberrant respiratory-swallow pattern for drink trials found in the study in this thesis also cannot be accounted for by bolus volume or delivery. This study used a bolus volume of 10ml self delivered by small cup; instructed to swallow 'in their own time' which has been shown in the literature not to influence respiratory-swallow pattern (Nishino & Hiraga, 1991; Dozier, Harris, Brodsky, & Michel, et al, 2006; Martin-Harris, 2008). Food trials that require chewing; as used in this study, have been shown in the literature to vary the use of respiratory-swallow patterns in normal populations (Matsuo, Palmer, & Hiemae, 2006; Gross, Atwood, Ross, & Olszewski, et al., 2009). However if this was the case, findings in the study in this thesis would have expected to show a difference in pattern between food and drink trials, yet the proportion of inhalation post swallow for food and drink trials were relatively equal. Therefore this may not be the only factor to influence the respiratory-swallow pattern for food trials.

Deviation to the normal respiratory-swallow coupling has been acknowledged in the literature to be due to disease or disorder, as discussed in chapter three. Additionally, two studies investigating the respiratory-swallow pattern in COPD subjects also suggest disease is a factor in altering this pattern (Shaker, Ren, Townsend, & Dodds, et al., 1992; Gross, Atwood, Ross, & Olszewski, et al., 2009). The use of strict inclusion criteria, bolus volume and delivery, alongside historical normative and COPD findings in the literature, enables findings in this study to conclude that disease is most

likely a contributing factor in altering respiratory-swallow pattern in COPD in this study.

### *Swallow Apnoea*

Swallow apnoea duration during the respiratory-swallow pattern was measured from videofluoroscopy recordings matched with LPSG readings. Descriptive analysis revealed median scores for apnoea duration in stable phase was 1.6 seconds (0.960-2.00 sec) for drink trials and 1.2 seconds (1.00-2.70 sec) for food trials; and 1.6 seconds (0.850-2.80 sec) and 1.5 seconds (0.830-4.00 sec) for drink and food trials respectively during exacerbation phase. Earlier work within the literature suggests swallow apnoea duration is shorter than the pharyngeal stage duration of (approximately) 750 milliseconds (Love & Webb, 1996). However findings in this study tend to concur with more recent studies that suggest swallow apnoea can be initiated within the oral preparatory and oral stages of the swallow, or continue after the pharyngeal stage has completed (discussed in chapter two) (Martin-Harris, Brodsky, Price, & Michel, et al., 2003; Martin-Harris, Brodsky, Michel, & Ford, et al., 2005), thereby observing longer apnoea durations than previously known. This finding may also confirm the use of spontaneous compensatory manoeuvres seen in objective two (see section 6.5.2iii); the majority of which employed by subjects require increase airway protection; subsequently increasing apnoeic durations. The observed longer swallow apnoea durations may also account for the low rates of aspiration found in this study. This concurs with a study by Nilsson and Ekberg et al (1997) who suggested shorter swallow apnoea and longer pharyngeal transit times increased the incidence of aspiration and

penetration. However Martin-Harris and Brodsky et al (2005) found healthy patients over the age of 81 exhibited longer swallow apnoeas (mean=1.69 seconds) when compared to a younger group (21-40years, mean=1.04 seconds). Age may have been a factor contributing to the increased duration of swallow apnoea within the findings in the study detailed in this thesis; however it is most likely that the significant use of spontaneous compensatory manoeuvres (that require longer airway closure) is also a major contributing factor. The impact of eliciting spontaneous manoeuvres on swallow apnoea duration requires further larger scale research to confirm this potentially clinically significant finding.

### **7.3.3ii) *Respiratory-swallow pattern verses biomechanical analysis.***

The final objective explored the relationship between the predominant respiratory phase used post swallow by COPD subjects in this study (inhalation) with 'overall dysphagic' ratings documented in objective two to investigate if the use of inhalation post swallow was a contributing factor to dysphagic characteristics. However there was no significant relationship in either phase of COPD for food or drink trials found. A likely factor contributing to this result may have been the lack of variability within the sample, with scores clustered in the higher observations for both inhalation post swallow and swallows considered dysphagic.

Methodology and data analysis within this objective was unique, as it investigated the relationship using a range of dysphagic characteristics, such

as impaired chewing, premature loss of the bolus, oral and pharyngeal residue, delay pharyngeal initiation, as well as aspiration scores by phase of COPD. Other studies that have explored the respiratory-swallow pattern have either not commented on observed simultaneous swallow function (Martin-Harris, Brodsky, Price, & Michel, et al., 2003; Gross, Atwood, Ross, & Olszewski, et al., 2009) or correlated the respiratory pattern with rates of penetration and/or aspiration only (Nilsson, Ekberg, Bulow, & Hindfelt, 1997; Martin-Harris, Brodsky, Michel, & Ford, et al., 2005; Dozier, Harris, Brodsky, & Michel, et al., 2006; Cvejic, Harding, Churchward, & Turton, et al., 2011). Of these, Nilsson and Ekberg et al (1997) used dysphagic stroke patients, whilst Martin-Harris and Brodsky et al (2005) and Dozier and Harris et al (2006) aimed to explore normal patterns. Unsurprisingly the latter two studies found no aspiration or penetration among normal subjects and subsequently no significant respiratory-swallow pattern correlation. However Nilsson and Ekberg et al (1997) did not comment on respiratory phases surrounding the swallow, therefore cannot be compared with findings in this study. Interestingly, Cvejic and Harding et al (2011) found aspiration occurred in more stable COPD subjects (4/16) than normal controls (1/15) ( $p=0.07$ ), with a preferred respiratory-swallow pattern in COPD subjects of INH/EXH than normal controls ( $p=0.02$ ) during 100ml drink trials. However the relationship between respiratory-swallow pattern and rates of aspiration was not documented.

## **7.4 Overall considerations**

This study aimed to estimate true prevalence within a general COPD population. As COPD and oropharyngeal dysphagia are complex conditions, it would be impossible to obtain a truly homogeneous sample population. However we can exclude some factors in an attempt to make the sample population as homogeneous as possible. It is noteworthy that subjects were classified as moderate to severe COPD as per COPD NICE Clinical Guidelines 12 (National Collaborating Centre for Acute and Chronic Conditions., 2004); guidelines in practice at the time of protocol development and data collection. However subjects would have been classified as severe to very severe within the revised guidelines (National Clinical Guideline Centre, 2010).

Subjects included in the study were not previously diagnosed with dysphagia, had no co-morbidities that may account for the study's findings, however 11/14 met one or two of the five independent predictors of aspiration pneumonia (reduced locomotion and altered diet) (Langmore, Skarupski, Park, & Fries, 2002).

Previous studies have reported prevalence within their findings (Coelho, 1987; Good-Fratturelli, Curlee, & Holle, 2000) including the development of the SWAL-QOL (McHorney, Robbins, Lomax, & Rosenbek, et al., 2002); however recruitment was obtained from pre-existing or historical Speech and Language Therapy caseloads (see section 2.8). This would endeavour to provide an estimated prevalence within a subgroup of COPD patients. In my opinion, these studies cannot estimate true prevalence; and I concur with O'Kane and Groher's (2009) systematic review of the literature, stating no



previous literature has provided an estimate of true prevalence of oropharyngeal dysphagia in the COPD population. Estimates using patient perception and biomechanical assessment; by phase of COPD shown in the study detailed in this thesis, is the first known study to provide estimates of true prevalence within a general COPD population.

The study detailed in this thesis was also interested in investigating the detrimental effects of dysphagia on health and wellbeing in patients with COPD. Therefore a repeated measures design was used to follow subjects up during stable phase once they had been discharged from hospital. This allowed findings from the study to evaluate the progressive 'decompensation' of the swallow, rather than measuring just an acute episode (Langmore, Skarupski, Park, & Fries, 2002). Additionally, a quality of life measurement was included in this study to provide a holistic perspective of the impact of dysphagia, which is not routinely included in assessment procedures or management decisions (Higginson & Carr, 2001). However the literature acknowledges that quality of life is highly individual, and a standardised, 'forced choice' questionnaire struggles to truly capture the essence of what is important to a particular individual. In my opinion, inclusion of both patient perspective and clinical judgement is crucial within research to ensure future holistic intervention strategies become embedded within the evidence base.

Findings in this study were reported *per subject* and also as a '*percentage of swallows*' *per subject* for objectives two and three. Most studies in the literature investigating oropharyngeal dysphagia report findings 'per subject' (Coelho, 1987; Logemann, Pauloski, Rademaker, & Kahrilas, 2002; Mokhlesi, Logemann, Rademaker, & Stangl, et al., 2002); whereas studies

analysing the respiratory-swallow pattern tend to report their findings as percentage of swallows per subject (Klahn & Perlman, 1999; Charbonneau, Lund, & McFarland, 2005; Kelly, Huckabee, Jones, & Carroll, 2007; Gross, Atwood, Ross, & Olszewski, et al., 2009). Both types of analysis provide valuable information and therefore were utilised in the study in this thesis where appropriate (see chapter five). Estimating prevalence requires information analysed per subject; and for this study a dysphagic characteristic or respiratory-swallow pattern that was observed in 50% or more of the swallows for food and/or drink trials was included. A figure of 50% or more of trials was chosen to ensure the characteristic or pattern observed did not occur by chance; not always as rigorously administered within the literature. However this measure excludes characteristics or patterns that occur less than 49%; therefore further non parametric analysis on the data used percentage of swallows per subject which highlighted the variability *within* subjects.

Non parametric testing in this study employed dependent (Wilcoxon Signed Rank Test) and independent analysis (Mann Whitney U Test) within subjects (stable verses exacerbation phase) and between subjects (COPD verses normal control) respectively. This method of analysis increased the statistical validity within this study's small sample size (Machin, Campbell, & Walters, 2010). However due to Wilcoxon Signed Rank Tests using related sets of data, four subjects who did not complete stable phase of the study were omitted from this part of the analysis. When these subjects are included into data analysis (therefore treating stable and exacerbation phases as two independent sets of data), then COPD subjects were shown to aspirate and

penetrate on drink trials significantly more during exacerbation phase than during stable phase of COPD. This highlights the importance of the findings of the study in this thesis; however a larger sample size is required to confirm these findings.

## **7.5 Potential Causes of Oropharyngeal Dysphagia in COPD**

This study focused on increasing the evidence base in attributing COPD with oropharyngeal dysphagia, with some interesting statistically and clinically significant results. However with all diagnoses of dysphagia, it is important to not only identify symptoms, but to also understand the potential cause.

Some studies in the literature attribute oropharyngeal dysphagia as a consequence of ageing (Beal, Chesson, Garcia, & Caldito, et al., 2004; Butler, Stuart, & Kemp, 2009). However there is more robust evidence to suggest normal age swallowing is not associated with aspiration of bolus, use of spontaneous manoeuvres, or perceived lowered swallowing related quality of life (Robbins, Hamilton, & Lof, 1992; Allen, White, Leonard, & Belafsky, 2010).

More recently however, research interest has focused on altered lung volume and/or reduced subglottic pressure as contributing factors to oropharyngeal dysphagia. Historically swallowing and breathing mechanisms were considered to be independent of each other, with more current evidence acknowledging breathing and swallowing to be interconnected via central pattern generators found in the medulla, with sensory receptors found in the pharynx and larynx as previously discussed (discussed in chapter

two). Gross and Steinhauer et al (2006) further postulated that the larynx is not just an organ for vocalisation, but contains mechanoreceptors in the subglottis which are important in providing sensory feedback to the medulla; ensuring a safe and efficient swallow. They hypothesise that these subglottic mechanoreceptors are dependent on lung volume; with higher lung volumes creating sufficient subglottic pressure to stimulate the mechanoreceptors. High lung volumes would place respiration *post swallow* in exhalation phase (either end inhalation or mid exhalation phases during swallow apnoea); confirmed by findings on the respiratory-swallow pattern in normal adults (Martin-Harris, Brodsky, Michel, & Ford, et al., 2005). As shown in objective three of this study and in the literature (Shaker, Ren, Townsend, & Dodds, et al., 1992; Gross, Atwood, Ross, & Olszewski, et al., 2009), patients with COPD tend to inhale post swallow predominately more than historic normals; placing their swallows in low lung volumes, thereby reducing pressure on the subglottic mechanoreceptors and increasing the duration of the pharyngeal stage. The altered respiratory-swallow pattern induced by COPD may be a significant contributing factor to oropharyngeal dysphagia, however further research is required to confirm this theory.

## **7.6 Limitations of the Study**

This study provided preliminary information to inform future studies in areas such as statistical power, research design, and recruitment and retention issues using a prescribed sample size. A larger sample would have provided more statistical information however was challenging to obtain for a number of reasons; mostly related to ethical requirements, time and budget constraints. As the subjects were not originally from a Speech and Language Therapy caseload, ethical considerations added extra challenges to the recruitment procedure and payment was required for videofluoroscopy sessions and research team involvement. Two years of protected research time (two days per week) from my normal clinical duties was allocated to complete the study. With strict research ethics and governance protocols requiring a stringent application procedure completed; this allowed 10 months for the recruitment phase. Under ethics stipulation, recruitment was required to be undertaken by Dr RL (Respiratory Consultant part of the research team), and once initial consent was gained, I was then permitted to approach the potential subject to finalise consent and initiate assessments. A more straight forward recruitment selection process would have been to use a pre-existing Speech and Language Therapy caseload, enabling the potential subjects to be approached directly. However one of the aims of the study was to gain true prevalence of oropharyngeal dysphagia in patients with COPD; therefore this recruitment selection pathway was deemed unsatisfactory for the needs of this study. Although the method utilised in this study improved on the recruitment process compared to those reported within the literature (dysphagic patients), it still only recruited a subgroup of COPD patients; that is patients admitted to hospital who were willing to

consent to the study. This is further highlighted by this study recruiting only moderate and severe COPD subjects, as mild COPD patients tended to be managed at home (National Clinical Guideline Centre, 2010). This weakness may be overcome by using a wider recruitment selection process to capture community and hospital based COPD patients, however this would have incurred larger costs and challenges with subject recruitment processes which were beyond the scope of this preliminary study.

The study detailed in this thesis used strict inclusion/exclusion criteria to strengthen the statistical validity of the results; yet this in turn may have limited the clinical validity of the findings. Approximately 15% (6/39) of potential subjects were excluded due to co-morbidities with known associations with oropharyngeal dysphagia. Such strict inclusion criteria was imperative in this study as any identified dysphagic characteristics within the research group found needed to be directly associated with a diagnosis of COPD. However it is acknowledged that patients with COPD are associated with multiple co-morbidities (Cosio & Agusti, 2010), with studies showing patients with COPD and co-morbidities such as stroke, further increase the likelihood of developing dysphagia (Ding & Logemann, 2000; Ramsey, Smithard, & Kalra, 2005; Sellars, Bowie, Bagg, & Sweeney, et al., 2007). Future research may be required to explore the effect of one or more co-morbidities alongside a diagnosis of COPD on oropharyngeal dysphagia.

Initial recruitment occurred during admission to hospital due to exacerbation of pre existing COPD. This presented an ethical dilemma as recruitment occurred when the subject was medically unstable; resulting in 10% (4/39) considered too unwell to be included. Given the unpredictable nature of

exacerbations, it would have been challenging to recruit during stable phase with the follow-up phase occurring during exacerbation phase. This was due to subjects being admitted into any Sheffield Teaching Hospital for their exacerbation (or being treated at home), and the inability to 'flag' admissions to the research team due to conflict of confidentiality. Therefore recruiting initially during exacerbation phase was considered the most reliable way to control the follow-up phase of the study, whereby subjects were given a follow-up appointment to attend an outpatient clinic (with Dr RL); alongside completion of the second element of the study once in stable phase. This recruitment process may also have contributed to the low retention rate. Of subjects recruited during exacerbation phase, 28% (n=4) failed to meet criteria to undergo stable phase assessment. However this may also reflect the variability of medical stability and fragility within the subject group.

The study would have also benefitted from a case control design where the control group completed all of the objectives. However the normal healthy control group was only able to complete the SWAL-QOL for objective one of the study due to research ethical and governance stipulations. The small amount of radiation was deemed appropriate for COPD subjects (not already referred) as it was unlikely to be identified with any health detriment from participation in this study (chapter four). Even though normal healthy adults have completed videofluoroscopy assessments under the same circumstances in studies found in the literature (Logemann, Rademaker, Pauloski, & Ohmae, et al., 1998; Logemann, Pauloski, Rademaker, & Colangelo, et al., 2000; Logemann, Pauloski, Rademaker, & Kahrilas, 2002; Cvejic, Harding, Churchward, & Turton, et al., 2011) this was not deemed

satisfactory and therefore declined by the research ethics and governance committee, and the Radiology Department at Sheffield Teaching Hospitals.

Three videofluoroscopy sessions were initially allocated to occur on one day per week, thus recruitment could only take place one to two days per week in order to ensure exacerbation phase assessment was within the first 48 hours of admission (see chapter five). However successful negotiation of additional sessions on a separate day allowed for increased recruitment time over two to three days. Additional to these procedural challenges, COPD admission rates declined during the recruitment phase for two main reasons. Firstly, COPD admission rates show expected seasonal fluctuations, with an estimated 50% increase in exacerbations more likely to occur during the winter months (Donaldson & Wedzicha, 2006). However the recruitment phase in this study coincided mostly during the warmer months. Secondly, Sheffield Teaching Hospitals reported a 50% reduction in COPD admissions as a result of coinciding with a project piloting Telehealth within the COPD population during the recruitment phase of this study (Confederation of British Industry (CBI), 2010).

Data collection and analysis was not blinded to the researcher or the subject. Videofluoroscopy and LPSG readings were subject to interpretation, and subjects may have attempted to 'perform' for the research during videofluoroscopy. To reduce the bias potential this may have created, and to increase the validity of results, inter and intra rater reliability was conducted on all data collection. All data was entered into SPSS twice to highlight any inputting errors and any anomalies within the data before statistical analysis was performed. Interrater reliability was conducted on both LPSG and



videofluoroscopy data, with a 75-100% agreement on main objectives achieved, as documented in chapter six. Furthermore, dichotomous outcome measures for LPSG and videofluoroscopy were selected for their known high interrater reliability. (Martin-Harris, Brodsky, Price & Michel, 2003).

Additionally, subjects were given sufficient information to understand and consent to the research process, but television monitors showing 'live swallows' under x-ray were positioned out of eyesight of the patient, and exact measures and results were not discussed with the subject until after the follow-up was completed during stable phase.

Combining the LPSG use of nasal canula with chest excursion strap readings to measure respiratory movements during the swallow proved vital, as accuracy of nasal canula readings in this study were variable. Possible causes for the reduced efficiency may be the high percentage of subjects requiring oxygen through an additional nasal canula. The flow of oxygen may have disrupted or masked the airflow through the nares; subsequently altering pressure readings within the transducer. This difficulty has not been documented in other studies using nasal canula readings exclusively, nor has the use of providing oxygen via an additional nasal canula been documented within previous studies to allow comparison of findings (Martin-Harris, Brodsky, Michel, & Ford, et al., 2005; Gross, Atwood, Ross, & Olszewski, et al., 2009). Another possible reason may have been the frequency of mouth-breathing during measurement, and therefore not allowing airflow direction to be picked up on the nasal transducer. However, as the use of LPSG machine during videofluoroscopy has not been documented previously in the literature, it is difficult to draw conclusions.

Another issue regarding reliability pertains to combining respiratory and swallow data in order to code respiratory-swallow patterns. Readings from videofluoroscopy and LPSG were measured simultaneously, however data points from the separate recordings required to be combined manually. This was achieved by using the event marker on the LPSG readings (I placed for every start of oral and pharyngeal stage based on live videofluoroscopy monitor pictures), digital timer on the videofluoroscopy readings and ensuring trial presentation was consistent for every subject (three drink, three food, three drink) for ease of corresponding videofluoroscopy readings with LPSG output. Whilst this method proved effective, it was time consuming, as each swallow required individual matching. Other studies have gathered similar data using a 'swallow station'. This machine automatically records and documents respiration alongside the swallow during videofluoroscopy. However this new technology is expensive and was not available within the clinic at Sheffield Teaching Hospitals at the time of this study. Nevertheless, with increased evidence, LPSG alongside videofluoroscopy may prove to be useful in cash strapped clinics in the future. One possible solution to reduce costs of the study would have been to incorporate non-visual instrumentation of the swallow such as electromyography (EMG) instead of using videofluoroscopy; seen within the literature (see chapter two and chapter four). This would have reduced costs as the radiology clinic would not have been required; consequently increasing recruitment potential as assessment could have been performed any working day and at bedside or outpatient clinic, and also be less invasive. However, as discussed previously, the use of non-visual instrumentation would not have provided the same level of

content validity that videofluoroscopy offers, nor would it have been able to provide concurrent data on the physiology of the respiratory-swallow pattern (Martin-Harris, Brodsky, Price, & Michel, et al., 2003) alongside physiological findings of the swallow. In my opinion it would have been methodologically flawed to use non-visual instrumentation in this study when videofluoroscopy; the most predominant method to measure swallowing (Martin-Harris, Brodsky, Michel, & Ford, et al., 2005) was available.

## **7.7 Implications for Clinical Practice**

This study has shown emerging evidence of the potential under-diagnosis and therefore under-management of oropharyngeal dysphagia occurring for patients with COPD. Furthermore, this study provides emerging evidence for incorporating patient wellbeing and respiratory-swallow pattern analysis into the diagnostic and monitoring processes. Once confirmed by larger scale studies in the future, these preliminary findings may have direct implications on clinical practice, and subsequently COPD guidelines and national policies. Current intervention pathways do not acknowledge dysphagia as a risk factor for patients with COPD, nor do guidelines acknowledge dysphagia specialists as part of the core multidisciplinary team or include within pulmonary rehabilitation sessions (National Clinical Guideline Centre, 2010). Perhaps following an increased evidence base, oropharyngeal dysphagia diagnosis and management will be recognised within these essential multidisciplinary team intervention strategies. I would envisage this may encompass the following at a national and multiprofessional level;

- Acknowledging the evidence within government guidelines and national policies.
- Education provided to professionals, patient and carers.
- Risks and symptoms of dysphagia; with referral to Speech and Language Therapy (or dysphagia specialists) included within patient care pathways.
- Dysphagia education given to patients and carers, via individual session and group sessions, such as pulmonary rehabilitation.

However improving quality of care for patients with COPD who are dysphagic may also occur at the level of the Speech and Language Therapist (or dysphagia specialist) in the following way;

- Education in the evidence base for assessing patients with COPD
- Inclusion of respiratory analysis during assessment
- Intervention to include self management techniques, such as respiration-swallow pattern therapy or consistency modification

There appears to be urgency within the NHS to provide leaner, more efficient packages of care with reduced waiting times (Department of Health, 2004).

However, 'packages of care', or group programming alone is unlikely to address specific needs of this patient group. Thus, group sessions would need to be supported by a larger component of individualised assessment and intervention, which can tailor recommendations to support individual needs, such as intervention described in McKinstry and Tranter et al's (2009) study. If future evidence supported that oropharyngeal dysphagia

deteriorated alongside increasing severity of COPD, early screening and monitoring protocols which harnesses multidisciplinary teams to maximize and educate early may delay, reduce or even prevent onset of potentially avoidable eating and/or drinking issues. This in turn may impact length or duration of exacerbations and hospital stay, reduce use of antibiotics, stabilize weight or increase quality of life. Such a package of care may turn statements such as '*I stop eating for (up to) seven days*' (discussed in section 1.3) to '*After my assessment and advice provided.... I know how to eat/drink, or I know what is safe/easy to eat/drink when I am unwell*', or '*I know who to contact when I am having difficulties with my swallowing*'.

## **7.8 Implications for Future Research**

The aims and objectives of the study detailed in this thesis tested assumptions and methodological design using the Medical Research Council Health Services and Public Health Research Board's framework for defining and developing complex interventions (2000). These preliminary findings may be furthered within the current theme and or by exploring other questions becoming apparent as the study in this thesis highlighted, which are now discussed.

### **7.8.1 Extending the current research design**

The preliminary study detailed in this thesis completed the first two stages of the MRC framework for development and evaluation of complex interventions (Medical Research Council Health Services and Public Health Research Board, 2000); stages of Development and Feasibility. As such, it explored the current evidence base and the feasibility of employing specific assessment measures and research design to investigate prevalence and the nature of oropharyngeal dysphagia in patients with COPD. Thus findings may inform future studies investigating the final two stages of the MRC Framework (2000); stages of Evaluation and Implementation, and therefore build on methodological design discussed within the study detailed in this thesis (also highlighted within section 7.6) and aid power calculations to estimate expected proportions.

#### ***7.8.1i) Study Design***

Future studies building on preliminary findings detailed in the study within this thesis may benefit from using a prospective, longitudinal, repeated measures cohort study design.

#### ***7.8.1ii) Aims and Objectives***

Using the above study design, future studies may then aim:

- To compare swallowing related quality of life, perception and biomechanical swallowing and respiratory-swallow patterns in normal controls, dysphagic and non dysphagic COPD patients.

- To compare swallowing related quality of life, perception and biomechanical swallowing and respiratory-swallow patterns in dysphagic and non dysphagic COPD patients by severity.
- To compare long term swallowing related quality of life and health changes in normal controls, dysphagic and non dysphagic COPD patients.

#### **7.8.1iii) Study Time Frame**

Due to the longitudinal time frame considered necessary to investigate the impact on quality of life and health, subjects recruited to the subject should be followed up for a minimum of two years. This would allow or seasonal fluctuations observed as discussed previously.

#### **7.8.1vi) Recruitment**

To meet the aims and objectives, I envisage recruitment would be within three main groups;

- 1) COPD patients with dysphagia.
- 2) COPD patients without dysphagia
- 3) Normal healthy matched controls.

This research design and longer time frame would adequately investigate the nature of the swallowing problems in greater depth and any sequelae as the condition progressed.

The two COPD research groups may then be further analysed according to severity of disease (mild, moderate and severe).

It is essential to be able to compare data to healthy age matched peers; however in my opinion when investigating patients with COPD, it is equally important to include a second control group within the methodological design; such as COPD patients without signs of oropharyngeal dysphagia. This would allow the researcher to assess the longitudinal effects of unmanaged dysphagia (with or without trace aspiration), and allow evaluation of any longitudinal detrimental medical complications in an already compromised and deteriorating pulmonary system.

#### **7.8.1v)      *Sample Size***

A cohort study design described above would require a minimum sample size of 539 subjects. This overall sample size estimates 77 subjects will be required within each variable building in a potential 20% fallout rate. Based on standard power calculations (Machin, Campbell, & Walters, 2010), this provides an 80% power and is able to detect a 0.5SD clinically important change in quality of life scores.

If mortality was included within the data analysis, using data from the preliminary study within this thesis would suggest a true rate of mortality would be less than 20%. However, this could either be accounted for by the estimated fallout rate, or could be added to the estimated sample size; which would increase the estimated sample size to be 90 subjects per variable.



### **7.8.1vi)      *Assessment Procedure and inclusion/exclusion criteria***

The three main measures used within the study detailed in this thesis (swallowing related quality of life questionnaire, videofluoroscopy and respiratory-swallow analysis) and inclusion/exclusion criteria revealed a valid approach in measuring patient and clinically relevant variables and therefore could be easily reproduced within a larger scale study. Each group would ideally complete identical assessment measures (as detailed in chapter five with the limitations acknowledged and potential solutions discussed in section 7.6) every 3 months over a two year period.

### **7.8.1vii)      *Data Collection and Analysis***

Data collected to meet potential aims may measure health and quality of life outcomes, such as frequency of:

- Chest infections
- Chest related admissions to hospital or prescription of antibiotics
- Exacerbations
- Mortality

as well as measuring:

- Prevalence and nature of dysphagic characteristics
- Changes in swallowing related quality of life
- Changes in oral regime- diet and fluid consistencies
- Use of swallowing compensatory strategies

As shown by the findings within the study detailed within this thesis, aspiration is only one aspect of oropharyngeal dysphagia; as a patient can be diagnosed as dysphagic with or without aspiration being present.

Therefore including clinically and patient relevant measures within overall outcomes provides a holistic approach to the research design.

### **7.8.1viii) Summary**

Investigations into current evidence base, justifications into methodology combined with preliminary findings within the study detailed in this thesis may be used as a base on to which further investigate dysphagia with patients with COPD.

### **7.8.2 Further Research Questions**

Research tends to highlight more questions than it answers, and as this study progressed, areas in need for further investigation became apparent. Potential research questions for future investigation raised throughout this study have been highlighted within each relevant objective, and are combined in the summary table 37 with other relevant questions now discussed.

Although physiological and survival measures are important outcomes for professionals and patients, they do not fully explore the holistic experience for patient and carer. This study explored patient perception of the impact of swallowing on their quality of life, however it did not include family and/or carers' perceptions of the difficulty, the impact on their quality of life resulting from looking after the person with COPD, nor did it investigate any gender differences. The literature suggests (stereotypically) females tend to do the

shopping and cooking more than their male partners(Arnold, Ranchor, DeJongste, & Koeter, 2005), so could swallowing difficulties directly affect female COPD patients more than males (in the role as the carer or as the COPD patient)? Furthermore could patients with COPD who live alone have reduced swallowing related quality of life; more than patients who live with a spouse, family member or have carers helping with preparation of mealtimes?

Throughout the assessment process subjects in this study (and occasionally their spouse) were interested in discussing their specific swallow idiosyncrasies precipitated from the questionnaire, and were keen to watch a replay of their own swallow assessment under x-ray. Discussion of individual results occurred only after the subject had completed the assessment process of the study (after completion of stable phase). This interest suggests further potential qualitative research; such as inclusion of patient and carer focus groups which is under explored in the literature.

**Table 38: Summary table of potential future research questions evolving from this thesis.**

- What is the clinical significance of changes in quality of life scores between phases of COPD?
- What is the true prevalence and impact on health and wellbeing of oropharyngeal dysphagia by severity of COPD?
- What is the impact of oropharyngeal dysphagia on COPD carer health and wellbeing?
- Are there gender differences in rates of oropharyngeal dysphagia and impact on wellbeing in patients with COPD?
- What is the association between oropharyngeal dysphagia and COPD with or without relevant co-morbidities?
- What are the longitudinal effects of unmanaged oropharyngeal dysphagia; with or without aspiration on health and wellbeing in COPD patients?
- What is the impact of using compensatory manoeuvres on long term health and wellbeing in COPD patients?
- What effect does teaching exhalation post swallow have on COPD health and wellbeing?

## **7.9 Conclusion**

Successful intervention strategies aim to reduce the personal and social burden of COPD by improving patient symptoms, functional status and quality of life (Gupta & Kant, 2009). However prevalence; whether via the clinician's or the patient's perspective, and the nature of the problem must first be established in order to provide good quality, evidence based intervention strategies on which to be based. The theoretical phase of this study revealed there was still a need for research to focus on providing preliminary evidence, and clinical observations confirmed the potential unmet need within the COPD population. Findings from the study detailed in this thesis revealed COPD subjects in this study varied from the normal swallow, and respiratory-swallow pattern documented within the literature; with

increased signs of oropharyngeal dysphagia during exacerbation phase. Additionally, subjects seemed aware of their physiological vulnerability; via the self report swallowing symptoms and swallowing related quality of life questionnaire, and subconsciously enlisted airway protective mechanisms to avoid pulmonary complications. The holistic approach in this study using triangulation methodology has revealed that aspiration is only one aspect of dysphagia. A person with COPD may be considered to exhibit dysphagic characteristics clinically and perceive swallowing difficulties, yet still have a physiologically functional swallow. Due to the complex nature of COPD, multifactorial causes have been shown to contribute to the presence of oropharyngeal dysphagia; with psychosocial and personality traits, and social support system influencing how the patient views the difficulties or attempts to overcome them. We in the medical profession seem increasingly interested in 'whether the patient has aspirated or not', which has been shown to be only part of the wider picture throughout this thesis. There does not have to be a large clinical finding to have a significant impact on quality of life, and this study has shown the importance of incorporating patient reported perception and quality of life issues into assessment and diagnosis to explore dysphagia quality of care more holistically.

This preliminary study has revealed emerging evidence suggesting oropharyngeal dysphagia is more prevalent than previously documented, however larger sample longitudinal studies are still required to confirm these findings. Furthermore, this study may inform future statistical power required and methodological design.

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**McPhee, Kelly (Speech & Language Therapy)**

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**From:** McHorney, Colleen A [colleen\_mchorney@merck.com]  
**Sent:** 09 October 2006 15:08  
**To:** McPhee, Kelly (Speech & Language Therapy)  
**Subject:** RE: SWAL QOL

Kelly, I would be delighted if you used the SWAL-QOL in your studies.

Colleen

---

**From:** Kelly.McPhee@sth.nhs.uk [mailto:Kelly.McPhee@sth.nhs.uk]  
**Sent:** Monday, October 09, 2006 9:18 AM  
**To:** McHorney, Colleen A  
**Cc:** Sue.Pownall@sth.nhs.uk  
**Subject:** SWAL QOL

Dear Dr McHorney,

I am writing to you on behalf of my colleague Sue Pownall, and myself to request permission to use the SWAL-QOL survey as part of our PhD investigations.

We are Speech and Language Therapists undertaking PhDs, supervised by Professor Pam Enderby at the University of Sheffield. The two research projects are:

1. An investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia. (Kelly McPhee)
2. An investigation into whether dysphagic stroke patients managed with thickened fluids have outcomes which are equally as good as patients managed with other Speech and Language Therapy treatment strategies. (Sue Pownall).

---

Yours sincerely  
Kelly  
Kelly McPhee  
Specialist Speech and Language Therapist  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield S10 2JF  
(0114) 2712676

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09/10/2006

## Appendix 2: Field Testing- Ethics and Research and Development approval letters



North Sheffield Ethics Office  
1st Floor Vickers Corridor

Direct Line: 0114 271 4894 or 271 4011  
Fax: 0114 256 2469  
Email: sue.rose@sth.nhs.uk

Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

24 February 2005

Dr Rod Lawson  
Consultant and Honorary Senior Lecturer  
Royal Hallamshire Site  
Sheffield Teaching Hospitals  
Glossop Road  
Sheffield  
S10 2JF

Dear Dr Lawson

**Full title of study:** *What is the extent and impact of dysphagia and undernutrition amongst people diagnosed with chronic obstructive pulmonary disease (COPD)*

**REC reference number:** 05/Q2308/7

Thank you for your letter of 15 February 2005, 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 Chairman.

### 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].

### 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.

**Please ensure the consent form is updated to refer to the correct version and date of the information sheet.**

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type:	Version:	Dated:	Date Received:
Application	2	15/02/2005	17/02/2005
Investigator CV	CI, Student, Supervisor		18/01/2005
Protocol	2	15/02/2005	17/02/2005

An advisory committee to South Yorkshire Strategic Health Authority

Summary/Synopsis		14/01/2005	18/01/2005
Peer Review		14/01/2005	18/01/2005
Copy of Questionnaire	(new contact name noted)		18/01/2005
Letters of Invitation to Participants	To be from consultant in charge of care	17/01/2005	18/01/2005
Consultant Information Sheets		17/01/2005	18/01/2005
Participant Information Sheet	2.2	15/02/2005	17/02/2005
Participant Consent Form	1	17/01/2005	18/01/2005
Response to Request for Further Information		15/02/2005	17/02/2005

#### Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

#### Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the sheet enclosed with the provisional opinion letter dated 9<sup>th</sup> February 2005.

#### Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

#### 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.

<b>05/Q2308/7</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project,

Yours sincerely



**Dr G P M Clark**  
**CHAIRMAN – North Sheffield Research Ethics Committee**

E-mail: [april.dagnall@sth.nhs.uk](mailto:april.dagnall@sth.nhs.uk)

#### Enclosures

*Standard approval conditions*  
*Site approval form (SF1)*

*Copy to: Kelly McPhee (student), Wendy Baird (supervisor)*

Ref: DP/STH13949

4 April 2005

Dr Rod Lawson  
Respiratory Medicine  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield S10 2TJ

Dear Dr Rod Lawson

**Authorisation of project**

STH ref: STH13949

**Study title:** What is the extent and impact of dysphagia and undernutrition amongst people diagnosed with chronic obstructive pulmonary diseases (COPD)?

**Chief Investigator:** Dr Rod Lawson (STH)  
**Principal Investigator:** Ms Kelly McPhee (STH)

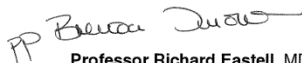
**Sponsor:** Sheffield Teaching Hospitals NHS Foundation Trust  
**Funder:** Trent Focus – University of Nottingham

The Research Department has received the required documentation for the study as listed below:

- |  |                                      |
|--|--------------------------------------|
| 1. STH registration document: completed and signed   | Dr Rod Lawson,<br>18-Jan-2005        |
| 2. Evidence of favourable scientific review          | ScHARR, 14-Jan-2005                  |
| 3. Protocol – final version                          | V2, 15-Feb-2005                      |
| 4. Participant Information sheet – final version     | V2.2, 15-Feb-2005                    |
| 5. Consent forms – final version                     | V1, 17-Jan-2005                      |
| 6. Signed letters of indemnity                       | STH                                  |
| 7. ARSAC / IRMER certificate                         | N/A                                  |
| 8. Evidence of hosting approval from STH directorate | 21-Mar-2005                          |
| 9. Letter of approval from REC                       | North Sheffield LREC,<br>24-Feb-2005 |
| 10. Proof of locality approval                       | N/A                                  |
| 11. Clinical Trial Authorisation from MHRA           | N/A                                  |
| 12. Honorary Contract                                | N/A                                  |
| 13. Associated documents                             |                                      |
| Invitation letter                                    | V2, 17-Jan-2005                      |
| Consultant information sheet                         | V2, 17-Jan-2005                      |
| Questionnaire  | V2, 15-Feb-2005                      |
| 14. Signed financial agreement/contract              | Trent Focus, 20-Oct-2004             |

The project has been reviewed by the Research Department and authorised by the Director of Research on behalf of STH Trust to begin.

Yours sincerely



**Professor Richard Eastell** MD, FRCP (UK, Edinburgh, Ireland), FRCPATH, FmedSci  
Director of Research and Development for the Sheffield Teaching Hospitals Trust  
Telephone +44 (0)114 271 3740, Fax +44 (0)114 261 1790. e-mail [r.eastell@sheffield.ac.uk](mailto:r.eastell@sheffield.ac.uk)

cc: Dr Rod Lawson, Ms Kelly McPhee, STH R&amp;D

## Appendix 3: Field Testing- Participant Pack

17JAN05[v2]

Sheffield Teaching Hospitals 

NHS Foundation Trust

Department of Respiratory Medicine

Royal Hallamshire Hospital

Glossop Road

Sheffield

S10 2JF

(0114) 271 2958

Dear

You are invited to volunteer to take part in a research study relating to COPD (Chronic Obstructive Pulmonary Disease).

You have been invited because you have been seen at the Royal Hallamshire Hospital in the past because of COPD. We hope that by doing this research we can improve care for people with this condition in the future.

Your decision to take part in this research is completely voluntary. It is separate from any care or treatment you receive from the hospitals. That care and treatment will continue whether or not you agree to take part in the research.

I have sent an information sheet to explain the research in detail. When you have read this, if you are happy to take part in the research, please fill in and return the enclosed consent form and questionnaire.

The consent form also asks you to agree to the research team (who work at the Royal Hallamshire Hospital) having access to your hospital records. As always within the hospital, information would be treated carefully to protect your privacy.

If you prefer for any reason not to take part in the research, it would be very helpful if you could let us know.

Many thanks for taking the time to consider this. You are welcome to contact us with any queries or comments should you wish.

Yours sincerely

(Respiratory Consultant)

Centre Number:  
Study Number:  
Patient Identification Number for this trial:

## CONSENT FORM

### Title of Project:

How often does swallowing problems and under-nutrition occur amongst people with chronic obstructive pulmonary disease (COPD) and what are the consequences of this?

Name of Researcher: Ms Kelly McPhee, Mrs Sarah Church, Dr Rod Lawson

### Please initial box

1. I confirm that I have read and understand the information sheet dated 15<sup>th</sup> February 2005 (version 2.2) 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 sections of any of my medical notes may be looked at by the research team (Kelly McPhee, Sarah Church) from [Sheffield Teaching Hospitals NHS Foundation Trust]

I give permission for these individuals to have access to my records.

4. I understand that sections of any of my Dietetic or Speech and Language Therapy notes may be looked at by the research team (Kelly McPhee, Sarah Church,) from [Sheffield Teaching Hospitals NHS Foundation Trust].

I give permission for these individuals to have access to my records.



Centre Number: :  
Study Number:  
Patient Identification Number for this trial:

## CONSENT FORM part 2

### Title of Project:

How often does swallowing problems and under-nutrition occur amongst people with chronic obstructive pulmonary disease (COPD) and what are the consequences of this?

Name of Researchers: Ms Kelly McPhee, Mrs Sarah Church, Dr Rod Lawson

**Please initial box**

5. I agree to complete the survey
6. I am happy for my GP to be advised of my involvement
7. I am happy for my Consultant to be informed of any concerns raised by participating in the study.

Name of Participant \_\_\_\_\_ 2005 \_\_\_\_\_  
Date Signature

Kelly McPhee \_\_\_\_\_ 2005 \_\_\_\_\_  
Researcher Date Signature

2 copies: 1 for participant; 1 for researcher.

## Patient Information Sheet

### Study Title

How often does swallowing problems and under-nutrition occur amongst people with chronic obstructive pulmonary disease (COPD) and what are the consequences of this?

### Invitation

You are being invited to take part in a research study. Before you decide whether you would like to take part, 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You' This leaflet gives more information about medical research and looks at some questions you may want to ask.

A copy may be obtained from CERES, PO Box 1365, London N16 0BW. Thank you for reading this.

### What is the purpose of the study?

In some patients who have Chronic Obstructive Pulmonary Disease it is thought that under-nutrition (shown by weight loss, poor appetite and a reluctance to eat) puts them at risk of repeated admission to hospital and or picking up a chest infection more readily. Under-nutrition is known to occur in patients with COPD but it is not known how many health care professionals actually know how to identify those patients with the risk of developing problems.

The development of Swallowing problems (or dysphagia) is known to increase the risk of the development of a chest infection but it is not known if swallowing problems occur in patients with COPD or whether they are affecting these patients in some way.

The aims of this study is to look at how under-nutrition and swallowing problems are identified by health care professionals but also the amount of patients that are showing signs of any difficulties in these areas.

### Why have I been chosen?

You have been randomly selected for all the patients with COPD related admissions to hospital in the last year. 200 patients are included in the study.

### Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and are asked to sign a consent form. If you decide to take part you are still free to withdraw at

anytime and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

**What will happen to me if I take part?**

There are no plans to see you directly as the study primarily involves looking through your medical and professional notes. There is also a survey we would like you to complete (enclosed).

**What information will be gathered from my medical and professional notes?**

The researchers will look at all hospital admissions over 6 months in 2004 for details of reason for admission, references made to nutritional factors like weight, or weight loss, poor appetite and also to any swallowing difficulties. The professional notes of the Dietitian and Speech and Language Therapists will be accessed if you have had any contact with them during this same time period. They are looking for the reason for getting involved with your care and what treatment was offered.

**What do I have to do?**

If you are happy to be included in the study then you only need to complete the consent form and send it back in the stamped addressed envelope. If you are happy to complete the questionnaire please do so and send back in the same envelope but you do not have to consent to both aspects. Please indicate on the consent form if you have agreed to both.

**What is the procedure that is being tested?**

There is no direct treatment procedure that is being tested in this study.

**What are the side effects of any treatment received when taking part?**

There is no direct treatment planned in this study.

**What are the possible disadvantages and risks of taking part?**

There are no known major disadvantages or risks to taking part in the study. The information collected from the medical notes is about what happened in the past and not related to your current health. The questionnaire does involve some of your time to complete but also it is based on how you feel now and recently so it may leave you with some questions or concerns relating to your health at present. Written information is available relating to these areas of concern if requested or can be discussed with the researchers;

Sarah Church, Dietitian  
Department of Dietetics  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2617

Kelly McPhee, Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF

Telephone 0114 271 2676

**What if I am harmed?**

If you are harmed by your participation in this study there are no special compensation arrangements. If you are harmed due to someone's negligence then you may have grounds for legal action.

**What are the possible benefits of taking part?**

If you are having problems maintaining your weight then you may benefit from the information leaflet enclosed. If there were problems in the past these can only be identified to your Doctors with your permission (see consent form). If from the overall study there are concerns about the process used by health care staff to identify nutritional and swallowing problems then we will be highlighting these to the staff groups and working with them to establish improvements so any future problems will be identified more readily and enable more action taken to support patients directly.

**What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the treatment being studied. This is unlikely as in this study we are not actually doing anything directly to you but if there was a change in your position regarding consent then you can withdraw at any time without prejudice to your care. We would also contact you to discuss continued consent if there were any relevant changes and you would be asked to sign an updated consent form.

**What happens when the research stops?**

If by taking part you have concerns regarding your nutrition and the leaflet does not address these at the time then you can contact the Dietitian or the Speech and language therapist who can offer more support as appropriate but your Doctor can refer you to Dietitian and or the Speech and Language Therapist at any time after the research has finished.

**What if something goes wrong?**

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study. If you have any complaints or concerns please contact ;

Ms Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

Or you can use the normal hospital complaints procedure and contact;  
Professor Chris Welsh  
Sheffield Teaching hospital Trust  
Glossop Road  
S10 2JF

Telephone: 0114 271 1900

**Will me taking part in the study be confidential?**

Information that is collected by you during the course of the research will be kept strictly confidential and will only be held by the lead researcher Kelly McPhee. Any information which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

**What will happen to the results of my study?**

The results from this research will be published at the end of the study and may lead to changes in treatment for you and others who have COPD. A copy of the published results will be sent to you. You will not be identified in any publication. If you want your doctor to be advised of any specific concerns that were picked up by looking through you old medical and therapy notes then please tick the relevant consent box.

**Who is organising and funding the research?**

The lead researcher is Kelly McPhee a Speech and Language Therapist and her co-researcher is Sarah Church a Dietitian who will be organising and conducting the research. Funding for this study is from a grant by Trent Research and Development Unit. The Dietitian and the Speech and Language Therapist are not being paid for including or advising you in the study.

**Who has reviewed the study?**

The North Sheffield Research Ethics Committee and the Sheffield University School of Health and Related Research have reviewed this study.

For further information about this study contact

Ms Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

Thank you for considering taking part in this study. If you do take part you will be given a copy of the information sheet and a signed consent form to keep.

**INSTRUCTIONS FOR COMPLETING THE SURVEY**

Thank you for taking the time to complete this survey. It should take about 15-20 minutes to complete. This survey is to find out if you do, or do not have signs of swallowing difficulties.

If you do not think you have difficulties swallowing, PLEASE CONTINUE TO COMPLETE THE SURVEY ANYWAY. The choices of answers will take into account that you do, or do not feel that swallowing problems are impacting on your everyday life.

If you need help with filling out or sending the survey, or would like to ask more questions about the research, please contact the following number:

Ms. Kelly McPhee  
Research Lead  
Royal Hallamshire Hospital  
(0114) 2712676, OR (0114) 2712533

The survey and consent form can be sent using the enclosed self-addressed envelope.

Ms Claire Scholey  
Secretary  
Respiratory Medicine  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield S10 2JF

**INSTRUCTIONS FOR COMPLETING THE SURVEY**

Please take your time to carefully read and answer each question. Some questions may look like others, but each one is different.

Here's an example of how the questions in the survey will look.

PLEASE CIRCLE ONE NUMBER THAT YOU FEEL DESCRIBES HOW YOU FEEL

1. In the last month, how often have you experienced each of the symptoms below?

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
FEEL WEAK	1	2	3	4	5

Thank you for your help in taking part in this survey.

**IMPORTANT NOTE:** We understand that you may have a number of physical problems. Sometimes it is hard to separate these from swallowing difficulties, but we hope that you can do your best to concentrate **only** on your **swallowing problem**. Thank you for your efforts in completing this questionnaire.

1. Below are some general statements that people with **swallowing problems** might mention. In the last month, **how true** have the following statements been for you.

*(circle one number on each line)*

	<b>Very much true</b>	<b>Quite a bit true</b>	<b>Somewhat true</b>	<b>A little true</b>	<b>Not at all true</b>
Dealing with my swallowing problem is very difficult.	1	2	3	4	5
My swallowing problem is a major distraction in my life.	1	2	3	4	5

2. Below are aspects of day-to-day eating that people with **swallowing problems** sometimes talk about. In the last month, **how true** have the following statements been for you?

*(circle one number on each line)*

	<b>Very much true</b>	<b>Quite a bit true</b>	<b>Somewhat true</b>	<b>A little true</b>	<b>Not at all true</b>
Most days, I don't care if I eat or not.	1	2	3	4	5
It takes me longer to eat than other people.	1	2	3	4	5
I'm rarely hungry anymore.	1	2	3	4	5
It takes me forever to eat a meal.	1	2	3	4	5
I don't enjoy eating anymore.	1	2	3	4	5



3. Below are some physical problems that people with **swallowing problems** sometimes experience. In the last month, **how often** you have experienced each problem as a result of your swallowing problem?

*(circle one number on each line)*

	<b>Almost always</b>	<b>Often</b>	<b>Sometimes</b>	<b>Hardly ever</b>	<b>Never</b>
Coughing	1	2	3	4	5
Choking when you eat food	1	2	3	4	5
Choking when you take liquids	1	2	3	4	5
Having thick saliva or phlegm	1	2	3	4	5
Gagging	1	2	3	4	5
Drooling	1	2	3	4	5
Problems chewing	1	2	3	4	5
Having excess saliva or phlegm	1	2	3	4	5
Having to clear your throat	1	2	3	4	5
Food sticking in your throat	1	2	3	4	5
Food sticking in your mouth	1	2	3	4	5
Food or liquid dribbling out of your mouth	1	2	3	4	5
Food or liquid coming out your nose	1	2	3	4	5
Coughing food or liquid out of your mouth when it gets stuck	1	2	3	4	5

4. Next, please answer a few questions about how your **swallowing problem** has affected your diet and eating in the last month.

*(circle one number on each line)*

	<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
Figuring out what I can and can't eat is a problem for me.	1	2	3	4	5
It is difficult to find foods that I both like and can eat.	1	2	3	4	5

5. In the last month, **how often** have the following statements about communication applied to you because of your **swallowing problem**?

(circle one number on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
People have a hard time understanding me.	1	2	3	4	5
It's been difficult for me to speak clearly.	1	2	3	4	5

6. Below are some concerns that people with **swallowing problems** sometimes mention. In the last month, **how often** have you experienced each feeling?

(circle one number on each line)

	Almost always	Often	Sometimes	Hardly ever	Never
I fear I may start choking when I eat food.	1	2	3	4	5
I worry about getting pneumonia.	1	2	3	4	5
I am afraid of choking when I drink liquids.	1	2	3	4	5
I never know when I am going to choke.	1	2	3	4	5

7. In the last month, how often have the following statements **been true** for you because of your **swallowing problem**?

(circle one number on each line)

	Always true	Often true	Sometimes true	Hardly ever true	Never true
My swallowing problem depresses me.	1	2	3	4	5
Having to be so careful when I eat or drink annoys me.	1	2	3	4	5
I've been discouraged by my swallowing problem.	1	2	3	4	5
My swallowing problem frustrates me.	1	2	3	4	5
I get impatient dealing with my swallowing problem.	1	2	3	4	5

8. Think about your social life in the last month. How strongly would you agree or disagree with the following statements?

*(circle one number on each line)*

	<b>Strongly agree</b>	<b>Agree</b>	<b>Uncertain</b>	<b>Disagree</b>	<b>Strongly disagree</b>
I do not go out to eat because of my swallowing problem.	1	2	3	4	5
My swallowing problem makes it hard to have a social life.	1	2	3	4	5
My usual work or leisure activities have changed because of my swallowing problem.	1	2	3	4	5
Social gatherings (like holidays or get-togethers) are not enjoyable because of my swallowing problem.	1	2	3	4	5
My role with family and friends has changed because of my swallowing problem.	1	2	3	4	5

9. In the last month, **how often** have you experienced each of the following physical symptoms?

*(circle one number on each line)*

	<b>All of the time</b>	<b>Most of the time</b>	<b>Some of the time</b>	<b>A little of the time</b>	<b>None of the time</b>
Feel weak?	1	2	3	4	5
Have trouble falling asleep?	1	2	3	4	5
Feel tired?	1	2	3	4	5
Have trouble staying asleep?	1	2	3	4	5
Feel exhausted?	1	2	3	4	5

10. Do you now take any food or liquid through a feeding tube?

(circle one)

No ..... 1

Yes ..... 2

11. Please circle the letter of the one description below that best describes the consistency or texture of the food you have been eating most often in the last week.

**Circle one:**

- A. Circle this one if you are eating a full normal diet, which would include a wide variety of foods, including hard to chew items like steak, carrots, bread, salad, and popcorn.
- B. Circle this one if you are eating soft, easy to chew foods like casseroles, canned fruits, soft cooked vegetables, ground meat, or cream soups.
- C. Circle this one if you are eating food that is put through a blender or food processor or anything that is like pudding or pureed foods.
- D. Circle this one if you take most of your nutrition by tube, but sometimes eat ice cream, pudding, apple sauce, or other pleasure foods.
- E. Circle this one if you take all of your nourishment through a tube.

12. Please circle the letter of the one description below that best describes the consistency of liquids you have been drinking most often in the last week.

Circle one:

- A. Circle this if you drink liquids such as water, milk, tea, fruit juice, and coffee.
- B. Circle this if the majority of liquids you drink are thick, like tomato juice or apricot nectar. Such thick liquids drip off your spoon in a slow steady stream when you turn it upside down.
- C. Circle this if your liquids are moderately thick, like a thick milkshake or smoothie. Such moderately thick liquids are difficult to suck through a straw, like a very thick milkshake, or drip off your spoon slowly drop by drop when you turn it upside down, such as honey.
- D. Circle this if your liquids are very thick, like pudding. Such very thick liquids will stick to a spoon when you turn it upside down, such as pudding.
- E. Circle this if you did not take any liquids by mouth or if you have been limited to ice chips.

13. In general, would you say your health is:

*(circle one)*

- Poor ..... 1
- Fair..... 2
- Good..... 3
- Very Good..... 4
- Excellent ..... 5

**GENERAL QUESTIONS ABOUT YOU**

1. What is your name? \_\_\_\_\_
2. What is your date of birth? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Day Month Year
3. What is your current BODY MASS INDEX? \_\_\_\_\_  
If you don't know this, please tell us your current:  
WEIGHT \_\_\_\_\_  
HEIGHT \_\_\_\_\_
4. Please tell us (approximately) how many times were you admitted to hospital in the last 6 months because of exacerbation of your COPD or chest infections? \_\_\_\_\_

**PLEASE CIRCLE THE APPROPRIATE ANSWER**

5. Are you MALE .....1.  
FEMALE.....2
6. Which of the following best describes your **main** ethnic origin?  
WHITE BRITISH.....1  
WHITE OTHER.....2  
BLACK AFRICAN.....3  
BLACK CARRIBEAN.....4  
BLACK OTHER.....5  
INDIAN.....6  
PAKISTANI.....7  
BANGLADESHI.....8  
CHINESE.....9  
ASIAN OTHER.....10  
OTHER (PLEASE SPECIFY).....11
7. What is your current marital status?

NEVER MARRIED.....1  
MARRIED.....2  
DIVORCED.....3  
SEPARATED.....4  
WIDOWED.....5

8. Did anyone help you with the survey?

NO, I did it myself.....1  
YES, someone helped me fill it out.....2

9. IF someone helped you fill out this survey, how did that person help you?

Read the questions/wrote the answers.....1  
Answered the questions for you.....2  
Helped in some other way.....3

**LAST PAGE**

**COMMENTS:**

Do you have any comments about the survey? We welcome your comments about the survey in general or about specific questions, especially any that were unclear or confusing for you.

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Please send the consent form and the survey in the self addressed envelope provided in the pack. If you have difficulty posting this, please contact Kelly McPhee on 0114-2712676.

**Thank you for completing the survey.**



## Appendix 4: Evaluation Stage; Ethics and Research and Development approval letters



### National Research Ethics Service

#### North Sheffield Local Research Ethics Committee

1st Floor Vickers Corridor  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Telephone: 0114 271 4011  
Facsimile: 0114 256 2469

17 May 2007

Ms Kelly McPhee  
Highly Specialist Speech and Language Therapist  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
S10 2JF

Dear Ms McPhee

**Full title of study:** A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health.  
**REC reference number:** 07/Q2308/32

Thank you for your letter of 25 April 2007, 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 Chairman.

#### 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 favourable opinion applies to the research sites listed on the attached form.

#### 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.

***In the paragraph "What will happen if I decide not to continue" in the patient information sheet, "with your permission" should be added to the statement that you will need to keep the data.***

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber 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

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application		02 March 2007
Investigator CV		01 February 2007
Investigator CV	Student	01 February 2007
Protocol	3	01 April 2007
Summary/Synopsis	2	01 December 2006
Letter from Sponsor		01 March 2007
Peer Review		
Interview Schedules/Topic Guides	2	01 December 2006
Questionnaire - SWAL - QOL		
Advertisement	for focus group	
GP/Consultant Information Sheets	1	01 March 2007
Participant Information Sheet: research group	3	01 April 2007
Participant Information Sheet: control group	2	01 April 2007
Participant Information Sheet: focus groups	1	01 April 2007
Participant Consent Form: focus group	1	01 April 2007
Participant Consent Form	1	01 March 2007
Response to Request for Further Information		25 April 2007
Radiation Protection Adviser's Letter		27 December 2006
invite letter research	2	01 April 2007
Invite letter control	2	01 April 2007

### R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from  
<http://www.rdforum.nhs.uk/rdform.htm>.

### 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.

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The National Research Ethics Service (NRES) represents the NRES directorate within  
 The National Patient Safety Agency and Research Ethics Committees in England

**Feedback on the application process**

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

<https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx>

**We value your views and comments and will use them to inform the operational process and further improve our service.**

07/Q2308/32	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



**Dr C A Moore**  
Chairman – North Sheffield Research Ethics Committee

Email: [april.dagnall@sth.nhs.uk](mailto:april.dagnall@sth.nhs.uk)

**Enclosures:**                    *Standard approval conditions [SL-AC1 for CTIMPs, SL-AC2 for other studies]*  
   *Site approval form*

**Copy to:**                         Sheffield Teaching Hospitals R & D Department (sponsor)

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The National Research Ethics Service (NRES) represents the NRES directorate within  
The National Patient Safety Agency and Research Ethics Committees in England

Ref: STH14598/GMcV

- |   |  |
|---|--|
| <b>7. Signed letters of indemnity</b>   | Standard NHS/University Indemnity applies  |
| <b>8. ARSAC / IRMER certificate</b>   | RPA Assessment, Giles Morrison, dated 5/4/2007<br>STH Finance Form signed by Giles Morrison 2/1/07, Wendy Inman 16/4/06 & Dr Michael Collins 12/4/07 |
| <b>9. Evidence of hosting approval from STH directorate</b>                                     | Dr C Austin, STH Finance Form, 16/4/07<br>Rev M Cobb, STH Finance Form, 23/4/07  |
| <b>10. Evidence of approval from STH Data Protection Officer</b>                                | Peter Wilson, STH Finance Form, 16/4/07  |
| <b>11. Letter of approval from REC</b>  | North Sheffield REC, 07/Q2308/32, 17/5/07  |
| <b>12. Proof of locality approval</b>   | North Sheffield REC, 07/Q2308/32, 17/5/07  |
| <b>13. Clinical Trial Authorisation from MHRA</b>   | N/A  |
| <b>14. Honorary Contract</b>  | N/A - Kelly McPhee is employed by the Sheffield PCT and there is a formal contract between PCT and STH in place.                                     |
| <b>15. Associated documents</b>   |  |
| <b>Advert<br/>Invitation letter from control group<br/>Invitation letter for research group</b> | No version/date<br>Version 2, April 2007<br>Version 2, April 2007  |
| <b>16. Signed financial agreement/contract</b>  | STH Finance Form, J Broscomb & T Smeeton April 2007  |

The project has been reviewed by the Research Department and authorised by the Director of R&D on behalf of STH NHS Foundation Trust to begin.

Yours sincerely



**Professor S Heller**  
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust  
Telephone +44 (0) 114 2713740  
Fax +44 (0) 114 2711790

**North Sheffield Local Research Ethics Committee**  
**LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION**

*For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.*

<b>REC reference number:</b>	07/Q2308/32	<b>Issue number:</b>	0	<b>Date of issue:</b>	17 May 2007
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**Chief Investigator:** Ms Kelly McPhee

**Full title of study:** A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health.

*This study was given a favourable ethical opinion by North Sheffield Local Research Ethics Committee on 23 May 2007. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.*

<b>Principal Investigator</b>	<b>Post</b>	<b>Research site</b>	<b>Site assessor</b>	<b>Date of favourable opinion for this site</b>	<b>Notes <sup>(1)</sup></b>
Ms Kelly McPhee	Highly Specialist Speech and Language Therapist	Sheffield Teaching Hospitals NHS Foundation Trust	North Sheffield Local Research Ethics Committee	17/05/2007	

Approved by the Chair on behalf of the REC:

*A. P. [Signature]* (delete as applicable) *Assistant* (Signature of Chair/Co-ordinator)

*April Devereux* (Name)



## National Research Ethics Service

**North Sheffield Local Research Ethics Committee**  
1st Floor Vickers Corridor  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Telephone: 0114 271 4011  
Facsimile: 0114 256 2469

10 July 2007

Ms Kelly McPhee  
Highly Specialist Speech and Language Therapist  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
S10 2JF

Dear Ms McPhee

**Full title of study:** A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health.  
**REC reference number:** 07/Q2308/32

Thank you for your letter of 31 May 2007, responding to the Committee's request for a minor change to the information sheet. The following document has been received:

- Information sheet (for research group) version 4 dated May 2007

This is now the approved version of this information sheet. Apologies for the delay in replying to your correspondence.

### 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.

**07/Q2308/32**

**Please quote this number on all correspondence**

Yours sincerely

**Mrs A Dagnall**  
Admin Assistant – North Sheffield Research Ethics Committee

Email: [april.dagnall@sth.nhs.uk](mailto:april.dagnall@sth.nhs.uk)

Copy to: Sheffield Teaching Hospitals R & D Department (sponsor)

This Research Ethics Committee is an advisory committee to Yorkshire and The Humber 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*

Ref: STH14598/GMcV

Date: 31 May 2007

Ms K McPhee  
Speech & Language Therapy Dysphagia Specialist  
SLT Department  
Royal Hallamshire Hospital  
Sheffield  
S10 2JF

Dear Ms McPhee

**Authorisation of project**

**STH ref:** STH14598

**Study title:** An investigation into the association between chronic obstructive pulmonary disease (COPD) and dysphagia during stable and exacerbation phases of the disease, and its impact on quality of life and health services.

**Chief Investigator:** Prof Pam Enderby, University of Sheffield

**Principal Investigator:** Ms Kelly McPhee, STH

**Sponsor:** STH

**Funder:** Respiratory Medicine Department, RHH

The Research Department has received the required documentation for the study as listed below:

- |  |  |
|--|--|
| 1. Sponsorship IMP studies (non-commercial)        | N/A  |
| Sponsorship responsibilities between institutions  | N/A  |
| Responsibilities of investigators                  | N/A  |
| Monitoring Arrangements                            | N/A  |
| 2. STH registration document: completed and signed | Kelly McPhee, COREC Form, 2/3/07   |
| 3. Evidence of favourable scientific review        | STH, 20/3/07   |
| 4. Protocol – final version                        | Version 3, April 2007  |
| 5. Participant Information sheet – final version   |  |
| <b>Research Group</b>                              | Version 3, April 2007 amended as requested by ethics and now Version 4, May 2007 |
| <b>Focus Group</b>                                 | Version 1, April 2007  |
| <b>Control Group</b>                               | Version 2, April 2007  |
| 6. Consent form – final version                    |  |
| General consent                                    | Version 1, March 2007  |
| Consent form for focus groups                      | Version 1, April 2007  |



## Appendix 5: Evaluation Stage; COPD letter of invitation, information letter and consent form

Participant invitation research COPD April 2007 V2

Sheffield Teaching Hospitals   
NHS Foundation Trust

Department of Respiratory Medicine  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
S10 2JF  
(0114) 271 2958

Date:

Dear

You are invited to volunteer to take part in a research study relating to COPD (Chronic Obstructive Pulmonary Disease). The title of the study is 'A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health'. The aim of the research is to investigate swallowing skills in people with COPD.

You have been invited because you have been diagnosed with COPD, and may or may not have swallowing problems. We hope that by doing this research we can improve care for people with this condition in the future.

Your decision to take part in this research is completely voluntary. You will also be free to withdraw at any stage without reason. It is separate from any care or treatment you receive from the hospitals. Your care and treatment will continue whether or not you agree to take part in the research.

Enclosed is an information leaflet, which explains the research in detail. Please read it carefully, you may wish to talk to your family about it too. Kelly McPhee (Speech and Language Therapist) or I will be happy to answer any questions you or your family have. If you agree to take part in the research, Kelly McPhee will talk through the research steps again, and what it will involve, and then ask you to sign a consent form.

All information gathered for the research will be kept strictly confidential and only the research team will have access to it.

If you prefer for any reason not to take part in the research, it would be very helpful if you could let us know.

Many thanks for taking the time to consider this. You are welcome to contact us with any queries or comments should you wish, on 271 2676, or 271 2958.

Yours sincerely



Dr Rod Lawson  
Consultant Respiratory Medicine



Chairman: David Stone OBE • Chief Executive: Andrew Cash OBE



**Information Sheet (for research group)**

**Study Title**

A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia (swallowing difficulties), and its impact on health.

**Invitation**

You are being invited to take part in a research study. Before you decide whether you would like to take part, 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of the study?**

The development of swallowing problems (or dysphagia) is known to increase the risk of developing chest infections. It is unknown if swallowing problems occur in patients with COPD and if so how it affects health and quality of life.

The aim of this study is to explore any links between COPD and swallowing ability and its impact on health.

This study is a student project undertaken as part of postgraduate studies (PhD).

**Why have I been chosen?**

You have been chosen because you have been diagnosed with COPD with no other medical conditions.

**Do I have to take part?**

It is completely up to you to take part in the study. If you do decide to take part in the study, you will be given this information sheet to keep and are asked to sign a consent form. You will be able to withdraw from the study at anytime and without giving a reason.

Either taking part or refusing to take part in the study will not affect your standard of care.

**What will happen if I decide not to continue with the study?**

If you withdraw from the study, we will destroy all identifiable information, but, with your permission, we will need to use the data collected up to the time of your withdrawal.



**Information Sheet (for research group)**

**Study Title**

A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia (swallowing difficulties), and its impact on health.

**Invitation**

You are being invited to take part in a research study. Before you decide whether you would like to take part, 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of the study?**

The development of swallowing problems (or dysphagia) is known to increase the risk of developing chest infections. It is unknown if swallowing problems occur in patients with COPD and if so how it affects health and quality of life.

The aim of this study is to explore any links between COPD and swallowing ability and its impact on health.

This study is a student project undertaken as part of postgraduate studies (PhD).

**Why have I been chosen?**

You have been chosen because you have been diagnosed with COPD with no other medical conditions.

**Do I have to take part?**

It is completely up to you to take part in the study. If you do decide to take part in the study, you will be given this information sheet to keep and are asked to sign a consent form. You will be able to withdraw from the study at anytime and without giving a reason.

Either taking part or refusing to take part in the study will not affect your standard of care.

**What will happen if I decide not to continue with the study?**

If you withdraw from the study, we will destroy all identifiable information, but, with your permission, we will need to use the data collected up to the time of your withdrawal.



**What will happen to me if I take part?**

You will be asked to attend two videofluoroscopy sessions (x-ray of your swallow which is explained more below) at the Royal Hallamshire Hospital Radiology clinic. These sessions will take place once during your inpatient admission at the Royal Hallamshire Hospital, and once on the same day as your outpatient follow-up appointment. During these sessions, you will be asked to complete a questionnaire and have your swallowing and respiratory skills recorded in the radiology department. Swallowing skills assessment will use a drink and a biscuit with barium (Barium helps the food and drink show up on the x-ray). Your breathing pattern will be recorded at the same time as your swallowing. It is not painful and should take about 15-20 minutes.

The results of your videofluoroscopy will be discussed with you directly after the examination. If the examination shows some difficulty with swallowing, we will also discuss contacting your GP, consultant and refer you to the Speech and Language Therapy service for further assessment and advice, once you have consented.

**What information will be gathered from my medical and professional notes?**

You will be asked to consent the researcher to gain information from your hospital medical notes and from your GP. Information gathered from these sources will be severity of COPD, Forced expiratory volume in one second (FEV<sub>1</sub>), number of hospital admissions, number of chest infections and number of antibiotics in a certain time frame

**What do I have to do?**

If you are happy to be included in the study then you need to complete the consent form. The lead researcher will organise two videofluoroscopy appointments with you and your medical team.

**What is the procedure that is being tested?**

Videofluoroscopy is an examination used to look at your swallow in the radiology clinic. We do this by using an x-ray machine which gives us moving images to record. During the examination, you will be asked to eat some biscuit and drink some water. These will include barium, which helps the food and drink show up on the x-ray. It does not hurt, you can eat and drink normally before the examination, and you can wear your normal clothing throughout the session.

Your breathing will be examined at the same time as your swallow. It will be recorded using a belt across your chest, which will record you breathing in and out.

Before you go into the videofluoroscopy session, you will be asked to complete a questionnaire and how you think you are swallowing.

The whole session should take about 15-20 minutes.

The procedure will be recorded for later analysis. All recordings will be coded so you will not be identified at a later date and stored in a locked cabinet.

**What are the side effects of any treatment received when taking part?**

Most people have no side effects from this examination. The barium should clear from your body within 24 hours.

**What are the possible disadvantages and risks of taking part?**

There are no known disadvantages to taking part in the study. Participation in this study requires you to have two x-ray videos taken while you are swallowing. The total radiation exposure you will receive is equivalent to approximately 14 months' natural background radiation. The Health Protection Agency Radiation Protection Division describes exposures equivalent to 'a few years' natural background radiation as 'Low Risk'. Since you will receive less than this it is unlikely that you would notice any additional health detriment arising from the exposure.

You may feel you have some questions or concerns after the examination and can be discussed at the time, or contact Kelly McPhee in the future:

Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

**Will taking part in the study be confidential?**

Information collected during the course of the research will be coded and kept strictly confidential. Only the research team will have access to your information during the study. When the study is finished, all recordings will be destroyed. Any information that leaves the hospital will have your name and address removed, so that you cannot be recognised from it.

**What are the possible benefits of taking part?**

We cannot promise the study will help you, but the information we get from this study will help improve the treatment of people with chronic obstructive pulmonary disease (COPD).

**What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the treatment being studied. We would also contact you to discuss continued consent if there were any relevant changes and you would be asked to sign an updated consent form.

**What if I am harmed?**

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against Sheffield Teaching Hospital NHS Foundation Trust, but you may have to pay for your legal costs. The Normal National Health Service (NHS) complaints mechanisms will still be available to you (if appropriate).

**What will happen to the results of the study?**

The results from this research will be published at the end of the study and may lead to changes in treatment for you and others who have COPD. A copy of the published results will be sent to you. You will not be identified in any publication.

**Who is organising and funding the research?**

The lead researcher is Kelly McPhee, a Speech and Language Therapist. There is no specific funding allocated to this research project. The study is sponsored by Sheffield Teaching Hospitals NHS Foundation Trust.

**Who has reviewed the study?**

The North Sheffield Research Ethics Committee has favourably reviewed this study in February 2007.

**What if something goes wrong?**

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study. If you have any complaints or concerns please contact ;

Ms Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

Or you can use the normal hospital complaints procedure and contact;

Dr Simon Hellor  
Sheffield Teaching hospital Trust  
Glossop Road  
S10 2JF  
Telephone: 0114 271 1900

For further information about this study contact

Ms Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language Therapy  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

Thank you for considering taking part in this study. If you do take part you will be given a copy of the information sheet and a signed consent form to keep.

Centre Number:  
Study Number:  
Participant Identification Number for this trial:

## CONSENT FORM

### Title of Project:

A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia (swallowing difficulties), and its impact on health.

Name of Researcher: Ms Kelly McPhee

**Please tick box to consent**

1. I confirm that I have read and understand the information sheet dated April 2007 (version 3) for the above study and have had the opportunity to ask questions.	<input type="checkbox"/>
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.	<input type="checkbox"/>
3. I consent to the research team to access my medical notes from Sheffield Teaching Hospitals NHS Foundation Trust	<input type="checkbox"/>
4. I consent to the research team contacting my GP to advise of involvement in the study and to gain medical information specific to the study.	<input type="checkbox"/>
5. I consent to participate in the study.	<input type="checkbox"/>

\_\_\_\_\_  
**Participant Name**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Researcher Name**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Witness Name**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature**

2 copies: 1 for participant; 1 for researcher.



Chairman: David Stone OBE • Chief Executive: Andrew Cash OBE

## Appendix 6: Evaluation Stage; COPD Group- letter to GP

COPD GP April 2007 Version2

Sheffield Teaching Hospitals **NHS**

NHS Foundation Trust

Department of Respiratory Medicine  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield S10 2JF  
(0114) 2712958

Date:  
Study Number: STH14598

Dear Dr

**Re: Research Title: A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health.**

**Name of Participant:**

Mr/s \_\_\_\_\_ has volunteered to be included in the above research and consented for the research team to contact you ask request medical information. **The research team would therefore be grateful if you could forward a printout of medication prescribed over the last two years using the self addressed envelope provided.** The research team consists of Dr Rod Lawson (Respiratory Consultant) and Kelly McPhee (Speech and Language Therapist). This study was approved by North Sheffield Local Research Ethics Committee on 17 May 2007.

The main objective of the study is to explore the link between respiration and swallowing disorders, and the significance of exacerbations and severity of disease.

The study will require Mr/s \_\_\_\_\_ to complete a questionnaire on swallowing ability and undergo videofluoroscopy and respiration assessment during one exacerbative phase (during inpatient admission at the Royal Hallamshire Hospital) and one stable phase (during outpatient follow-up appointment at the Royal Hallamshire Hospital) of their COPD. This assessment will be conducted at the Royal Hallamshire Hospital Sheffield in 2007/8. Dr Rod Lawson will be responsible for their medical care during their admission and outpatient follow-up sessions.

**We would be grateful for this information within two weeks of receipt of this letter.**

If you have any questions regarding this letter or the study, please contact either myself on (0114) 271 2958 or Kelly McPhee (0114) 2712676 or via email: [Kelly.McPhee@sth.nhs.uk](mailto:Kelly.McPhee@sth.nhs.uk).

Yours sincerely



Dr Rod Lawson  
Consultant Respiratory Medicine

## Appendix 7: Evaluation Stage; Control Group- Letter of invitation and information letter.

Participant invitation control COPD April 2007 V2

Sheffield Teaching Hospitals 

NHS Foundation Trust

Department of Respiratory Medicine  
Royal Hallamshire Hospital  
Glossop Road  
Sheffield  
S10 2JF  
(0114) 271 2958

Date: 20 November 2007

Dear Sir/Madam,

You are invited to volunteer to take part in a research study investigating swallowing skills in people with Chronic Obstructive Pulmonary Disease (COPD). The title of the study is 'A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia, and its impact on health'.

You have been invited because you do not have COPD, any swallowing problems, or have any known medical conditions that may cause swallowing problems (such as a stroke or Parkinson's disease). Your information will be compared with information gathered from people diagnosed with COPD. We hope that by doing this research we can improve care for people with this condition in the future.

Your decision to take part in this research is completely voluntary and anonymous. You will also be free to withdraw at any stage without reason by not returning the questionnaire.

Enclosed is an information leaflet, which explains the research in detail, and a questionnaire. Please read it carefully, you may wish to talk to your family about it too. Kelly McPhee (Speech and Language Therapist) or I will be happy to answer any questions you or your family have. If you agree to take part in the research, please complete the questionnaire enclosed in the pack, it should take approximately 15 minutes. Please return the questionnaire using the stamped, self-addressed envelope included.

All information gathered for the research will be kept strictly confidential and only the research team will have access to it.

If you prefer for any reason not to take part in the research, it would be very helpful if you could let us know.

You are welcome to contact us with any queries or comments should you wish, on 271 2676, or 271 2958.

Yours sincerely



Dr Rod Lawson  
Consultant Respiratory Medicine



Chairman: David Stone OBE • Chief Executive: Andrew Cash OBE



### Information Sheet (control group)

#### Study Title

A preliminary investigation into the association between chronic obstructive pulmonary disease (COPD) and oropharyngeal dysphagia (swallowing difficulties), and its impact on health.

#### Invitation

You are being invited to take part in a research study. Before you decide whether you would like to take part, 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 and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

#### What is the purpose of the study?

The development of swallowing problems (or dysphagia) is known to increase the risk of developing chest infections. It is unknown if swallowing problems occur in patients with COPD and if so how it affects health and quality of life.

The aim of this study is to explore any links between COPD and swallowing ability and its impact on health.

This study is a student project undertaken as part of postgraduate studies (PhD).

#### Why have I been chosen?

You have been chosen because you do not have any swallowing problems, and have no known medical conditions that may cause swallowing problems.

#### Do I have to take part?

It is completely up to you to take part in the study. If you do decide to take part, you will be given this information sheet to keep. You will be able to withdraw from the study at anytime and without giving a reason by not returning the questionnaire.

#### What will happen to me if I take part?

There are no plans to see you directly as the study. You will be asked to complete a questionnaire (enclosed).

#### What do I have to do?

If you are happy to be included in the study then you need to complete the questionnaire and sent it in the stamped, self addressed envelope enclosed. There is no need to put your name on the questionnaire. It should take about 10-15 minutes to complete.



**What is the procedure that is being tested?**

The questionnaire will ask you about your swallowing ability and if you experience any difficulties with eating and drinking.

**What are the side effects of any treatment received when taking part?**

There are no known side effects from completing this questionnaire.

**What are the possible disadvantages and risks of taking part?**

There are no known disadvantages to taking part in the study.

You may feel you have some questions or concerns after completing the questionnaire, and these can be discussed by contacting Kelly McPhee:

Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

**Will taking part in the study be confidential?**

The questionnaire will not ask for your name or any identifying information. All information given will be kept strictly confidential and accessed only by the research team according to Sheffield Teaching Hospital policy.

**What are the possible benefits of taking part?**

The information we get from this study will help improve the treatment of people with chronic obstructive pulmonary disease (COPD).

**What if I am harmed?**

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against Sheffield Teaching Hospital NHS Foundation Trust, but you may have to pay for your legal costs. The Normal National Health Service (NHS) complaints mechanisms will still be available to you (if appropriate).

**What will happen to the results of the study?**

The results from this research will be published at the end of the study and may lead to changes in treatment for people who have COPD.

**Who is organising and funding the research?**

The lead researcher is Kelly McPhee, a Speech and Language Therapist. There is no specific funding allocated to this research. This study is sponsored by Sheffield Teaching Hospitals NHS Foundation Trust.

**Who has reviewed the study?**

The North Sheffield Research Ethics Committee has favourably reviewed this study in April 2007.

**What if something goes wrong?**

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study. If you have any complaints or concerns please contact;

Ms Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language therapy  
Claremont Crescent  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

Or you can use the normal hospital complaints procedure and contact;  
Professor Chris Welsh  
Sheffield Teaching hospital Trust  
Glossop Road  
S10 2JF  
Telephone: 0114 271 1900

*For further information about this study contact*

Ms Kelly McPhee  
Speech and Language Therapist  
Department of Speech and Language Therapy  
Royal Hallamshire Hospital  
S 10 2 JF  
Telephone 0114 271 2676

Thank you for considering taking part in this study. If you do take part you will be given a copy of the information sheet and a signed consent form to keep.

## Appendix 8: Evaluation Stage; Control Group- Biographical questions requested at the end of the SWAL-QOL<sub>(ab)</sub>

COPD SWAL-QOL

### GENERAL QUESTIONS ABOUT YOU

1. What is your date of birth? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Day Month Year

2. What is your current BODY MASS INDEX? \_\_\_\_\_

If you don't know this, please tell us your current:

WEIGHT \_\_\_\_\_

HEIGHT \_\_\_\_\_

#### PLEASE CIRCLE THE APPROPRIATE ANSWER

3. Are you MALE .....1.  
FEMALE.....2

4. Do you have a history of smoking? YES/NO  
If yes, how often and how many years? \_\_\_\_\_

5. Have you been diagnosed with any of the following medical conditions?  
SWALLOWING PROBLEMS 1  
STROKE 2  
PARKINSONS DISEASE 3  
MOTOR NEURON DISEASE 4  
CANCER OF MOUTH OR THROAT 5

OTHER: Please state: \_\_\_\_\_

6. Which of the following best describes your **main** ethnic origin?

- WHITE BRITISH.....1
- WHITE OTHER.....2
- BLACK AFRICAN.....3
- BLACK CARRIBEAN.....4
- BLACK OTHER.....5
- INDIAN.....6
- PAKISTANI.....7
- BANGLADESHI.....8
- CHINESE.....9
- ASIAN OTHER.....10
- OTHER (PLEASE SPECIFY).....11

7. What is your current marital status?

- NEVER MARRIED.....1
- MARRIED.....2
- DIVORCED.....3
- SEPARATED.....4
- WIDOWED.....5

8. Did anyone help you with the survey?

- NO, I did it myself.....1
- YES, someone helped me fill it out.....2

9. IF someone helped you fill out this survey, how did that person help you?

- Read the questions/wrote the answers.....1
- Answered the questions for you.....2
- Helped in some other way.....3

COPD SWAL-QOL

**COMMENTS:**

Do you have any comments about the survey? We welcome your comments about the survey in general or about specific questions, especially any that were unclear or confusing for you.

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Thank you for completing the survey.

## Appendix 9: Evaluation Stage; COPD Group- SWAL-QOL<sub>(ab)</sub>

COPD SWAL-QOL

### SWAL-QOL (ABRIDGED) SELF REPORT QUESTIONNAIRE:

<b>INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE</b>
--

Thank you for taking time to complete this questionnaire.

Please take your time to carefully read and answer each question, *even if you do not think you have a problem swallowing*. Some questions may look like others, but each one is different.

Here is an *example* of how the questions look like:

Please circle one number that you feel describes how you feel:

1. In the last week, how often have you experienced each of the symptoms below as a result of your swallowing?

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
FEEL WEAK	1	2	3	4	5

SWAL-QOL questionnaire continued:

**IMPORTANT NOTE:** We understand that you may have a number of physical problems. Sometimes it is hard to separate these, but we hope that you try to concentrate only on your swallowing ability when answering these questions.

1. In the last week, ***how true*** have the following statements been for you as a result of your swallowing?

Circle one number on each line.

	VERY MUCH TRUE	QUITE A BIT TRUE	SOMEWHAT TRUE	A LITTLE TRUE	NOT AT ALL TRUE
Dealing with my swallowing is very difficult	1	2	3	4	5
Swallowing is a major distraction in my life	1	2	3	4	5

2. In the last week, ***how true*** have the following statements been for you as a result of your swallowing?

Circle one number on each line.

	VERY MUCH TRUE	QUITE A BIT TRUE	SOMEWHAT TRUE	A LITTLE TRUE	NOT AT ALL TRUE
Most days, I don't care if I eat or not.	1	2	3	4	5
It takes me longer to eat than other people	1	2	3	4	5
I'm rarely hungry anymore	1	2	3	4	5
It takes forever to eat a meal	1	2	3	4	5
I don't enjoy eating anymore	1	2	3	4	5



SWAL-QOL questionnaire continued:

3. In the last week, **how often** have you experienced each of these symptoms as a result of your swallowing?

Please circle one number on each line.

	VERY MUCH TRUE	QUITE A BIT TRUE	SOMEWHAT TRUE	A LITTLE TRUE	NOT AT ALL TRUE
Coughing	1	2	3	4	5
Choking on food	1	2	3	4	5
Choking on liquids	1	2	3	4	5
Have thick saliva or phlegm	1	2	3	4	5
Gagging on food or drink	1	2	3	4	5
Drooling	1	2	3	4	5
Problems chewing	1	2	3	4	5
Having excess saliva or phlegm	1	2	3	4	5
Having to clear your throat	1	2	3	4	5
Food sticking in your throat	1	2	3	4	5
Food sticking in your mouth	1	2	3	4	5
Food or liquid dribbling out of your mouth	1	2	3	4	5
Food or liquid coming through your nose	1	2	3	4	5
Coughing food or liquid out of your mouth when it gets stuck	1	2	3	4	5

## SWAL-QOL questionnaire continued

4. In the last week, ***how often*** have you experienced the following feeling as a result of your swallowing?

Please circle a number on each line.

	STRONGLY AGREE	AGREE	UNCERTAIN	DISAGRE E	STRONGLY DISAGREE
Figuring out what I can and can't eat is a problem for me.	1	2	3	4	5
It is difficult to find foods that I both like and can eat	1	2	3	4	5
I fear I may start choking when I eat food	1	2	3	4	5
I worry about getting pneumonia	1	2	3	4	5
I am afraid of choking when I drink liquids	1	2	3	4	5
I never know when I am going to choke	1	2	3	4	5

5. In the last week, ***how often*** have the following statements been true for you as a result of your swallowing?

Please circle one number on each line.

	ALWAYS TRUE	OFTEN TRUE	SOMETIMES TRUE	HARDLY EVER TRUE	NEVER TRUE
My swallowing depresses me	1	2	3	4	5
Having to be so careful when I eat and drink annoys me	1	2	3	4	5
I have been discouraged by my swallowing	1	2	3	4	5
My swallowing frustrates me	1	2	3	4	5
I get impatient dealing with me swallowing.	1	2	3	4	5

*SWAL-QOL questionnaire continued.*

6. In the last week, ***how strongly*** would you agree or disagree with the following statements as a result of your swallowing?

Please circle one number on each line.

	<b>STRONGLY AGREE</b>	<b>AGREE</b>	<b>UNCERTAIN</b>	<b>DISAGREE</b>	<b>STRONGLY DISAGREE</b>
I do not go out to eat because of my swallowing issues	1	2	3	4	5
My swallowing issues make it hard to have a social life	1	2	3	4	5
My usual work or leisure activities have changed because of my swallowing issues.	1	2	3	4	5
Social gatherings (like holidays or get togethers) are not enjoyable because of my swallowing issues	1	2	3	4	5
My role with family and friends has changed because of my swallowing issues.	1	2	3	4	5

<b>GENERAL QUESTIONS ABOUT YOU</b>
------------------------------------

1. What is your name? \_\_\_\_\_
2. What is your date of birth? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
Day                      Month                      Year
3. What is your current BODY MASS INDEX? \_\_\_\_\_  
If you don't know this, please tell us your current:  
WEIGHT \_\_\_\_\_  
HEIGHT \_\_\_\_\_
4. Please tell us (approximately) how many times were you admitted to hospital in the last 6 months because of exacerbation of your COPD or chest infections? \_\_\_\_\_

**PLEASE CIRCLE THE APPROPRIATE ANSWER**

5. Are you                      MALE .....1.  
    FEMALE.....2
6. Which of the following best describes your **main** ethnic origin?  
    WHITE BRITISH.....1  
    WHITE OTHER.....2  
    BLACK AFRICAN.....3  
    BLACK CARRIBEAN.....4  
    BLACK OTHER.....5  
    INDIAN.....6  
    PAKISTANI.....7  
    BANGLADESHI.....8  
    CHINESE.....9  
    ASIAN OTHER.....10  
    OTHER (PLEASE SPECIFY).....11

7. What is your current marital status?

- NEVER MARRIED.....1
- MARRIED.....2
- DIVORCED.....3
- SEPARATED.....4
- WIDOWED.....5

8. Did anyone help you with the survey?

- NO, I did it myself.....1
- YES, someone helped me fill it out.....2

9. IF someone helped you fill out this survey, how did that person help you?

- Read the questions/wrote the answers.....1
- Answered the questions for you.....2
- Helped in some other way.....3

COMMENTS:

Do you have any comments about the survey? We welcome your comments about the survey in general or about specific questions, especially any that were unclear or confusing for you.

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Thank you for completing the survey.

## Appendix 10: Evaluation Stage; COPD Group- VAS and Modified Borg

VISUAL ANALOGUE SCALE  
BREATHLESSNESS

How breathless are you at the moment?

No breathlessness at all

worse breathlessness ever

### **MODIFIED BORG DYSPNOEA SCALE**

This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0 where your breathing is causing you no difficulty at all and progresses through to number 10 where your breathing difficulty is maximal.

**How much difficulty is your breathing causing you right now?**

- 0 Nothing at all
- 0.5 Very, Very Slight (just noticeable)
- 1 Very Slight
- 2 Slight
- 3 Moderate
- 4 Somewhat Severe
- 5 Severe
- 6
- 7 Very Severe
- 8
- 9 Very, Very Severe (almost maximal)
- 10 Maximal

# Appendix 11: Evaluation Stage; COPD Group- Videofluoroscopy and Penetration/Aspiration scoring sheet

## VIDEOFLUOROSCOPIC EXAMINATION OF SWALLOWING

Patients Name: ..... D.O.B.: ..... Date of Study: .....

Radiographic Evaluation	5ml	Sip	cup																	
<b>Lateral View - Preparation to Swallow</b>																				
Cannot hold food in mouth anteriorly																				
Material falls into anterior sulcus																				
Material falls into lateral sulcus																				
Abnormal hold position																				
<b>Oral Phase</b>																				
Tongue moves forward to start swallow																				
Impaired bolus formation																				
Disturbed Lingual Transit																				
Incomplete tongue to palate seal																				
Adherence to hard palate																				
Reduced anterior/posterior tongue movement																				
Repetitive lingual rolling																				
Premature leakage into pharynx																				
Piecemeal deglutition																				
Impaired chewing																				
Residue in oral cavity after swallow																				
Other																				



ASPIRATION EVALUATION	5ml		Sip		cup	
Pharyngeal Phase						
Spillage into Vallecular prior to swallow						
Spillage into pyriform sinus prior to swallow						
Delayed swallow						
Inadequate base of tongue and pharyngeal wall contact						
Penetration of airway followed by aspiration						
Penetration of airway but no aspiration						
Aspiration before swallow						
Aspiration during swallow						
Reduced laryngeal elevation						
Reduced laryngeal closure						
Inco-ordinated swallow						
Cough						
Coating pharyngeal wall after swallow						
Vallecular residue after swallow						
Residue in pyriform sinuses						
Second spontaneous swallow (multiple)						
Aspiration from residue in vallecular						
Aspiration from residue in pyriform sinus						

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Rosenbek Penetration/Aspiration Scale  
(Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996)

CATEGORY	SCORE	DESCRIPTIONS
No Penetration or Aspiration	1	Contrast does not enter the airway
	2	Contrast enters airway, remains above the vocal folds; no residue
Penetration	3	Contrast remains above the vocal folds; visible residue remains
	4	Contrast contacts vocal folds; no residue
	5	Contrast contacts vocal folds; visible residue remains
	6	Contrast passes glottis; no subglottic residue visible
Aspiration	7	Contrast passes glottis; visible subglottic residue despite patient response
	8	Contrast passes glottis; visible subglottic residue; absent patient response

## Appendix 12: Evaluation Stage; COPD Group- Respiratory Phase scoring sheet

### Respiratory Phase Score Sheet

Subject number: \_\_\_\_\_

Phase of COPD: \_\_\_\_\_

Trial Type and number	Respiratory Phase	Respiratory Phase	Swallow Apnoea Duration (msec)
	Pre swallow	Post Swallow	
Drink 1			
Drink 2			
Drink 3			
Food 1			
Food 2			
Food 3			
Drink 4			
Drink 5			
Drink 6			

# Appendix 13: Presentations, Grants and Awards.

## A Preliminary Investigation into the Association between COPD and Oropharyngeal Dysphagia.

Sheffield Teaching Hospitals NHS Foundation Trust

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### Abstract

**Aims and Objectives:**  
 This pilot study aims to explore the association between oropharyngeal dysphagia in patients with COPD and its impact on health.

**Background:**  
 The prevalence of oropharyngeal dysphagia amongst the COPD population, and the significance of the potential association in exacerbations of COPD is under researched. The limited literature supporting associations between COPD and oropharyngeal dysphagia fail to combine perceptual and objective measures, and use this to explore the impact of swallowing difficulties in COPD.

**Methods:**  
 Volunteers were recruited from Sheffield Teaching Hospitals NHS Foundation Trust (STH) between 2007-2008. Normal controls (n=36) and COPD subjects completed a validated questionnaire (SWAL-QOL). COPD subjects were further assessed using videofluoroscopy and respiratory measures (LPSG) consecutively in exacerbation phase (n=14) and followed up in stable phase (n=10).

**Results:**  
 Qualitative and non parametric testing revealed clinically and statistically significant results for the chosen outcomes.

**Quality of Life:** Non parametric tests showed a significant difference in all six sections of the SWAL-QOL when normal control scores were compared with scores from stable phase COPD (p<0.000). Two sections of the SWAL-QOL were significantly different when stable phase COPD scores were compared with exacerbation phase COPD scores: Eating Duration and Desire (p<0.021) and Fear (p<0.043).

**Objective Measures:** During videofluoroscopy, 70% (n=10) of COPD volunteers were found to have dysphagic characteristics on drinks in stable phase, compared to 100% in exacerbation phase. 20% (n=14) of COPD volunteers were found to have dysphagic characteristics on food in stable phase, compared to 55% in exacerbation phase. COPD volunteers increased dysphagic characteristics during exacerbation phase for drink (p= 0.035) and food (p= 0.046).

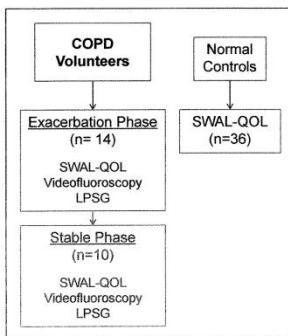
**Respiratory-Swallow Pattern:** COPD volunteers tended to inhale post swallow for drink (7/10) and food (5/10) during stable phase, and drink (8/14) and food (8/14) during exacerbation phase, and the difference between stable and exacerbation phase did not meet statistical significance.

**Conclusions:**  
 This study showed the presence (perceptual and objective) of oropharyngeal dysphagia in COPD with symptoms increasing during exacerbation. This finding was clinically and (in part) statistically significantly different from a 'normal swallowing pattern'. This was a small sample pilot and further research is required to build on this evidence and follow on to provide resources to enhance diagnosis and management of the condition.

### Objectives

1. Investigate the impact of swallowing on quality of life for COPD volunteers, compared with Normal Controls
2. Investigate dysphagic characteristics by phase of COPD using objective measures .
3. Investigate Respiratory-Swallow Pattern by phase of COPD.

### Methods



### Methods



Figure 1 : Example set up for Speech Therapist with a volunteer in the Radiology suite.



Figure 2 : Example set up for volunteers with Limited Polysomnography (LPSG) for respiration analysis during videofluoroscopy.

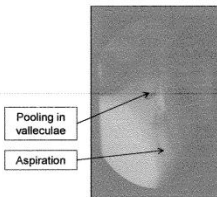


Figure 3: Videofluoroscopy image: lateral view of oropharynx.

### Acknowledgements

I wish to thank Dysphagia SIG Scotland for supporting this research project.  
 A special thanks to staff at Sheffield Teaching Hospitals for their support and advice.  
 Consent given for use of images.

### Contact information

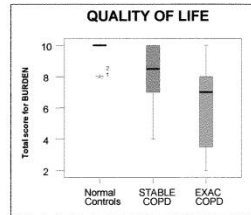
For further information please contact Kelly McPhee via [kelmcphee@hotmail.com](mailto:kelmcphee@hotmail.com)

### References

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### Results

COPD volunteers showed altered swallowing patterns for all objectives, increasing during exacerbation phase for the following outcomes:



Score of 10 = no problems.

Figure 4: Box plot of median and range values for SWAL-QOL<sup>3</sup> section 'BURDEN' (of swallowing). Differences between Normal controls and Stable COPD (p<0.05), and between stable and exacerbation phase COPD (p=0.084)

OROPHARYNGEAL DYSPHAGIA		
	STAB COPD n=10	EXAC COPD n=14
Considered Dysphagic*	70%	100%
Penetration of bolus*	10%	50%
Aspiration of bolus	0	21%
Spontaneous Manoeuvres	60%	78%
Altered Respiratory-Swallow Pattern <sup>1,2</sup>	70%	86%

\* statistically significant p<0.05

Table 1: Percentage of COPD volunteers considered to exhibit 'overall' and specific dysphagic characteristics on videofluoroscopy for ≥50% of six barium water trials.

### Conclusions

- Patients with COPD have more symptoms related to oropharyngeal dysphagia (including reduced quality of life) than normals, increasing further during exacerbations.
- The incidence of dysphagia was confirmed using functional measures
- Further research is required to determine whether dysphagia may be a cause of some exacerbations; and/or whether it slows recovery secondary to recurrent infection or under-nutrition.

### Presentations

2010	<b>20<sup>th</sup> European Respiratory Annual Congress (ERS), Barcelona, Spain</b> E-Communication Presentation (power point and poster) 'A preliminary investigation into the association between COPD and oropharyngeal dysphagia'. Poster included in Appendix
2008	<b>Lothian Dysphagia Special Interest Group (SIG)</b> 'Oropharyngeal Dysphagia and COPD'
2006	<b>Speech and Language Therapy Department, Sheffield Teaching Hospitals</b> 'Managing a Multidisciplinary Designated Research Team'
2005	<b>Trent Dysphagia SIG</b> 'What is the extent and impact of dysphagia in patients with COPD?'
2005	<b>South Yorkshire COPD Network</b> 'What is the prevalence of dysphagia in COPD?'

### Grants and Awards

2010	<b>ERS Congress, Barcelona Spain</b> Travel Award for Best Abstract	1000Euros
2010	<b>Scottish Dysphagia SIG</b> Bursary Award	£325
2007	<b>University of Sheffield</b> Post Graduate Fee Waiver	2007-2011
2006	<b>Sheffield Teaching Hospitals</b> Research Grant	£20 000
2005	<b>HSA Charitable Trust</b> Postgraduate Award	£2300
2004	<b>Trent Research and Development Support Unit (RDSU)</b> DRT Grant	£32 000
2004	<b>Sheffield Speech and Language Therapy Department</b> Research Award	2 days protected research time for 12 months

